

## IPL TREATMENT PROTOCOL

### CONTRAINDICATIONS AND EXCLUSION CRITERIA FOR VENUS VERSA™ IPL APPLICATOR TREATMENTS

#### CONTRAINDICATIONS

- Superficial metal or other implants in the treatment area.
- Current or history of cancer, or current condition of any type of cancer, or pre-malignant moles.
- Pregnancy and nursing.
- Diseases which may be stimulated by light at the wavelengths used, such as history of Systemic Lupus Erythematosus, Porphyria, and Epilepsy.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Poorly controlled endocrine disorders, such as Diabetes or Polycystic Ovary Syndrome.
- Any active condition in the treatment area, such as sores, Psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- Use of medications, herbs, food supplements, and vitamins known to induce photosensitivity to light exposure at the wavelengths used, such as Isotretinoin (Accutane) within the last six months, Tetracyclines, or St. John's Wort within the last two weeks.
- Any surgical procedure in the treatment area within the last three months or before complete healing.
- Treating over tattoo or permanent makeup.
- Excessively tanned skin from sun, tanning beds or tanning creams within the last two weeks.
- Vitiligo. (Health Canada & CE)
- As per the practitioner's discretion, refrain from treating any condition which might make it unsafe for the patient.

#### PRECAUTIONS (SR & AC DUAL APPLICATORS)

- When treatment is carried out on the face, avoid treating the areas that have undergone facial laser resurfacing and deep chemical peeling within the last month.
- In case of Botox injection, natural fillers and implants in the treatment area, wait one month after the last injection before starting a treatment.
- Tanned skin should not be treated. Instruct patients to avoid tanning throughout the treatment sessions.

#### PRECAUTIONS (HR APPLICATORS) – HEALTH CANADA & CE

- When treatment is carried out on the face, avoid treating the areas that have undergone facial laser resurfacing and deep chemical peeling within the last month.
- In case of Botox injection, natural fillers and implants in the treatment area, wait one month after the last injection before starting a treatment.
- Tanned skin should not be treated. Instruct patients to avoid tanning throughout the treatment sessions.

#### PRECAUTIONS (HR APPLICATORS) – FDA

- Caution: Hair removal by laser or Intense Pulsed Light (IPL) sources can cause increased hair growth in some individuals. Based upon currently available data, the highest risk groups for this response are females of Mediterranean, Middle Eastern, and South Asian heritage treated on the face and neck.
- Caution: Do not use the device in non-indicated skin types (namely, V and VI) for hair reduction or removal. The use of this device for hair reduction or removal on skin types V and VI has not been evaluated. The use of the device on non-indicated skin types could result in the skin absorbing too much laser light, potentially resulting in injury (e.g., burns, discoloration, scarring).
- Caution: When treatment is carried out on the face, avoid treating the areas that have undergone facial laser resurfacing and deep chemical peeling within the last month.
- Caution: In case of Botox injection, natural fillers and implants in the treatment area, wait one month after the last injection before starting a treatment.
- Caution: Tanned skin should not be treated. Instruct patients to avoid tanning throughout the treatment sessions.

#### VENUS VERSA™ IPL TREATMENT

STEP 1	Identify model/patient
STEP 2	Model/patient to complete clinical documents: Medical History, Informed Consent
STEP 3	Treatment provider to review completed documents and confirm model/patient does not fall under exclusion criteria

STEP 4	Treatment provider to skin type model/patient
STEP 5	Identify treatment and test spot area (face or body)
STEP 6	Photograph treatment and test spot area
STEP 7	Check back of device to ensure there is appropriate amount of distilled water in device (between lines of window on left hand side)
STEP 8	If there is not enough water, place red funnel in spot for IPL applicator and fill with distilled water
STEP 9	Turn on device (switch on back of device at bottom)
STEP 10	Select 3 parameters (low, medium, high based on skin condition concerns)
STEP 11	Shave (if using HR applicators) and clean test spot area
STEP 12	Apply clear ultrasound gel
STEP 13	Select appropriate applicator and test spot settings <b>**SR515 applicator cannot be used on skin types IV-VI and HR650 applicator cannot be used on skin types V-VI**</b>
STEP 14	Set device by setting following on screen: <ul style="list-style-type: none"> <li>• Skin Type (top left-hand corner of screen – use arrow)</li> <li>• Cooling (under skin type <b>**only 100% cooling for HR applicators**</b>)</li> <li>• Joules (top right-hand corner)</li> <li>• Milliseconds (under joules icon)</li> <li>• Hertz (under msec — use arrow on left side of icon to activate) and select speed</li> <li>• Select “ready” and ensure flashing has stopped and the tip has cooled</li> </ul>
STEP 15	Place applicator on skin and press trigger on applicator
STEP 16	Conduct 3 test spots (behind ear if treating face, or on treatment area if treating body)
STEP 17	Select “standby” once test spots are completed
STEP 18	Assess and photograph test spot area
STEP 19	SR clinical endpoints: <ul style="list-style-type: none"> <li>• <b>Pigment</b> – browning/darkening of pigment, purplish or black tint, crusting and flaking off, erythema and edema. Lasts approximately 3 - 7 days.</li> <li>• <b>Vascular</b> – blanching, greying, deep purple or blackening of the vessel. Lasts approximately 3 - 7 days.</li> </ul>
STEP 20	AC dual clinical endpoints: deepening the colour, tenderness to the lesions (if cystic), blanching/greying of vessels/vascular scars, intense edema and erythema lasting 5 - 10 days
STEP 21	HR clinical endpoints: perifollicular erythema (not common with the Venus Versa™), edema. Lasts approximately 5 - 7 days. Can be accompanied by itching sensations in the area.
STEP 22	Can proceed with treatment 15 minutes post-test spots (skin types I - IV), 48 hours post-test spots (Asian and skin types V - VI)
STEP 23	Shave (if using HR applicators) and clean treatment area
STEP 24	Mark out treatment area if appropriate using white eyeliner
STEP 25	Apply clear ultrasound gel
STEP 26	Select appropriate applicator
STEP 27	Set device using appropriate test spot setting (follow step 8)
STEP 28	Start treatment
STEP 29	Post treatment: photograph treatment area
STEP 30	Post treatment: document treatment on treatment log in patient file
STEP 31	Give patient/model post care instructions
STEP 32	Schedule next treatment
STEP 33	Subsequent treatments: increase the joules by maximum 2 J and/or reduce the ms by 5 ms maximum

## OVERVIEW OF PROTOCOL: SR AND AC DUAL APPLICATORS

### Number of Treatments:

4-5 treatments for **IPL 515** and **580**, all conditions  
8-10 treatments for **AC DUAL**

### Test Spots:

Always perform three test spots—one low, one medium, and one high—for all conditions. For Fitzpatrick skin types I – IV, wait 15 minutes, then proceed if everything is fine with the highest setting chosen that produced the clinical endpoint you are seeking.

For Fitzpatrick skin type V, wait 48 hours. Darker and Asian skin types will take time to respond, so a 48-hour period is necessary. Frequency:

1 treatment every 3-4 weeks for **IPL 515** and **580**, all conditions  
1 treatment two times a week for **AC DUAL**, leaving three to four days between treatments.

### Number of Passes:

**IPL 515 – 580:** 1 - 2 passes, except with Fitzpatrick skin type V and Asian skin types  
For Fitzpatrick skin type V and Asian skin types: 1 pass only (These skin types retain more heat for longer and will respond more intensely.)

**AC DUAL:** 1 pass with a double pulse on the lesions of concern

### Pigment Cooling:

0–100% (As low as needed for dermal heating and epidermal heating, depending on the area where the lesions reside and the Fitzpatrick skin type of the patient.) The shallower the patient's pigment, the lower cooling you'll use. For deeper pigments, use higher cooling settings.

Note: some Fitzpatrick skin types will not allow lower cooling for safety purposes.

### Vascular Cooling:

For the treatment of telangiectasia only use 0–100%. Use 0 if possible to reduce the constricting of vessels, but increase the setting as needed to protect the tissue (especially for darker Fitzpatrick skin types IV–V and Asian skin types) and ensure patient comfort. Note: some Fitzpatrick skin types will not allow lower cooling for safety purposes.

### Subsequent Treatments:

Increase the joules by a maximum of two joules and/or reduce the pulse duration setting by 5 ms maximum. If a very intense response was seen following the patient's previous treatment, maintain the same energy, reduce the energy by 1- 2 joules, or increase the pulse duration setting by 5 ms.

### Maintenance:

Two to four maintenance sessions per year, one treatment each with one to two passes.

## CLINICAL ENDPOINTS

### Skin Rejuvenation:

**Pigment:** Browning/darkening of the pigment, purplish or black tint to dark pigment (crusting of the pigment over a few days, crusting flakes off), erythema, and edema may result and last approximately 3 - 7 days post-treatment.

**Vascular:** Blanching of the vessel, greying of the vessel, deep purple tinting or blackening of the vessel may occur. Over the course of a few days, the damaged tissue will be broken down and absorbed. This lasts approximately 3 - 7 days post-treatment.

### Acne:

Deepening of the color of the lesions, tenderness to the lesions (if cystic), blanching/greying of vessels and/or vascular scars, intense edema, and erythema lasting 5-10 days may occur.

**OVERVIEW OF PROTOCOL: HAIR REMOVAL APPLICATORS**

Number of Treatments:

6-10 treatments, depending on the treatment area

Test Spots:

Perform three test spots—one low, one medium, and one high. For Fitzpatrick skin types I–IV, wait 15 minutes, then proceed (if everything is fine) with the highest setting chosen that produced the clinical endpoint you are seeking. For Fitzpatrick skin types V and VI and Asian skin types, wait 48 hours. These skin types retain more heat for longer and will respond more intensely.

Frequency:

For the first three sessions, treat at an interval of every 4-8 weeks on the body and 4-6 weeks on the face. Increase the intervals as required when hair becomes sparser and finer.

Number of Passes:

1 pass

Subsequent Treatments:

Increase the Joules setting by maximum 2 Joules, and/or reduce the pulse duration setting by 5 ms maximum. If a very intense response was seen following the patient’s previous treatment, maintain the same energy setting, reduce the energy by 1- 2 Joules, or increase the pulse duration setting by 5 ms.

Maintenance:

As required, but the entire area is to be done; do not do spot treatments.

**CLINICAL ENDPOINTS**

Perifollicular erythema and edema (not typical to see perifollicular erythema with Venus Versa™ treatments) may occur and last approximately 5 - 7 days. This may be accompanied by itching sensations in the treated area.

**GENERAL IPL POINTS TO REMEMBER**

- Always use CLEAR conductive gel.
- Always use a white pencil to mark out areas on the skin.
- Overlap by approximately 20% for a uniform treatment.
- Shave the treatment area immediately prior to treatment. Do not leave stubble or hairs on the surface of the skin.
- Use the Hz setting for larger areas (2 - 3 Hz). Use manual mode or 1 - 1.5 Hz for smaller areas.
- Clean the crystal immediately post-treatment using alcohol and dry off thoroughly.
- Advise patients to remain out of the sun for the duration of the treatment protocol and wear adequate sun protection.
- For the first two days post-treatment, patients should avoid hot baths, saunas, massages, or the like.
- Acne patients can return to their regular medical skin care regime 1 - 2 days post-treatment.
- Blisters or ulcerated skin may be treated with a prescribed antibiotic ointment or burn treatment cream.
- Patients can keep scabs soft with lubricating ointment, and should avoid picking or scrubbing them off. Allow for natural exfoliation to occur.

**PIGMENTED LESIONS**

Applicator	Fitzpatrick Skin Type	Energy Output (J/cm2)	Pulse Duration (ms)	Frequency (Hz)	Cooling
SR515	I - II	14 - 20	10 - 20	Up to 3	0 - 100
	III	10 - 16	10 - 20	Up to 3	0 - 100
	IV, V, VI				

**PIGMENTED LESIONS**

Applicator	Fitzpatrick Skin Type	Energy Output (J/cm <sup>2</sup> )	Pulse Duration (ms)	Frequency (Hz)	Cooling
SR580	I - II	14 - 20	10 - 20	Up to 3	0 - 100
	III	10 - 16	10 - 20	Up to 3	0 - 100
	IV	8 - 14	10 - 20	Up to 3	60 - 100
	V	5 - 10	10 - 20	Up to 3	80 - 100
	VI				

**VASCULAR LESIONS**

Applicator	Fitzpatrick Skin Type	Energy Output (J/cm <sup>2</sup> )	Pulse Duration (ms)	Frequency (Hz)	Cooling
SR515	I - II	14 - 20	10 - 20	Up to 3	0 - 100
	III	10 - 16	10 - 20	Up to 3	0 - 100
	IV, V, VI				
SR580	I - II	16 - 22	10 - 20	Up to 3	0 - 100
	III	12 - 18	10 - 20	Up to 3	0 - 100
	IV	8 - 14	15 - 20	Up to 3	60 - 100
	V	6 - 12	15 - 20	Up to 3	80 - 100
	VI				

**HAIR REMOVAL (USE LARGER SPOT SIZE FOR LARGE AREAS)**

Applicator	Fitzpatrick Skin Type	Energy Output (J/cm <sup>2</sup> )	Pulse Duration (ms)	Frequency (Hz)	Cooling
HR650	I - II	14 - 20	20 - 50	Up to 3	100
	III	10 - 16	20 - 50	Up to 3	100
	IV	6 - 12	30 - 50	Up to 3	100
	V, VI				
HR690	I - II	14 - 20	20 - 50	Up to 3	100
	III	10 - 16	20 - 50	Up to 3	100
	IV	6 - 14	30 - 50	Up to 3	100
	V	5 - 12	30 - 50	Up to 3	100
	VI	5 - 10	30 - 50	Up to 3	100
HR650XL	I - II	12 - 18	20 - 50	Up to 3	100
	III	10 - 16	20 - 50	Up to 3	100
	IV	6 - 12	30 - 50	Up to 3	100
	V, VI				

**HAIR REMOVAL (USE LARGER SPOT SIZE FOR LARGE AREAS)**

Applicator	Fitzpatrick Skin Type	Energy Output (J/cm <sup>2</sup> )	Pulse Duration (ms)	Frequency (Hz)	Cooling
HR690XL	I - II	12 - 18	20 - 50	Up to 3	100
	III	10 - 16	20 - 50	Up to 3	100
	IV	6 - 12	30 - 50	Up to 3	100
	V	5 - 10	50	Up to 3	100
	VI	5 - 10	50	Up to 3	100

**AC DUAL**

Applicator	Fitzpatrick Skin Type	Energy Output (J/cm <sup>2</sup> )	Pulse Duration (ms)	Frequency (Hz)	Cooling
AC415 - 480 & 630 (red & blue)	I - II	12 - 16	10	Up to 2	100
	III	10 - 14	15	Up to 2	100
	IV	8 - 12	20	Up to 2	100
	V	8	20	Up to 2	100
	VI	8	20	Up to 2	100

**HYPERPIGMENTATION**

Fitzpatrick Skin Type	515 or 580	J/cm <sup>2</sup>	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515 580	10 - 15 10 - 20	10 - 15 10 - 20	Lower for shallow pigment 40-60% Higher for deeper pigment 80-100%	N/A
II	515 580	10 - 15 10 - 20	10 - 15 10 - 20	Lower for shallow pigment 40-60% Higher for deeper pigment 80-100%	N/A
III	515 580	10 - 15 10 - 20	10 - 15 10 - 20	Lower for shallow pigment 40-60% Higher for deeper pigment 80-100%	N/A
IV	580	8 - 14	15 - 20	Higher to protect epidermis for darker Fitzpatrick type 100%	N/A
V	580	6 - 12	15 - 20	Higher to protect epidermis for darker Fitzpatrick type 100%	N/A
VI					

**MELASMA**

Fitzpatrick Skin Type	515 or 580	J/cm <sup>2</sup>	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515 580	10 - 14 10 - 14	15 - 20 15 - 20	100% 100%	N/A
II	515	10 - 12	15 - 20	100%	N/A
III	580	10 - 13	15 - 20	100%	N/A
IV	580	9 - 12	15 - 20	100%	N/A
V, VI					

## EPHELIDES

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515/580	14 - 20	10 - 20	Lower for shallow pigment 40-60%, higher for deeper pigment 80-100%	N/A
II	515/580	14 - 20	10 - 20	Lower for shallow pigment 40-60%, higher for deeper pigment 80-100%	N/A
III	515/580	14 - 20	10 - 20	Lower for shallow pigment 40-60%, higher for deeper pigment 80-100%	N/A
IV	580	8 - 14	15 - 20	Higher to protect epidermis for darker Fitzpatrick type 100%	N/A
V	580	8 - 14	15 - 20	Higher to protect epidermis for darker Fitzpatrick type 100%	N/A
VI					

## NEVI

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515 580	12 - 22 12 - 22	10 - 15 10 - 15	100% 100%	N/A
II	515 580	12 - 20 12 - 20	10 - 15 10 - 15	100% 100%	N/A
III	515 580	10 - 16 10 - 18	10 - 15 10 - 15	100% 100%	N/A
IV	580	8 - 14	15 - 20	100%	N/A
V	580	5 - 10	15 - 20	100%	N/A
VI					

## CAFÉ-AU-LAIT MACULES

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515 580	12 - 18 12 - 16	10 - 20 10 - 20	80 - 100% 80 - 100%	N/A
II	515 580	12 - 16 12 - 16	10 - 20 10 - 20	80 - 100% 80 - 100%	N/A
III	515 580	12 - 16 10 - 17	10 - 20 10 - 20	80 - 100% 80 - 100%	N/A
IV, V, VI					

## PORT WINE

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515 580	12 - 20 12 - 20	10 - 15 10 - 15	40 - 80% 40 - 80%	N/A
II	515 580	10 - 18 12 - 20	10 - 20 10 - 20	40 - 80% 40 - 80%	N/A
III	580	10 - 16	15 - 20	40 - 80%	N/A

## PORT WINE

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
IV	580	8 - 13	15 - 20	40 - 80%	N/A
V, VI					

## HEMANGIOMAS

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515	12 - 18	10 - 20	100%	N/A
	580	12 - 18	10 - 20	100%	
II	515	12 - 18	10 - 20	100%	N/A
	580	12 - 18	10 - 20	100%	
III	515	10 - 15	15 - 20	100%	N/A
	580	10 - 16	15 - 20	100%	
IV	580	10 - 16	15 - 20	100%	N/A
V	580	5 - 12	15 - 20	100%	N/A
VI					

## TRUNCAL AND LEG TELANGIECTASIA

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515	10 - 15	10 - 15	60 - 100%	Up to 3
	580	10 - 15	10 - 15	60 - 100%	
II	515	10 - 15	10 - 15	60 - 100%	Up to 3
	580	10 - 15	10 - 15	60 - 100%	
III	580	10 - 15	10 - 15	60 - 100%	Up to 3
IV	580	8 - 12	10 - 15	100%	Up to 3
V	580	5 - 10	15 - 20	100%	Up to 3
VI					

## ROSACEA AND FACIAL TELANGIECTASIA

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515	12 - 21	10 - 15	0 - 100%	N/A
	580	12 - 21	10 - 15	0 - 100%	
II	515	14 - 20	10 - 20	0 - 100%	N/A
	580	14 - 20	10 - 20	0 - 100%	
III	515	10 - 16	10 - 20	0 - 100%	N/A
	580	10 - 18	10 - 20	0 - 100%	
IV	580	8 - 14	15 - 20	60 - 100%	N/A
V	580	5 - 10	15 - 20	80 - 100%	N/A
VI					



## ANGIOMAS

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515	14 - 20	10 - 15	100%	N/A
	580	14 - 20	10 - 15	100%	
II	515	14 - 20	10 - 15	100%	N/A
	580	14 - 20	10 - 15	100%	
III	580	10 - 18	10 - 15	100%	N/A
IV	580	8 - 14	15 - 20	100%	N/A
V	580	5 - 10	15 - 20	100%	N/A
VI					

## SPIDER ANGIOMAS

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515	14 - 20	10 - 15	0 - 100%	N/A
	580	14 - 20	10 - 15	0 - 100%	
II	515	14 - 20	10 - 15	0 - 100%	N/A
	580	14 - 20	10 - 15	0 - 100%	
III	580	10 - 18	10 - 20	0 - 100%	N/A
IV	580	8 - 15	15 - 20	60 - 100%	N/A
V	580	5 - 10	15 - 20	80 - 100%	N/A
VI					

## POILILODERMA OF CIVATTE

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515	14 - 20	10 - 20	100%	N/A
	580	14 - 20	10 - 20	100%	
II	515	12 - 18	10 - 15	100%	N/A
	580	14 - 20	10 - 15	100%	
III	580	10 - 16	15 - 20	100%	N/A
IV	580	7 - 13	15 - 20	100%	N/A
V	580	5 - 10	15 - 20	100%	N/A
VI					

## LEG VEINS

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	580	15 - 25	15 - 25	40 - 80%	Up to 3
II	580	15 - 25	15 - 25	40 - 80%	Up to 3
III	580	15 - 21	15 - 25	40 - 80%	Up to 3

**LEG VEINS**

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
IV	580	10 - 17	15 - 25	40 - 80%	Up to 3
V, VI					

**VENUS MALFORMATIONS**

Fitzpatrick Skin Type	515 or 580	J/cm2	ms	% Cooling 0, 20, 40, 60, 80, 100	HZ (0 - 3)
I	515 580	12 - 21 12 - 21	10 - 15 10 - 15	100% 100%	N/A
II	515 580	14 - 20 14 - 20	10 - 20 10 - 20	100% 100%	N/A
III	515 580	10 - 16 10 - 18	10 - 20 10 - 20	100% 100%	N/A
IV	580	8 - 14	15 - 20	100%	N/A
V	580	5 - 10	15 - 20	100%	N/A
VI					

## RF™ & PEMF TREATMENT PROTOCOL

### CONTRAINDICATIONS AND EXCLUSION CRITERIA FOR VENUS VERSA™ RF AND PEMF APPLICATOR TREATMENTS

#### CONTRAINDICATIONS

Treatment with the device is contraindicated for patients with any of the following conditions:

- Implantable defibrillators, cardiac pacemakers, and other metal implants Pregnancy and nursing.
- Subjects with any implantable metal device in the treatment area.

#### EXCLUSION CRITERIA

- Actinic keratosis
- Current or history of cancer and premalignant condition
- Demyelinating diseases
- Defibrillator/Pacemaker
- Uncontrolled disorder of the thyroid gland
- Epilepsy
- Fever
- Infection in the treated area
- Multiple sclerosis
- Mental diseases
- Metal implants near the treated area, excluding dental implants
- Moles at the treated area
- Ongoing use of Isotretinoin (e.g. Roaccutane)
- Pregnancy or IVF procedure
- Active inflammation and/or infection in the treated area
- Degenerative neurologic diseases
- Diseases stimulated by heat (such as recurrent herpes simplex in the treatment area)
- Varicose veins
- Skin related autoimmune diseases
- Silicone implants and injections in treated area

#### PRECAUTION CRITERIA

- Botox injection and implants in the treatment area (wait for one month after last injection before starting a treatment)
- Breast feeding
- Epilepsy
- Facial laser resurfacing and deep chemical peeling within the last month, if face is treated
- Fresh scars, wounds, or scarification of the skin in the treated area
- Telangiectasia
- Thyroid gland (it is not recommended to perform the treatment over the thyroid)
- Recent injection of fillers
- Recent surgical procedure or special medications
- Rosacea (not recommended if the face is treated; but not a constraint if treating other body areas)

#### VENUS VERSA™ RF/PEMF APPLICATOR

STEP 1	Identify model/patient
STEP 2	Model/patient to complete clinical documents: Medical History, Informed Consent
STEP 3	Treatment provider to review completed documents and confirm model/patient does not fall under exclusion criteria
STEP 4	Identify treatment area (face or body)
STEP 5	Photograph treatment area
STEP 6	Turn on device (round button on front of device)
STEP 7	Take baseline temperature using external temperature gun
STEP 8	Treating face: clean area
STEP 9	Treating face: apply Glide
STEP 10	Treating arms: mark treatment area using eyeliner and treatment sheet

STEP 11	Treating arms: weigh model/patient, measure treatment area
STEP 12	Treating arms: clean area
STEP 13	Treating arms: apply Glide
STEP 14	Enter login on device (AAAAAAA)
STEP 15	Select appropriate applicator by pressing arrow beside picture of applicator
STEP 16	Select setting by pressing on second icon from left hand corner on screen
STEP 17	Select number on screen that coincides with treatment area
STEP 18	Press play (arrow on bottom right hand side)
STEP 19	Start treatment
STEP 20	Place applicator on treatment area ensuring all electrodes are in contact with the skin, slow, irregular pattern never stopping or “parking” on skin
STEP 21	Take baseline temperature with external temperature gun 1-1.5 minutes into treatment
STEP 22	As required according to patient comfort, adjust RF setting, decreasing by 5%. Once complete, continue with treatment.
STEP 23	Switch treatment side when indicator rings
STEP 24	Continue treatment until completed
STEP 25	Post treatment: clean treatment area
STEP 26	Post treatment: photograph treatment area
STEP 27	Post treatment: document treatment on treatment log in patient file
STEP 28	Give patient/model post care instructions
STEP 29	Schedule next treatment
STEP 30	Clean applicator: 1. Remove excess Glide 2. Use wipes supplied to clean 3. Use dry cloth to dry

KEY NOTES TO REMEMBER FOR VENUS VERSA™ RF™ AND PEMF APPLICATOR TREATMENTS

- Use the patient’s first treatment to establish their comfort parameters
- Venus Concept™ Glide must be used during all (MP)<sup>2</sup> treatments to ensure patient efficacy and safety
- DiamondPolar™ applicator is used for the face, neck and small body parts such as arms
- OctiPolar™ is used for body parts such as arms, legs, abdomen, flanks and buttocks\_

OctiPolar™ Applicator:

As soon as the body has reached the therapeutic range (42 – 45°C), as warm as tolerable to the patient within this range (should take about a minute), continue the treatment until the patient says they are finding it is getting too warm. Ensure you keep slow and steady pace covering the area in random movements, but ensuring that the area is completely and uniformly covered.

When the patient feels too warm, reduce the percentage of energy by five per cent at a time until the patient is comfortable.

The speed of treatment should remain the same to ensure the temperature of the skin remains in the therapeutic range, as warm as the patient can tolerate in this range to avoid constant adjustments to the energy setting.

After the first treatment, note the beginning and ending parameters (percentage of energy). These are now your baseline parameters for subsequent treatments with this patient. Once the patient’s personal parameters are established, you can begin the next treatment at the preset energy settings and reduce to the last comfortable recorded energy setting used during the last treatment after you have reached the therapeutic range and the patient states they are too warm.

DiamondPolar™ Applicator:

As soon as the face or neck treatment area has reached therapeutic range (39 – 41°C for the face; 39 – 41°C or 42 – 45°C for the neck), as warm as tolerable to patient (should take about a minute), continue the treatment until the patient says they are finding it is getting too warm. Ensure you keep a slow and steady pace, covering the area in random movements but ensuring that the area is completely and uniformly covered.

When the patient feels too warm, reduce the percentage of energy by five per cent at a time.

If the patient continues to feel discomfort or is too warm, reduce the energy setting by five per cent at a time. If the skin drops below the therapeutic range, you are either moving too fast (you sped up) or you decreased the energy setting by too much. You can increase the percentage of energy back up by five per cent at a time until the treatment area is back up to the therapeutic temperature range. The speed of treatment should remain the same to ensure the temperature of the skin remains in therapeutic range, as warm as the patient can tolerate in this range, to avoid constant adjustments to the energy setting.

After the first treatment, note the beginning and ending parameters (energy settings). These are now your baseline parameters for subsequent treatments with this patient. Once the patient’s personal parameters are established, you can begin the next treatment at the preset energy settings and reduce to the last comfortable recorded energy setting used during the patient’s last treatment after you have reached the therapeutic range and the patient states they are too warm.

Frequency of Treatments:

Face/Neck: One treatment per week for 6 weeks

Body: One treatment per week for 8 weeks

Maintenance: Once a month if desired, once a season is recommended

SKIN TIGHTENING AND WRINKLE REDUCTION: DIAMONDPOLAR™ AND OCTIPOLAR™ APPLICATORS

Area	Total Time	Applicator	Interval Time	RF Beginning	RF Reduction	Treatment Size/Area
Abdomen	30 min	OctiPolar™	N/A	Range: 50% - 90% Standard: 80%	5% at a time until patient comfort baseline is achieved	8.5 x 11 inches (21.59 x 27.94 cm)
Thighs	30 min	OctiPolar™	15 min per thigh	Range: 50 - 90% Standard: 80%	5% at a time until patient comfort baseline is achieved	8.5 x 11 inches (21.59 x 27.94 cm)
Calves	20 min	OctiPolar™	10 min per calf	Range: 30 - 65% Standard: 55%	5% at a time until patient comfort baseline is achieved	5.5 x 8.5 inches (13.97 x 21.5 cm)
Arms	20 min	OctiPolar™	10 min per arm	Range: 30 - 65% Standard: 55%	5% at a time until patient comfort baseline is achieved	5.5 x 4.25 inches (14 x 10.5 cm)
Arms	20 min	DiamondPolar™	10 min per arm	Range: 40 - 80% Standard: 60%	5% at a time until patient comfort baseline is achieved	5.5 x 4.25 inches (14 x 10.5 cm)
Flanks	20 min	OctiPolar™	10 min per flank	Range: 50% - 90% Standard: 80%	5% at a time until patient comfort baseline is achieved	5.5 x 4.25 inches (14 x 10.5 cm)
Bra Line	20 min	OctiPolar™	10 min per side	Range: 50% - 90% Standard: 80%	5% at a time until patient comfort baseline is achieved	5.5 x 4.25 inches (14 x 10.5 cm)
Buttocks	20 min	OctiPolar™	10 min per cheek	Range: 50% - 90% Standard: 80%	5% at a time until patient comfort baseline is achieved	5.5 x 8.5 inches (13.97 x 21.5 cm)
Hands (to wrist)	10 min	DiamondPolar™	5 min per hand	Range: 20% - 60% Standard: 40%	5% at a time until patient comfort baseline is achieved	Back of hands to wrist folds

SKIN TIGHTENING AND WRINKLE REDUCTION: DIAMONDPOLAR™ AND OCTIPOLAR™ APPLICATORS

Area	Total Time	Applicator	Interval Time	RF Beginning	RF Reduction	Treatment Size/Area
Face	30 min	DiamondPolar™	12.5 min per side of face, 5 min for forehead	Range: 20% - 40% Standard: 35%	5% at a time until patient comfort baseline is achieved	Full face to jawline; DOES NOT include neck or under chin
Neck	20 min	DiamondPolar™	10 min per side of the neck	Range: 20% - 60% Standard: 40%	5% at a time until patient comfort baseline is achieved	Jawline and under chin to the clavicle, avoiding the thyroid
Décolleté	10 min	DiamondPolar™	N/A	Range: 20% - 60% Standard: 40%	5% at a time until patient comfort baseline is achieved	Under clavicle to v-line on neck; NOT over breast tissue
Eyebrow	8 min	DiamondPolar™	4 min	Range: 15% - 35% Standard: 30%	5% at a time until patient comfort baseline is achieved	Eyebrow area on the brow bone
Eye Laxity	12 min	DiamondPolar™	3 min (MP) <sup>2</sup> ; 3 min PEMF only	Range: 15% - 35% Standard: 30%	5% at a time until patient comfort baseline is achieved	Periorbital area

**TREATING THE UNDER-EYE AREA AND LIFTING THE EYEBROWS - 20 MINUTES TOTAL (12 MINUTES UNDER THE EYES, 8 MINUTES ON THE BROW)**

STEP 1	Select the face setting on the device
STEP 2	Set the percentage of energy to 30%, the total treatment time to 20 minutes, and the interval times to 4 minutes, initially
STEP 3	Spread Glide on the whole lower half of the face and across the forehead, making sure that there is enough on the under-eye area. While you will only be treating on the zygomatic bone under the orbital soft tissue area, you will still require Glide to be placed in the soft tissue area to ensure that electrodes do not touch the bare skin.
STEP 4	Press "Play"
STEP 5	Begin slowly gliding the applicator over one side of the brow, focusing more passes on the brow bone (never parking it) and quickly moving on to the middle of the forehead to allow for an area to turn the applicator around and pass back over the brow area (remaining on the bone). You may make some sweeping motions.
STEP 6	You will reach the therapeutic temperature range very quickly and will likely need to reduce the energy setting as the area will become too hot. Reduce the energy setting by 5% at a time until the patient is comfortable.
STEP 7	Continue for 4 minutes, adjusting the energy setting as needed
STEP 8	After 4 minutes of treatment, pause the system. Record your final percentage of energy so you can return to that setting in the future once you have reached the therapeutic range using 30% to begin.
STEP 9	Repeat the steps above for the other side of the brow
STEP 10	After 4 minutes of treatment time, pause the system
STEP 11	Set the energy level to 30%, your total treatment time to 12 minutes, and your interval times to 3 minutes
STEP 12	Press "Play"
STEP 13	Begin slowly gliding the applicator over 1 half of the face, focusing more passes on the zygomatic bone under 1 eye (never parking it) and quickly moving on to the lower region of the face to allow for an area to turn the applicator around and pass back under the eye area (remaining on the bone).
STEP 14	You will reach the therapeutic range very quickly and will likely need to reduce the percentage of energy as the area will become too hot. Reduce it by 5% at a time until the patient is comfortable.
STEP 15	Continue for the remaining portion of the 3 minute total treatment time for the area
STEP 16	After 3 minutes of treatment, pause the system. Record your final percentage of energy so you can return to that setting in the future once you have reached the therapeutic range using 30% to begin.
STEP 17	Repeat the steps above for the other eye
STEP 18	After 3 minutes of treatment, pause the system

STEP 19	Press the (MP) <sup>2</sup> button to reduce the energy setting to 0
STEP 20	Press “Play”
STEP 21	Treat 1 half of the treatment area with magnetic pulses, only parking the device on the heavily colored areas, for a total of 3 minutes
STEP 22	Repeat on the other side

**TREATING DARK CIRCLES UNDER THE EYE  
12 MINUTES TOTAL (6 MINUTES PER EYE)**

STEP 1	Select the face setting on the device
STEP 2	Set the percentage of energy to 30%, the total treatment time to 12 minutes, and the interval time to 3 minutes
STEP 3	Spread Glide on the whole lower half of the face, making sure that there is enough on the under-eye area. You will only be treating on the zygomatic bone under the orbital soft tissue area but you still require Glide to be placed in the soft tissue area to ensure that electrodes do not touch the bare skin.
STEP 4	Press “Play”
STEP 5	Begin slowly gliding the applicator over one half of the face, focusing more passes on the zygomatic bone under one eye (never parking it) and quickly moving on to the lower region of the face to allow for an area to turn the applicator around and pass back under the eye area (remaining on the bone).
STEP 6	You will reach the therapeutic temperature range very quickly and will likely need to reduce the energy setting as the area will become too hot. Reduce it by 5% at a time until the patient is comfortable.
STEP 7	Continue for the remaining portion of the 3 minute total treatment time for the area, reducing the energy setting by 5% as needed
STEP 8	After 3 minutes of treatment, pause the system. Record your final percentage of energy so you can return to that setting in the future once you have reached the therapeutic range using 30% to begin.
STEP 9	Repeat the steps above for the other eye
STEP 10	After 3 minutes of treatment, pause the system
STEP 11	Press the (MP) <sup>2</sup> button to reduce the energy setting to 0
STEP 12	Press “Play”
STEP 13	Treat one half of the treatment area with magnetic pulses, only parking the device on the heavily colored areas, for a total treatment time of 3 minutes
STEP 14	Repeat on the other side



# VENUS VERSA

## NANOFRACTIONAL RF™ TREATMENT PROTOCOL

### PRE-TREATMENT

The Venus Versa™ system, using the NanoFractional RF™ applicator, is designed for use in dermatological procedures requiring ablation and resurfacing of the skin.

Through an array of small electrodes organized on a tip, NanoFractional Radio Frequency™ energy is transmitted into the tissue, producing an injury in a certain pattern on the skin. The unaffected areas promote faster healing. The end result is an improvement in the tone and texture of the skin.

### EXCLUSION CRITERIA

- Pacemaker, internal defibrillator, or any other active electrical implant anywhere in the body (e.g. cochlear implant)
- Permanent implant in the treated area, such as metal plates and screws, or an injected chemical substance
- Current or history of any type of cancer or pre-malignant moles
- Severe concurrent conditions, such as cardiac disorders
- Pregnancy and/or nursing
- Impaired immune system, whether due to immunosuppressive diseases, such as AIDS and HIV, or the use of immunosuppressive medications\*
- Patients with a history of diseases stimulated by heat, such as recurrent herpes simplex in the treatment area, may be treated only following a prophylactic regime
- Poorly controlled endocrine disorders, such as diabetes
- Any active condition in the treatment area, such as sores, psoriasis, eczema, or a rash
- History of skin disorders, such as keloids, abnormal wound healing, as well as very dry and fragile skin
- History of bleeding coagulopathies or the use of anticoagulants
- Face lift or eyelid surgery (if periorbital treatment is performed) within a year prior to treatment
- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months, if the face is being treated
- Neurotoxin/collagen/fat injections or other methods of augmentation with injected bio-material in the treated area within six months prior to treatment
- Use of isotretinoin (Accutane) within six months prior to treatment
- Use of non-steroidal anti-inflammatory drugs (NSAIDs, e.g. such as ibuprofen-containing agents) one week before and after each treatment session
- Any surgical procedure in the treatment area within six months before complete healing
- Treating over tattoo or permanent makeup
- Excessively tanned skin from sun, tanning beds, or tanning creams within two weeks prior to treatment
- As per the practitioner's discretion, refrain from treating any condition that may be unsafe for the patient

*(\*) Indicated conditions may be treated at the discretion of and under the full responsibility of the medical director/physician, although treatment is not recommended. In such cases, a small area should be treated and assessed a few days later to determine if the patient will tolerate the treatment without developing short-term adverse effects. Test spots cannot indicate long-term adverse events.*

### VENUS VERSA™ NANOFRACTIONAL RF™ APPLICATOR

STEP 1	Identify model/patient
STEP 2	Model/patient to complete clinical documents: Medical History, Informed Consent
STEP 3	Treatment provider to review completed documents and confirm model/patient does not fall under exclusion criteria
STEP 4	Treatment provider to skin type model/patient
STEP 5	Identify treatment and test spot area (face or body)
STEP 6	Photograph treatment and test spot area
STEP 7	Turn on device (round button on front of device)
STEP 8	Select 3 parameters (low, medium, high based on skin condition concerns)
STEP 9	Clean test spot area



STEP 10	Degrease test spot area using alcohol, ensure area is dry
STEP 11	Enter login on device (AAAAAAA)
STEP 12	Select appropriate applicator by pressing arrow beside picture of applicator
STEP 13	Put new tip on applicator
STEP 14	Using Basic Mode: set RF % (top right hand corner of screen)
STEP 15	Using MD Mode: change by pressing graph icon 2nd from the left hand corner
STEP 16	Using MD Mode: Set Volts by pressing “+ or -” on left side of graph icon; Set MS by pressing “+ or -” on right side of graph icon
STEP 17	Select tip pin pattern (under RF setting) by pressing arrow on right side and/or graph on left side
STEP 18	Select auto fire setting if desired (under tip pin pattern) by pressing arrows on left side
STEP 19	Conduct 3 test spots (behind ear if treating face or on treatment area if treating body)
STEP 20	Place applicator on skin and press trigger on applicator
STEP 21	Photograph test spot area (erythema and edema is common)
STEP 22	Remove and discard tip in sharps container
STEP 23	Can proceed with treatment 24-48 hours post test spots (skin types I-III), 5-7 days post test spots (Asian and skin types IV-VI)
STEP 24	To perform treatment follow steps 9 – 23, Select appropriate setting based on test spots
STEP 25	Ensure overlapping treatment approximately 10-20%
STEP 26	Post treatment: photograph treatment area
STEP 27	Post treatment: document treatment on treatment log in patient file
STEP 28	Give patient/model post care instructions
STEP 29	Schedule next treatment
STEP 30	Remove and discard tip in sharps container
STEP 31	Subsequent treatments: increase voltage and pulse duration up to 5% for Asian skin types and 10% for all other Fitzpatrick types

**VENUS VERSA™ NANOFRACTIONAL RF™ STANDARD TIP PARAMETERS FOR FITZPATRICK SKIN TYPES I – VI\***

Most physicians use the following parameters:

Indications	Voltage	Pulse Duration (MS)	Pattern	Number of Passes	Optimal Interval
Texture and Pores/Maintenance/Skin Rejuvenation	220 - 240	10 - 20	Full	1	Every 4 Weeks
Epidermal Pigmentation (Superficial)	230 - 235	20 - 30	Full	1	Every 4 Weeks
Dermal Pigmentation (Deeper)	250 - 260	20 - 30	Full	1	Every 4 Weeks
Fine to Very Moderate Wrinkles (1-4 on Fitzpatrick Wrinkle Scale)	220 - 230	15 - 20	Full	1	Every 4 Weeks
Deep Wrinkles (5-9 on Fitzpatrick Wrinkle Scale)	250 - 260	15 - 20	Full	1	Every 4 Weeks
Acne scars (Mild to Moderate; Never Over Active Acne)	235 - 240	10 - 20	Full	1	Every 4 Weeks
Deep Acne Scars (Never Over Active Acne)	245 - 260	15 - 20	Full	1	Every 4 Weeks
Rosacea	220 - 230	15 - 25	Full	1	Every 4 Weeks
Stretch Marks	230 - 240	15 - 25	Full	1	Every 4 Weeks

**VENUS VERSA™ NANOFRACTIONAL RF™ STANDARD TIP PARAMETERS FOR ASIAN SKIN TYPES**

Indications	Voltage	Pulse Duration (MS)	Pattern	Number of Passes	Optimal Interval
Texture and Pores	180 - 230	10 - 20	Half or Full	1	Every 4 Weeks
Epidermal Pigmentation	180 - 220	5 - 15	Half or Full	1	Every 4 Weeks
Fine Wrinkles	180 - 230	15 - 20	Half or Full	1	Every 4 Weeks
Deep Wrinkles	220 - 230	15 - 20	Half or Full	1	Every 4 Weeks
Acne Scars (Mild to Moderate)	220 - 240	10 - 20	Half or Full	1	Every 4 Weeks
Deep Acne Scars	230 - 270	20 - 30	Half or Full	1	Every 4 Weeks
Stretch Marks	180 - 240	15 - 25	Half or Full	1	Every 4 Weeks

**KEY NOTES TO REMEMBER FOR VENUS VERSA™ NANOFRACTIONAL RF™ APPLICATOR TREATMENTS**

- Test spots **MUST** be done on all patients prior to treatment. It is recommended to do three test spots (one with very low, moderate and higher parameters within the range stated on the table. The test spot must be done in the area where the treatment is being performed (example is the area behind the ear for treatments on the face, neck or décolleté).
- Test spots must be observed after 24 - 48 hours for Fitzpatrick I - III and 5 - 7 days for Fitzpatrick type IV - VI and Asian skin types. Positive clinical end points are mild to moderate erythema and edema, visible ablated zones (the size of a tiny pinpoint, with minute scabbing). The test spot was too aggressive if the area has excessive erythema and edema, pigment changes, bleeding, oozing, blisters, and excessive itching or sensitivity. The test spot was too mild if nothing is apparent on the tissue.
- Treatments on the body will take longer to heal/epithelize. It is imperative to use lower parameters and discuss the downtime with your patient.
- Treatment Increments: Voltage and pulse duration can be increased by 5% for Asian skin types, and up to 10% for all other Fitzpatrick skin types. This percentage setting is the value that represents the total emission from the applicator, and is a combination of volts (V) and milliseconds (ms). Depending on the patient's condition or concern, you will increase each accordingly.
- High power creates more ablation while a longer pulse duration creates more coagulation.
- Alternate pattern is used to decrease the risk of complications and is recommended in cases of sensitive skin, maintenance, and for patients with a need for very little downtime.
- Skin varies in thickness from patient to patient, thus relatively high power is chosen in greater skin thickness or deeper lesions.
- Apply nothing on the skin immediately post-treatment or a moisturizer may be applied. Recommendations from our KOL's include:

First 24 hours:	24 Hours Post:	72 Hours Post:
Venus Skin™ Stem Cell Recovery Complex Venus Skin™ Biocel Evian Spray Water Aquaphor	Venus Skin™ Post Treatment Recovery Kit Venus Skin™ Stem Cell Therapy Serum	Venus Skin™ Stem Cell Therapy Accelerator

- Products that contain many ingredients and preservatives will increase the risk of the patient experiencing a hyper response. The symptoms of a hyper response include, but are not limited to, prolonged erythema, increased edema, contact dermatitis lesions, and small pus-filled lesions. These symptoms may require topical and oral medications. Therefore, we do not recommend using post-treatment creams and serums.



# VENUS VERSA

- Sunblock should be used beginning 24 hours post-treatment if the skin has fully healed. Do not apply sunscreen over areas if they are open or oozing; seek medical advice for a topical treatment in these cases. Patients are advised that ongoing sun protection is necessary.
- Recommended protocol is a series of three treatments, consisting of one treatment, once a month.
- Maintenance is dependent on the skin condition. Generally, two to four treatments per year (one treatment every three to six months) will maintain results seen after a treatment series.

Frequency of Treatments: 3 Treatments

Face/Neck: One treatment every 4 weeks

Body: One treatment every 4 - 8 weeks

May take longer to heal in-between treatments