SkinPen®
PRECISION ELITE
MICRONEEDLING SYSTEM

User Manual/ Instructions for Use

SkinPen® Precision Elite Device
SkinPen® Precision Elite Charger Base

Inductive Charging

SMART Technology

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1. DEVICE DESCRIPTION

The SkinPen® Precision Elite device consists of a microneedling pen handpiece, and a sterile needle cartridge. The accessories are a charging base and a BioSheath. Each component and accessory will be explained to understand how SkinPen® Precision Elite works.

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

Fig 1.

SKINPEN® PRECISION ELITE COMPONENTS

SkinPen® Precision Elite Handpiece - Part #F5SP386 / REF 200

A Power Indicator Light

B Power On/Off Button

C LCD Screen

D Microneedling Connector

E Ergonomic Handle Grip

F Base Charger AC/DC Adapter - Part #P5SP215 or F5SP007

G Inductive Charging Base - Part #F5SP387 / REF 201

SKINPEN® PRECISION ELITE TREATMENT KIT

INCLUDES:

SKINPEN PRECISION ELITE CARTRIDGE

Part #F5SP388

EO (Ethylene Oxide) Sterilized, disposable needle cartridge packaged and labeled individually.

Proprietary needle cartridge with RFID (Radio Frequency Identification) feature in support of single-use device. *Cartridges are not to be resterilzed or reused.

The shelf life of this needle cartridge is 2 years from sterilization date.

SKINPEN PRECISION ELITE BIOSHEATH

Part #F5SP390

The SkinPen® Precision Elite and needle cartridge interface with a nonsterile and disposable BioSheath to prevent contamination of the SkinPen Precision Elite®.

LIFT HG

Part #F5SP023

Lift HG is a hydrogel wound dressing (without drugs and/or biologics) to protect against abrasion and friction during the microneedling procedure. It may be applied additionally the day of the procedure to prevent the skin from drying out post procedure.

2. INTENDED USE

The SkinPen® Precision Elite system is a microneedling device and accessories intended to be used as a treatment to improve the appearance of wrinkles of the neck for Fitzpatrick skin types II - IV and to improve the appearance of facial acne scars in adults with all Fitzpatrick skin types aged 22 years and older.

3. CONTRAINDICATIONS

The use of the SkinPen Precision Elite System should not be used on patients who:

- Have active skin cancer in the treatment area(s)
- Have open wounds, sores, or irritated skin in the treatment area(s)
- Have an allergy to stainless steel or anesthetics
- Have a hemorrhagic (bleeding) disorder or hemostatic (bleeding) dysfunction
- Are pregnant or nursing
- Are currently taking drugs with the ingredient isotretinoin (such as Accutane)

Note: This product is not intended for transdermal (under the skin) delivery of topical products such as cosmetics, drugs, or biologics.

4. WARNINGS

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Do not use any equipment not designed specifically for SkinPen® Precision Elite as to avoid interference with the device's intended performance.

The battery must not be replaced by the user. Do not remove the battery from the pen.

5. PRECAUTIONS

The SkinPen Precision Elite System has not been evaluated in the following patient populations (i.e. patients with the following conditions or taking the following medications): Actinic (solar) keratosis; active acne; collagen vascular diseases or cardiac abnormalities; diabetes; eczema, psoriasis and other chronic conditions in the treatment area or on other areas of the body; immunomodulatory or suppressive therapy; history of contact dermatitis; raised moles in the treatment area; rosacea; active bacterial, fungal, or viral (i.e. herpes, warts); keloid scars (a scar that grows outside of the boundaries of an original scar); patients on anticoagulants; scars and stretch marks less than one year old; scleroderma; and wound-healing deficiencies.

PLEASE NOTE: The SkinPen Precision Elite device allows for incremental increase in settings of up to 1.5 mm for acne scars and 2.5 mm for wrinkles on the neck to allow for variability in thickness of the skin. It is essential that the thickness of the patient's skin in each anatomical area to be treated is assessed by a qualified clinician to address any potential risk of injuring these structures. Such structures include (but are not limited to) the supra orbital nerve (the terminal branch of the frontal nerve that provides the sensory innervations for the skin of the forehead, mucosa of frontal sinus, and the skin of the upper eyelid) and the temporal, buccal and marginal mandibular branches of the facial nerve (motor nerve that controls facial muscle movement). No adverse events were observed relating to such structures in the SkinPen Precision clinical studies when treating at needle depths up to 1.5 mm (acne scars) and 2.5 mm (wrinkles on the neck). Please refer to Crown provided training module on superficial nerve and vessel facial anatomy for additional information.

6. ELECTRICAL SAFETY WARNINGS

- No modification of this equipment is allowed. Only use included SkinPen® Precision Elite adapter and charger base.
- Do not plug product into outlet with a voltage other than specified on the charger. (90-264 Vac).
- Never force plug into an outlet if it does not easily fit into the outlet, discontinue use.
- Discontinue use if product appears damaged in any way.
- Do not use or charge if cord or plug is damaged.
- Keep device and all accessories, including cord, away from heated surfaces.
- Do not store the pen and/or charger base near a sink or where it can fall or be pulled into water.
- For your safety from electrical shock, the SkinPen® Precision Elite and/or SkinPen® Precision Elite Charger base should not be opened or disassembled for trouble-shooting purposes.
- Do not use any equipment not designed specifically for SkinPen Precision Elite as to avoid interference with the device's intended performance.
- **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- **WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).
- The charger base transmitting frequency is between 110kHz and 205kHz.
- SkinPen Precision Elite & Charger base is suitable for use in industrial areas and hospitals
- **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- **WARNING:** A risk of increased emissions or decreased immunity may result if any additional cables are attached.
- **WARNING:** This device has not been tested for compatibility with all other potential RF Emitters such as X-ray, Metal Detectors, Electrosurgical Equipment, Diathermy Equipment, 5G Cellular, NFC, WPT, or Electronic Article Surveillance (EAS) devices. Caution should be used if such emitters are present within the use environment.
- **WARNING:** If used closer than 5cm to a 13.56 MHz RFID Reader, the display will become distorted and may show that the current cartridge has already been used. If this occurs, you must increase the separation distance, and replace the cartridge with a new one.

EMC – SKINPEN® PRECISION ELITE MICRONEEDLING SYSTEM

Guidance and manufacturer's declaration – electromagnetic emissions		
The REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, is intended for use in the electromagnetic environment specified below. The customer or the user of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, is intended for use in the electromagnetic environment specified below. The customer or the user of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, 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	+8kV contact +15kV air	+8kV contact +15kV 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 610004-4	+2kV for power supply lines	+2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	+1kV line(s) to line	+1kV line(s) to line	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	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, requires continued operation during power mains interruptions, it is recommended that the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, be powered from an uninterruptible power supply or a battery.
Power frequency (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.
NOTE: UT is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, is intended for use in the electromagnetic environment specified below. The customer or the user of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = [3.5/10] \sqrt{P}$ 80 MHz to 800 MHz $d = [7/10] \sqrt{P}$ 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 meters (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] Interference may occur in the vicinity of equipment marked with the following symbol:
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.			
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 REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, is used exceeds the applicable RF compliance level above, the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base.			

Guidance and manufacturer's declaration – electromagnetic immunity

The REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, is intended for use in the electromagnetic environment specified below. The customer or the user of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, should assure that it is used in such an environment.

Immunity test	IEC 60601 test level			Compliance level			Electromagnetic environment - guidance
	MHz	Modulation	Field Strength	MHz	Modulation	Field Strength	
IMMUNITY to proximity fields from RF wireless communications equipment	385	18 Hz	27 V/m	385	18 Hz	27 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: E = [6/d] √P d = [6/E] √P where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
	450	18 Hz	28 V/m	450	18 Hz	28 V/m	
	710	217 Hz	9 V/m	710	217 Hz	9 V/m	
	745	217 Hz	9 V/m	745	217 Hz	9 V/m	
	780	217 Hz	9 V/m	780	217 Hz	9 V/m	
	810	18 Hz	28 V/m	810	18 Hz	28 V/m	
	870	18 Hz	28 V/m	870	18 Hz	28 V/m	
	930	18 Hz	28 V/m	930	18 Hz	28 V/m	
	1720	217 Hz	28 V/m	1720	217 Hz	28 V/m	
	1845	217 Hz	28 V/m	1845	217 Hz	28 V/m	
	1970	217 Hz	28 V/m	1970	217 Hz	28 V/m	
	2450	217 Hz	28 V/m	2450	217 Hz	28 V/m	
	5240	217 Hz	9 V/m	5240	217 Hz	9 V/m	
	5500	217 Hz	9 V/m	5500	217 Hz	9 V/m	
	5785	217 Hz	9 V/m	5785	217 Hz	9 V/m	
IMMUNITY to proximity magnetic fields IEC 61000-4-39	0.1342	2.1kHz	65 A/m	0.1342	2.1kHz	65 A/m	
	13.56	50kHz	7.5 A/m	13.56	50kHz	7.5 A/m	
	0.030	CW	8 A/m	0.030	CW	8 A/m	

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

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base.

The REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, 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)			
	80 to 800 MHz $d = [3.5/3]\sqrt{P}$	800 MHz to 2.7 GHz $d = [7/3]\sqrt{P}$	710, 745, 780, 5240, 5500, 5785 MHz $d = [6/9]\sqrt{P}$	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 MHz $d = [6/28]\sqrt{P}$
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143

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.

Separation Distance from RFID Readers

The REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base has been tested and shown it is Immune to the following RFID Reader Technology, at a distance of 5cm away. If used closer than 5cm to a 13.56 MHz RFID Reader, there is a possibility that the display will become distorted and will show that the current cartridge has already been used. If this occurs, you must increase the separation distance, and replace the cartridge with a new one.

Frequency: 134.2kHz Field Strength: 65 A/m RMS	13.56 MHz RFID SELECT, I-BLOCK, STAY QUIET, AND INVENTORY COMMANDS Field Strength: 12 A/m RMS	860-960 MHz DSB-ASK and PR-ASK modulations Field Strength: 54 V/m RMS	2.4 GHz Field Strength: 54 V/m	Frequency: 433.92 MHz Modulation: FSK 3 V/m RMS Command: COLLECTION WITH UDB

EMC - BATTERY

Guidance and manufacturer's declaration – electromagnetic emissions		
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Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, or shielding the location.

Guidance and manufacturer's declaration – electromagnetic immunity			
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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+8kV contact +15kV air	+8kV contact +15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (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.
NOTE: UT is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms 0,15 MHz – 80 MHz 6 Vrms in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	$d = [3.5/10] \sqrt{P}$ 80 MHz to 800 MHz $d = [7/10] \sqrt{P}$ 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 meters (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] Interference may occur in the vicinity of equipment marked with the following symbol:
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.			
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 REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, is used exceeds the applicable RF compliance level above, the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base.			

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Immunity test	IEC 60601 test level			Compliance level			Electromagnetic environment - guidance
	MHz	Modulation	Field Strength	MHz	Modulation	Field Strength	
IMMUNITY to proximity fields from RF wireless communications equipment	385 450 710 745 780 810 870 930 1720 1845 1970 2450 5240 5500 5785	18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 18 Hz 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz	27 V/m 28 V/m 9 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m	385 450 710 745 780 810 870 930 1720 1845 1970 2450 5240 5500 5785	18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 18 Hz 18 Hz 18 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz 217 Hz	27 V/m 28 V/m 9 V/m 9 V/m 9 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 28 V/m 9 V/m 9 V/m 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $E = [6/d] \sqrt{P}$ $d = [6/E] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m), and E is the field strength in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
IMMUNITY to proximity magnetic fields IEC 61000-4-39	0.1342 13.56 0.030	2.1kHz 50kHz CW	65 A/m 7.5 A/m 8 A/m	0.1342 13.56 0.030	2.1kHz 50kHz CW	65 A/m 7.5 A/m 8 A/m	
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.							

Recommended separation distances between portable and mobile RF communications equipment as well as RF wireless communications equipment and the REF 200 SkinPen® Precision Elite Handpiece with REF 201 SkinPen® Precision Elite Inductive Charging Base.				
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Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	80 to 800 MHz d = [3.5/3] √P	800 MHz to 2.7 GHz d = [7/3] √P	710, 745, 780, 5240, 5500, 5785 MHz d = [6/9] √P	385, 450,810, 870, 930, 1720, 1845, 1970, 2450 MHz d = [6/28] √P
0.01	0.117	0.233	0.067	0.021
0.1	0.369	0.738	0.211	0.070
1	1.170	2.333	0.667	0.214
10	3.689	7.379	2.108	0.700
100	11.667	23.333	6.670	2.143
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.				

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Frequency: 134.2kHz Field Strength: 65 A/m RMS	13.56 MHz RFID SELECT, I-BLOCK, STAY QUIET, AND INVENTORY COMMANDS Field Strength: 12 A/m RMS	860-960 MHz DSB-ASK and PR-ASK modulations Field Strength: 54 V/m RMS	2.4 GHz Field Strength: 54 V/m	Frequency: 433.92 MHz Modulation: FSK 3 V/m RMS Command: COLLECTION WITH UDB

7. INSTRUCTIONS FOR USE

- Only use this device for the recommended applications. This device should only be used under medical supervision.
- Before administering any treatment, you should become acquainted with the operating procedures for the treatment, as well as the indications, contraindications, warnings, and precautions.

Prior to each use, examine the SkinPen Precision Elite Handpiece for the following:

- Deterioration of the pen body: ensure no cracks or breaks in the pen body are present.
- Ensure the power button works; that the pen can be turned on and off easily
- Examine the LCD screen for cracks and pitting. Examine the connection of the LCD screen to the pen body to ensure that the LCD is not beginning to detach.
- Examine all sealed areas of the pen to ensure there are no cracks in the seals which could allow for the ingress of body fluids.

If any signs of deterioration are noted, do not use the SkinPen Precision Elite pen. Contact your Crown representative for further information.

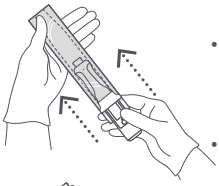
PRE-PROCEDURE PRECAUTIONS

- Avoid excessive sun exposure/burns 24 hours prior to procedure.
- Discontinue use of topical retinoids 24 hours prior to procedure.
- Avoid treatment on patients with active breakouts or open lesions.
- Allow at least 24 hours after immunotherapies and immunosuppressants before a SkinPen® Precision Elite treatment.
- Wait six months following oral isotretinoin use.
- Although not seen in the clinical study, in Fitzpatrick IV–VI, pigment may darken prior to lightening.

PROCEDURE INSTRUCTIONS

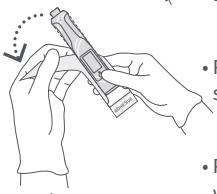
1. Have patient complete consent form.
2. Explain the SkinPen® procedure to the patient and set expectations.
3. Apply single use, non-latex gloves.
4. Cleanse patient's face with a gentle cleansing complex to effectively remove makeup, sunscreen and surface oils.
5. Take "before" pictures of the procedure area.
6. If a numbing agent was applied to provide patient comfort, the numbing agent must be removed from the skin with an antiseptic solution prior to the microneedling procedure.
7. Open the SkinPen® Treatment Kit and remove all contents. Keep the cartridge in the pouch until it is ready to use.
8. Apply the disposable BioSheath to the SkinPen®.

How to apply BioSheath:



- While wearing non-latex gloves, obtain a single use BioSheath and ensure the SkinPen® Precision Elite is clean/disinfected.

- While SkinPen® Precision Elite is powered off, insert the SkinPen® Precision Elite between the white tab and paper backing.



- Push SkinPen® Precision Elite through the BioSheath until the device is snug inside the BioSheath.

- Peel back the protective BioSheath cover by pulling on the Blue tab and white paper backing.

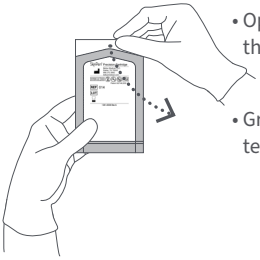
- Remove adhesive backing and seal end. SkinPen® Precision Elite is now protected and ready to use.

Note: The purpose of a sheath is to provide a covering that helps prevent the transmission of pathogens from one patient to another. SkinPen Precision Elite is intended to be used only with provided BioSheath.

9. Power on by pressing and holding the button on the front of SkinPen® Precision Elite for one second.

Note: this is only turning the device itself on. The motor will only turn on once prompted after the cartridge is properly installed.

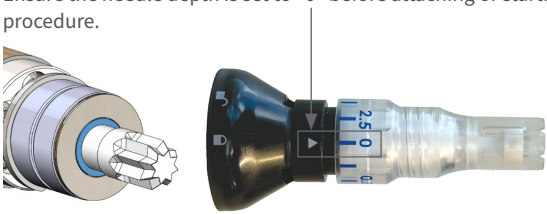
10. Install cartridge when prompted (Note that the arrow will blink)

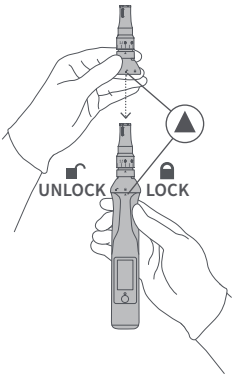


- Open the cartridge package by holding it right-side up and pulling back the protective covering at the sealed chevron.

- Grasp cartridge at locking end for attachment to handpiece. Use aseptic technique to ensure depth cup and needles remain sterile.

• Ensure the needle depth is set to "0" before attaching or starting a new procedure.

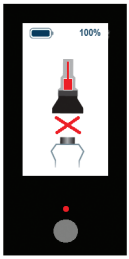




• Align the unlock symbol on the cartridge with the triangle symbol ▲ above the pen's LCD screen. Rotate the cartridge clockwise until the 'lock' symbol aligns with the indicator. Ensure the cartridge remains in the 'lock' position for proper pen functionality. The SkinPen Precision Elite cartridge is now securely attached.

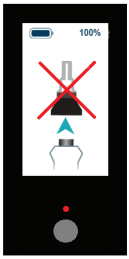
• If cartridge is Valid for Use, the Start Treatment Image will appear and go to Step 12 for next instruction.

***If a SkinPen® Precision Elite Cartridge becomes inadvertently contaminated before or during installation (ie. Dropped on floor, open/broken package, needles subjected to possible contamination), discard, and obtain new SkinPen® Precision Elite cartridge.**



• If either of the following images appear, the device will not function without a new cartridge:

o Used Cartridge– means that the cartridge has been used and cannot be used again.



o Unable to Read Cartridge - means SkinPen Precision Elite device is unable to connect to cartridge to start treatment. Please try re-installing, and contact Customer Service for a replacement if problem persists.

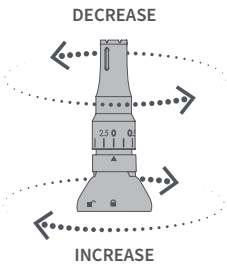
- **NOTE:** The cartridge contains a single-use lock-out feature through an RFID chip that prevents multi-use of a single cartridge. If either error message occurs, the current cartridge will need to be detached from the handpiece and a new cartridge will need to be attached per the previous instructions until the Start Treatment image appears. This safety feature ensures only a sterile single-use application.

11. Apply a thin layer of Skinfuse® Lift HG to protect the skin against abrasion and friction during the SkinPen® Precision Elite treatment. If the layer is too thick the microneedle cartridge may become clogged.

    Note: if the patient is allergic to any of the following ingredients, which are in the Skinfuse Lift HG hydrogel: purified water, glycerin, carbomer, potassium hydroxide, disodium EDTA, phenoxyethanol, caprylyl glycol, sorbic acid, SkinPen® Precision Elite treatment may not be safe.

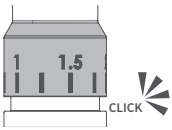
12. With a valid cartridge attached, adjust needle depth settings on the SkinPen® Precision Elite cartridge. New settings will be indicated by a "click" into place.

Instructions: How to adjust needle length:



- To increase the needle length, adjust on the cartridge according to indicated tick marks on the cartridge. New settings will be indicated by a "click" into place.
- Needle settings should be selected based on patient needs.
- It is recommended to start at a depth setting of 0.25mm.
- Increase by increments of 0.25 mm or 0.5 mm for the desired amount of erythema with a maximum depth of 2.5mm on the face and neck areas.

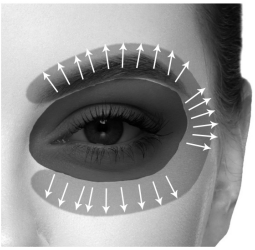
***Lower the setting of the cartridge to 0.25-0.5mm to perform the procedure around the orbital rim.**



- Decrease the needle length by adjusting according to the tick marks on the cartridge. New settings will be indicated by a "click" into place.

13. Select SkinPen® Precision Elite microneedle position based on patient needs. Start at a depth setting of 0.25mm. Increase in increments of 0.25 mm or 0.5mm until desired erythema is reached, with a maximum depth of 1.5 mm on the face and 2.5 mm on the neck areas, under the discretion of the physician. Lower to 0.25-0.5 mm to perform procedure around orbital rim.

Procedure Depth (Suggested Guidelines)
Forehead (0.25-1.0 mm)
Around the Orbital Rim* (0.25-0.5 mm)
Nose (0.25-0.75 mm)
Facial Acne Scars (up to 1.5 mm)
Neck Wrinkles (up to 2.5 mm)



Orbital Rim Guide

Orbital Rim Treatment area

Microneedling should not be used within the orbital rim

*Note: treatment can be performed around but not within the orbital rim

14. When treating the face for Acne Scars divide the face into four quadrants. Start with the right cheek, move to the chin/perioral/nose, then to left cheek, and finish with forehead. When treating the neck region, divide the neck into right and left halves and begin treating at the right jawline, moving downward and across into the left half of the neck and finishing at the left jawline.

15. From the Start Treatment Screen, push button to start treatment. When treatment is in progress, this image is shown

16. Hold the skin taut and glide the pen in controlled horizontal motions. Repeat with vertical motions in the same area. Repeat the pattern if the erythema endpoint is not reached. Depth may be increased within guidelines if necessary. Gentle, one-directional circular motions in small targeted areas is acceptable if needed to assist in reaching the erythema endpoint.

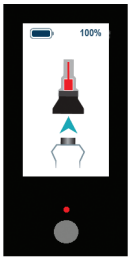
    For treatment of facial acne scars, a needle depth of 1.5mm may be used on the face and up to a depth of 2.5mm on the neck wrinkles under the discretion of the physician.

17. To pause treatment at any time, push the button again.

- To continue treatment, push the button to start the motor.

IMPORTANT: Do not remove the cartridge during a pause in treatment. This would render cartridge unusable and the device will not function without the use of a new cartridge.

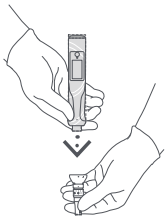
- If the device pauses itself due to an error, refer to Section 12 FAQ/ Troubleshooting for further information.
    - If a fatal error message occurs, remove the cartridge and power the device off. A fatal error is signaled by a blinking red light and includes error codes 001-018. Restart with a new cartridge.
- To continue treatment, push the button and the motor will start again.



18. When treatment is complete, pause the device and move the depth cup back to the "0" position, then press and hold the button for three seconds. A prompt to remove the cartridge will be shown, and you will not be able to restart the treatment with this cartridge. After two audible tones ("beeps") from the device, remove the cartridge and the device will automatically turn off.

NOTE: Once the shutdown process has started, you cannot return back to the treatment.

When prompted to Remove Cartridge, do the following:



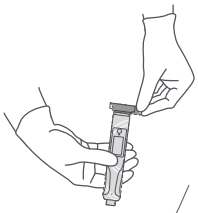
- To remove the cartridge, hold the SkinPen Precision Elite perpendicular to the floor, or with the cartridge attachment tip pointing downwards. Use one hand to rotate the cartridge "unlock" position to be in line with the pen tip triangle, and pull the cartridge off the device.

- Dispose of used SkinPen® Precision Elite cartridge via a Sharps container.

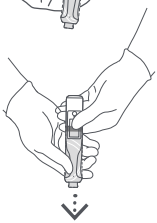
- The SkinPen® Precision Elite cartridge is designed for single use, with a lock-out feature prohibiting re-use of the cartridge.

19. Once the device is turned off, set aside to tend to the patient.
    a. Gently use sterile gauze to pat down the affected area.
    b. Skinfuse® RESCUE cosmetic calming complex may be applied the day after the procedure as needed to help soothe and calm the skin.
    c. Advise patient to avoid sweaty exercise and sun exposure for 72 hours post-procedure.
    d. It is recommended to avoid other facial aesthetic treatments the month following the SkinPen® Precision Elite treatment.
    e. Schedule next appointment after at least 4 weeks.
    f. Take "after" pictures before next appointment.

20. Remove biosheath.



- With the SkinPen Precision Elite device perpendicular to the floor, with the tip pointed downwards, and pull apart the adhesive strip of the BioSheath.



- Remove the BioSheath by carefully rolling it down the SkinPen Precision Elite to prevent soiling the handpiece.

- Dispose of the BioSheath in a biohazard container. BioSheaths are not intended to be reused.
- Disinfection of the SkinPen Precision Elite should be completed with the use of an approved disinfection method, **See Section 8- Cleaning of SkinPen Precision Elite and Charger Base.**

Note: Soiled gloves should always be disposed of in a biohazard container. Do not reuse disposable gloves.

21. After removal of the BioSheath and disinfection with an approved disinfection method is performed, users' gloves should be removed, hands cleaned, and a new pair of clean gloves worn before proceeding to the next patient.

22. Place SkinPen Precision Elite handpiece back on the charging base:

- Inductive charging is used between the SkinPen® Precision Elite charger base and the SkinPen® Precision Elite device.
- Plug the charger base into a live outlet.
- **Note:** If your SkinPen Precision Elite battery has run to zero percent, there will be no indication of charging when it is placed on the charging base. If after 10 minutes of charging, there is still no visual indication that your device is charging, please gently pick the pen up and place it back on the charger. The LED light should begin to blink to demonstrate that the pen is charging.
- Place the hand-piece into the base with the screen facing out. The device will be actively charging as shown on the screen with the LED light indicated in blue:

- Smart Charge Technology ensures the pen reaches and maintains a fully charged state. Charging is complete when the display shows 100% or a charge level above 96%. The pen may not display charging activity when placed on the charger base if already fully charged.

8. CLEANING OF SKINPEN® PRECISION ELITE AND CHARGER BASE

***Ensure SkinPen® Precision Elite device is powered down before cleaning, and SkinPen® Precision Elite charger base is unplugged.**

- Each device should be cleaned while holding the SkinPen® Precision Elite facing straight down while wiping the rotary area. Do not clean near the seal.
- Sani-Cloth AF3 wipes or an appropriate disinfection method should be used to clean the SkinPen® Precision Elite after each procedure. Sani-Cloth AF3 wipes may also be used to clean the SkinPen® Precision Elite Charger Base. Sani-Cloth AF3 wipes should be used to carefully wipe the SkinPen® Precision Elite for more than 3 minutes, according to their directions for use, found on the Sani-Cloth AF3 labeling. Attention should be paid to clean areas such as crevices, seams, and areas around where the SkinPen Precision Elite Cartridge attaches to the device.
- Sani-Cloth AF3 GUIDELINES FOR USE:
  SPECIAL INSTRUCTIONS FOR CLEANING & DECONTAMINATION AGAINST HIV-1 AND HBV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:
  - PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

- CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant.
- DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.
- CONTACT TIME: Leave surfaces wet for 3 minutes. Let air dry. Do not reuse towelette.

- GENERAL DISINFECTION METHOD: Please dilute bleach according to a concentration outlined by the CDC and EPA. For Clorox bleach (4.5% sodium hypochlorite) dilute 1/3 cup of bleach per gallon of water. Thoroughly wet a paper towel with the diluted bleach solution; the towel should be wet but not dripping. Thoroughly wipe all surfaces of the hand piece for a minimum of 1 minute making sure to keep the surfaces wet with the bleach solution. Allow the hand piece to dry for 10 minutes prior to handling or use. Do not immerse the hand piece in bleach.
- Do not immerse in liquids.
- Do not use solvents to clean device unless specified in the General Disinfection Method.
- Upon completion of cleaning, examine the SkinPen Precision Elite Handpiece to ensure that the pen is visually clean. There should be no visible body fluids, blood or Lift HG on the pen following cleaning. If any of these substances remain after cleaning, repeat the cleaning process. If contamination such as body fluids, blood or Lift HG is noted after cleaning a second time, remove the SkinPen Precision Elite pen from use and contact your Crown representative for information.

9. STORAGE

- For optimal performance of your SkinPen Precision Elite®, ensure the device is turned off and store the device in the SkinPen® Precision Elite charging base when not in use.
- If the device is ON and not connected to a charger base, the device will automatically shut off after 15 minutes if no cartridge is attached. If the device is ON and not connected to a charger base with a cartridge attached, the device will begin beeping after 30 minutes for one second with five seconds in between. This will continue until the device is placed on the charger, cartridge is removed, and/or device is turned off.

10. DISPOSAL

- Dispose of cartridges/needle tips as medical waste via a Sharps container.
- Properly dispose of all items in accordance with local regulations.
- You must dispose of SkinPen Precision Elite®, SkinPen® Precision Elite Charger, and all other SkinPen® Precision Elite components properly according to local laws and regulations. Because SkinPen® Precision Elite contains electronic components and a Lithium Ion rechargeable battery, SkinPen® Precision Elite must be disposed of separately from household waste. When SkinPen® Precision Elite reaches its end of life, contact local authorities for proper disposal and recycling options.

11. FAQ/TROUBLESHOOTING

Fault Indications: the following screen indicates an error in the device.

Please refer to the table below for specific error code definition and how to troubleshoot.

Error Code	Error Message	Issue	How to Troubleshoot
001 - 015	System Error	System Problem that can't be fixed by end user.	Try powering off and on again. If problem persists, contact customer service for assistance.
016	Temperature issue / Warm to room temp	Device being used in an environment below 17C.	Move the device to warmer environment and turn the device off. This will require a new cartridge. If problem persists, contact customer service for assistance.
017	Temperature issue / Cool to room temp	Device being used in an environment above 60C. Or Device has overheated.	Move the device to cooler environment and turn the device off. This will require a new cartridge. If problem persists, contact customer service for assistance.
018	Motor Over Heated	Device has overheated due to excessive use.	Provide time for the motor to cool down and turn the device off. This will require a new cartridge. If problem persists, contact customer service.
N/A	Motor Stall	Cartridge cannot penetrate surface.	Remove pen and re-start treatment by hitting the start button again. This will not require a new cartridge.
N/A	Motor Speed	Surface is causing slow needle movement.	Remove pen and re-start treatment by hitting the start button again. This will not require a new cartridge.

12. SPECIFICATIONS

Technical Information of SkinPen® Precision Elite

Product Name	SkinPen® Precision Elite
SkinPen® Precision Elite Handpiece Model Number	200
SkinPen® Precision Elite Charger Base Model Number	201
Crown Aesthetics FDA Registration #	3010392991
FCC ID	2AGLK-101 (SkinPen® Precision Elite Charging Base), 2AGLK-REF-200 (SkinPen® Precision Elite Handpiece)
IC	21314-101 (SkinPen® Precision Elite Charging Base), 21314-REF200 (SkinPen® Precision Elite Handpiece)
Weight and Unit	6 oz/153mm length and max. outer diameter of 38mm
Electrical Requirements	Charger Base Input: 5VDC, 2A max
Output voltage	5W (max)
Charger Time	From 10% charge to 90% charge within 8 hours.
Working Time	> 6 hours (under normal use conditions)
Needle Reciprocation Speed	6300 RPM - 7700 RPM
Needles	• 14 total solid needles • 32 BWG (gauge) • <32 RMS (roughness) • Medical grade Stainless Steel • EU RoHS compliant • Sharpness specification within the Radius 0.005mm (Max) • Maximum extension of the needles from the needle head surface is less than 2.75mm • needle length: 2.5 +/- 0.25mm exposed length • needle geometry: 0.25mm diameter with 1mm conical taper from needle tip • maximum penetration depth: 2.5 ± 0.25 mm • puncture rate: 1470-1797 punctures/sec
Operation	Cordless
AC Adapter	Medical Grade, Universally compatible power requirements: 90-264 VAC at 47-63 Hz
Charger base transmitting frequency	Between 110kHz and 205kHz

13. ENVIRONMENTAL CONDITIONS

Storage and Operating conditions:	Temperature: 17-30°C
	Relative humidity: 30-75% relative humidity non-condensing
	Atmospheric Pressure: 70 -106 kPa
Transportation conditions:	Temperature: -18-60°C
	Relative humidity: 30-85% relative humidity non-condensing

The EMISSIONS characteristics of the SkinPen® Precision Elite & Charger Base make it suitable for use in industrial areas and hospitals (CISPR 11 class A).

The device complies with Innovation, Science and Economic Development Canada's RSS-216.

This user manual is valid for SkinPen Precision Elite® handpiece, the SkinPen® Precision Elite Charger Base (with AC adapter), SkinPen® Precision Elite BioSheath and SkinPen® Precision Elite Treatment Kit.

This user manual is published by Crown Aesthetics. Crown Aesthetics does not guarantee its contents and reserves the right to improve and amend it at any time without prior notice. Amendments will however be published in a new edition of this manual.

Declaration of Conformity

Crown Aesthetics declares that the SkinPen® Precision Elite and SkinPen® Precision Elite charger base complies with the following normative documents:

IEC 62133, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62366, ISO 14971

IEC 62304, MDR 2017/745, RoHS, IEC 60601-1-6, IEC 60529, ISO 10993-1.

We Crown Aesthetics accept not having the SGS Mark on the SkinPen® Precision Elite device label, but our product is 60601 certified.

Conforms to AAMI STD ES 60601-1, Certified to CSA STD C22.2 #60601-1.

This device is classified as Class IIa per MDR 2017/745.

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.

CROWN

Supplier's Declaration of Conformity 47 CFR § 2.1077 Compliance Information

PRODUCT IDENTIFICATION: The SkinPen® Precision Elite Microneedling System, consisting of REF 200: SkinPen® Precision Elite Handpiece and REF 201: SkinPen® Precision Elite Inductive Charging Base

RESPONSIBLE PARTY (U.S. Contact Information required):

Bella-Medical, LLC DBA Crown Aesthetics
5005 Lyndon B. Johnson Fwy STE 370
Dallas, Texas 75244 USA

CONTACT NAME: Stanton Luther

TELEPHONE NUMBER AND/OR E-MAIL ADDRESS: 423.691.7205 / sluther@crownlabsseries.com

FCC COMPLIANCE STATEMENT:

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.

THIRD PARTY TESTING:

Intertek Cetecom
Address: 2309 Bering Drive, CA
Phone: 408-463-9000
Fax: 408-463-9001
Toll Free: 877-261-1152

www.intertek.com

RESPONSIBLE PARTY SIGNATURE:

Stanton Luther Digitally signed by Stanton Luther
DN: cn=Stanton Luther, c=US
Date: 2024.04.10 09:42:00 -05'00'

[signature]

Date: April 10, 2024

Name: Stan Luther

Title: QA Manager

Location: Dallas, TX USA

5005 LBJ Freeway, Ste 370
Dallas, TX 75244

www.crownaesthetics.com

888.516.7992

Note: 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.

Changes or modifications not expressly approved by Crown Aesthetics could void the user's authority to operate the equipment.

This radio transmitter 21314-REF200 has been approved by Innovation, Science and Economic Development Canada to operate with the antenna types listed below, with the maximum

permissible gain indicated. Antenna types not included in this list that have a gain greater than the maximum gain indicated for any type listed are strictly prohibited for use with this device.

14. CLINICAL STUDY SUMMARY – ACNE SCARS

A clinical study was conducted to support the safety and effectiveness of the SkinPen Precision System for the treatment of acne scars on the face.

The study was conducted at a single center and included treatments on day 1, day 30, and day 60, with follow-up visits at 1 month and 6 months after the final (day 60) treatment. Treatments were conducted by a trained aesthetician (skin care specialist). The face was cleaned and numbed prior to treatment. A thin layer of Skinfuse Lift HG was applied prior to treatment to protect against abrasion and friction during the procedure. The aestheticians were instructed to start at the lowest depth setting and gradually increase the depth until erythema was observed, with a maximum depth of 1.5mm. The instructions included a precaution that microneedling was used around but not within the orbital rim. The face was divided into quadrants for treatment to ensure that all acne scars were treated. Following treatment, Skinfuse Lift HG was applied to prevent the skin from drying out post procedure.

A total of 41 subjects completed the study. Only 20 of these subjects were treated with the SkinPen Precision System. The other 21 subjects were treated with a prototype device. There are technological differences between the SkinPen Precision System and the prototype device, including a greater number of needles in the SkinPen Precision cartridge and faster motor speed in the SkinPen Precision device, which may affect the device effectiveness results. Therefore, the safety assessments collected for both treatment groups are included in the summary below. However, for the effectiveness results, only the data for the SkinPen Precision group was considered.

Subjects enrolled in the study included both men (31.7%) and women (68.3%) over the age of 21. The study included 11/41 subjects with Fitzpatrick Skin Type (FST) V and VI.

Table 1: Summary of Demographic Information

	SkinPen Precision System		All Subjects	
N	20		41	
Age (years)				
Mean (standard deviation)	43.8 (12.7)		44 (11.9)	
Minimum, Median, Maximum	23, 48, 60		21, 46, 60	
	N	(%)	N	(%)
Sex				
Male	7	35	13	31.7
Female	13	65	28	68.3
Ethnicity				
Hispanic or Latino	6	30	13	31.7
Not Hispanic or Latino	14	70	28	68.3
Race				
American Indian or Alaska Native	1	5	2	4.9
Asian	3	15	9	22.0
Black or African American	6	30	10	24.4
White	10	50	20	48.8
Fitzpatrick Skin Type				
II	2	10	3	7.3
III	4	20	10	24.4
IV	7	35	17	41.5
V	4	20	7	17.1
VI	3	15	4	9.8

At each clinical visit, digital images were taken of each subject's facial acne scars. On day 1, day 30, and day 60, imaging was performed prior to treatment. A total of 3 full-face images were collected. Images were also collected at the 1 month and 6 month follow-up visit. These images were graded by two separate Board Certified Dermatologists after completion of the study using the following assessment tools and timepoints [Table 2]. Details of each of these assessment tools are provided below in Tables 3-5. The results of the study are provided in Tables 6-10.

Table 2: Study Endpoints

Primary effectiveness endpoints	Acne Scar Assessment Scale graded by two blinded dermatologists using photographs taken at baseline, day 30, day 60, 1-month post-treatment, and 6-months post-treatment
	Clinician's Global Aesthetic Improvement Assessment graded by two blinded dermatologists using photographs taken at 1-month post-treatment, and 6-months post-treatment
Secondary effectiveness endpoints	Self-assessed Scar Improvement Scale completed by subjects at baseline, 1-month post-treatment, and 6-months post-treatment
	Subject Global Aesthetic Improvement Scale completed by subjects at baseline, 1-month post-treatment, and 6-months post-treatment
	Patient Satisfaction Questionnaire completed by subjects at 1-month post-treatment and 6-months post-treatment
Safety Endpoint	Subject safety diaries provided to the subject at each treatment visit (day 1, 30, and 60) and completed for 30 days to record treatment responses
	Adverse event monitoring at each visit; baseline, day 30, day 60, 1-month post-treatment, and 6-months post-treatment

The photo grading included the following effectiveness assessments:

- Acne Scar Assessment Scale[1]

Table 3: Acne Scar Assessment Scale

Grade	Term	Description
0	Clear	No depressions are seen in the treatment area. Macular discoloration may be seen.
1	Very mild	A single depression is easily noticeable with direct lighting (deep). Most or all of the depressions seen are only readily apparent with tangential lighting (shallow).
2	Mild	A few to several, but less than half of all the depressions are easily noticeable with direct lighting (deep). Most of the depressions seen are only readily apparent with tangential lighting (shallow).
3	Moderate	More than half of the depressions are apparent with direct lighting (deep).
4	Severe	All or almost all the lesions can be seen with direct lighting (deep).

[1] Jwala Karnik, Leslie Baumann, Suzanne Bruce, Valerie Callender, Steven Cohen, Pearl Grimes, John Joseph, Ava Shamban, James Spencer, Ruth Tedaldi, William Philip Werschler, Stacy R. Smith, "A double-blind, randomized, multicenter, controlled trial of suspended polymethylmethacrylate microspheres for the correction of atrophic facial acne scars" Journal of the American Academy of Dermatology 71(1):77-83 (2014).

In addition to the clinician graded effectiveness measures, the following patient-reported measures were recorded throughout the study:

- Self-assessed Scar Improvement Scale

Table 4: Self-assessed Scar Improvement Scale

Rating	Description
-1	Exacerbation of Acne Scars
0	No change in appearance of acne scars
1	1% - 25% improvement in appearance of acne scars
2	25% - 50% improvement in appearance of acne scars
3	50% - 75% improvement in appearance of acne scars
4	75% - 99% improvement in appearance of acne scars

- Subject Global Aesthetic Improvement Scale

Table 5: Subject Global Aesthetic Improvement Scale

Rating	Description
1	**Very Much Improved:** Optimal cosmetic result.
2	**Much Improved:** Marked improvement in appearance from the initial condition, but not completely optimal.
3	**Improved:** Obvious improvement in appearance from initial condition.
4	**No Change:** The appearance is essentially the same as the original condition.
5	**Worse:** The appearance is worse than the original condition.

- Patient Satisfaction Questionnaire

  Three questions were asked to the subjects in the study regarding their level of satisfaction with the treatment. It was included as a secondary endpoint in the study. See individual questions and results in the section below.

  Safety information was collected throughout the study using subject safety diaries. Safety diaries were provided to the subject at each treatment visit (day 1, 30, and 60). The subject was instructed to record any observations related to treatment including common treatment responses. Common treatment responses are side effects that result from treatment which resolve on the order of days. Common treatment responses that persist may be categorized as adverse events when assessed by the investigator at the next visit.

  Subjects were informed of the following potential common treatment responses in the informed consent process: skin will be red and flushed similar to a moderate sunburn, skin tightness and mild sensitivity to the touch, redness, burning, tingling, stinging, itching, and/or scaling/dryness, edema (swelling), tenderness/discomfort, a possibility of developing an infection (an increase in redness, warmth, itching, or pus formation). The diaries included space for daily recording of observations for the 30 days in between treatment visits. Adverse events were assessed by the investigator at each subsequent visit.

Results:

Safety:

At the 6-month post-treatment visit, no adverse events persisted.

The following common treatment responses were reported in the subject safety diaries which were sent home with the subject:

- Dryness in 5/41 (12%) subjects lasting from 1-6 days
  - These responses were reported by 3 subjects with FST III, 1 subject with FST VI, and 1 subject with FST V
- Rough Skin in 3/41 (7%) of subjects lasting from 1-2 days
  - These responses were reported by 1 subject with FST III, and 2 subjects with FST V
- Tightness in 2/41 (4%) of subjects lasting from 1-2 days
  - These responses were reported by 2 subjects with FST VI
- Redness, Itching, Peeling Discomfort and Tenderness in 13/41 (31%) of subjects lasting 1-3 days
  - These responses were reported by 6 subjects with FST III, 2 subjects with FST IV, 3 subjects with FST V, and 2 subjects with FST VI
- Burning in 4/41 (9%) of subjects lasting 1-3 days
  - These responses were reported by 1 subject with FST III, 1 subject with FST VI, and 2 subjects with FST V

Over the course of the study, 1 subject reported an arthropod bite on the inner right thigh that was determined to be moderate and unlikely related to SkinPen prototype device. 1 subject (1/41, 2.4%) experienced an AE (skin striae [linear marks, ridges, or grooves] on the forehead and both sides of the face) that was determined to be mild and possibly related to use of the SkinPen Precision System. This AE was thought to be due to subject exposure to excess sunlight soon after treatment which was against study instructions, yet resolved without any additional complications.

Effectiveness:

Acne Scar Assessment Scale:

Results of photo grading using the Acne Scar Assessment Scale demonstrated that at baseline the mean population score was mild at 2.80. Following the three treatments and 6 months of follow-up, the mean population score was reported as mild at 2.35.

The evaluation by the blinded assessors indicated that seven subjects (7/20, 35%) had a 1-grade reduction in the Acne Scar Assessment Scale at 6-months post-treatment compared to baseline. The seven subjects reporting a 1-grade reduction included 1 subject with FST II, 2 subjects with FST III, 1 subject with FST IV, 2 subjects with FST V, and 1 subject with FST VI.

In addition, 4 subjects (20%) showed an improvement greater than 0 but less than 1 on the Acne Scar Assessment Scale, giving a total of 55% (11/20) of subjects showing improvement at 6-months post-treatment when compared with baseline. At 6-months post-treatment, the remaining 9 subjects (45%) reported no change in score when compared to baseline. The visual improvements seen in the photo grading results were considered to be clinically meaningful.

Table 6: Results of Photo Grading of Acne Scar Assessment Scale for SkinPen Precision System

Time Point	N	Mean	Standard Deviation	Minimum	Median	Maximum
Baseline	20	2.80	0.52	2.00	3.00	4.00
Day 30	20	2.78	0.57	2.00	2.75	4.00
Day 60	20	2.70	0.55	2.00	2.50	3.50
1-Month Post-Treatment	20	2.68	0.49	2.00	2.50	3.50
6-Months Post-Treatment	20	2.35	0.69	1.50	2.50	3.50

Table 7: Change from Baseline for Photo Grading of Acne Scar Assessment Scale for SkinPen Precision System

Time Point	N	Subject Improved (%)	Subject Worsened (%)	Mean Change	Standard Deviation for Change	Mean Change (%)
Day 30	20	30.0	20.0	-0.03	0.50	-0.9
Day 60	20	35.0	20.0	-0.10	0.50	-3.6
1-Month Post-Treatment	20	40.0	20.0	-0.13	0.58	-4.5
6-Months Post-Treatment	20	55.0	0.0	-0.45	0.46	-16.1

Self-assessed Scar Improvement Scale:

Treatment with SkinPen Precision produced an improvement in SASIS scores at 1 month post-treatment and 6-months post-treatment. At 1-month post-treatment, 17 (85%) subjects reported some percentage of improvement in the appearance of their acne scars, with 3 (15%) subjects reporting no change. At 6-months post-treatment, 18 (90%) subjects reported some percentage of improvement in the appearance of their acne scars, with 2 (10%) subjects reporting no change. The mean value for the population was = 1.65 and 1.70, at 1-month post-treatment and 6-months post-treatment respectively (1%-25% improvement in appearance of acne scars) when compared with a score of 0 (no change in appearance of acne scars). No subjects reported a negative score (i.e., exacerbation of acne scars) at either post-treatment timepoint.

Subject Global Aesthetic Improvement Scale:

Treatment with SkinPen Precision produced an improvement in SGAIS scores at 1 month post-treatment and 6 months post-treatment. At 1-month post-treatment, 7 (35%) subjects reported much improved, 9 (45%) subjects reported improved, and 4 (20%) subjects reported no change. At 6-months post-treatment, 2 (10%) subjects reported very much improved, 8 (40%) subjects reported much improved, 8 (40%) subjects reported improved, and 2 (10%) subjects reported no change. The mean value for the population was = 2.85 and 2.50, at 1-month post-treatment and 6-months post-treatment respectively (improved) when compared with a score of 4 (no change). No subjects reported a score of 5 (worse) at either post treatment timepoint.

Patient Satisfaction Questionnaire:

The results of the patient satisfaction questionnaire for all subjects indicated that a greater proportion of subjects selected favorable responses regarding treatments at 1 month and 6 months post-treatment for the following inquiries:

• Question 1: Do you notice any improvement in how your acne scars look in the treated area?

Table 8: Results of Patient Satisfaction Questionnaire - Question 1

Time Point	Yes [N (%)]	No [N, (%)]
1-Month Post-Treatment	16 (80.0)	4 (20.0)
6-Months Post-Treatment	18 (90.0)	2 (10.0)

• Question 2: How would you characterize your satisfaction with the treatment?

Table 9: Results of Patient Satisfaction Questionnaire – Question 2

Time Point	Extremely Satisfied [N (%)]	Satisfied [N (%)]	Slightly Satisfied [N (%)]	Neither Satisfied nor Dissatisfied [N (%)]	Slightly Dissatisfied [N (%)]	Dissatisfied [N (%)]	Very Dissatisfied [N (%)]
1-Month Post-Treatment	3 (15.0)	9 (45.0)	5 (25.0)	3 (15.0)	0 (0.0)	0 (0.0)	0 (0.0)
6-Months Post-Treatment	3 (15.0)	9 (45.0)	5 (25.0)	1 (5.0)	1 (5.0)	1 (5.0)	0 (0.0)

• Question 3: Would you recommend this treatment to your friends and family members?

Table 10: Results of Patient Satisfaction Questionnaire – Question 3

Time Point	Yes [N (%)]	No [N, (%)]
1-Month Post-Treatment	18 (90.0)	2 (10.0)
6-Months Post-Treatment	18 (90.0)	2 (10.0)

15. CLINICAL STUDY SUMMARY – WRINKLES

A clinical study was conducted to support the safety and effectiveness of the SkinPen Precision System for the treatment of wrinkles on the neck.

The single center study was conducted on a total of 35 subjects (2 male and 33 female), aged 44 years and older from various ethnic groups with multiple skin tones (pale to dark skin). Treatments were given on day 1, day 30, day 60, and day 90 with follow-up visits at 1 month and 3 months after the last treatment. Under direct supervision of a licensed Physician, treatments were conducted by a trained aesthetician (skin care specialist). The face and neck was cleaned and numbed prior to treatment. A thin layer of Skinfuse Lift HG was applied prior to treatment area to protect against abrasion and friction during the procedure. The aestheticians were instructed to treat at depths of up to 2.5 mm. Following treatment, Skinfuse Lift HG was applied to prevent the skin from drying out post procedure.

Table 11: Summary of Demographic Information Per Protocol

	SkinPen Precision System	
N	32	
Age (years)		
Mean (standard deviation)	56.3 (5.0)	
Minimum, Median, Maximum	44, 56.5, 65	
	N	(%)
Sex		
Male	2	6.3
Female	30	93.8
Ethnicity		
Hispanic or Latino	4	12.5
Not Hispanic or Latino	28	87.5
Race		
Other	4	12.5
White or Caucasian	28	87.5
Fitzpatrick Skin Type		
II	24	75.0
III	4	12.5
IV	4	12.5

At each clinical visit, digital images were taken of each subject's wrinkles on the neck. These images were graded by two separate independent blinded Board Certified Physicians after completion of the study using the following assessment tools and timepoints [Tables 12-15]. The results of the study are provided in Tables 16-20.

Table 12: Study Endpoints

Primary Effectiveness Endpoints	G. Lemperle Wrinkle Scale graded by two blinded graders using photographs taken at day 1 and 3-months post-treatment
Secondary Effectiveness Endpoint	Clinician's Global Aesthetic Improvement Assessment graded by two blinded graders using photographs taken at day 1 and 3-months post-treatment
	Subject Global Aesthetic Improvement Scale completed by subjects at 1-month post-treatment, and 3-months post-treatment
	Patient Satisfaction Questionnaire completed by subjects at 1-month post-treatment and 3-months post-treatment
Safety Endpoint	Subject safety diaries provided to the subject at each treatment visit (day 1, 30, 60 and 90) and completed for 30 days to record treatment responses
	Adverse event monitoring at each visit; day 1, day 30, day 60, day 90, 1-month post-treatment and 3 months post-treatment

Subjects had wrinkling assessed on the neck using the G. Lemperle Wrinkle Assessment Scale.

Table 13: Assessment of Wrinkling – G. Lemperle Wrinkle Scale

Class	Description
0	No wrinkles
1	Just perceptible wrinkle
2	Shallow wrinkles
3	Moderately deep wrinkle
4	Deep wrinkle, well-defined edges
5	Very deep wrinkle, redundant fold

At 1 month post-treatment and 3 months post-treatment, subjects also participated in the following procedures:

- Clinician's Global Aesthetic Improvement Scale

Table 14: Clinician's Global Aesthetic Improvement Scale (CGAIS)

Rating	Description
1	**Very Much Improved:** Optimal cosmetic result in this subject.
2	**Much Improved:** Marked improvement in appearance from the initial condition, but not completely optimal for this subject.
3	**Improved:** Obvious improvement in appearance from initial condition, but a re-treatment is indicated.
4	**No Change:** The appearance is essentially the same as the original condition.
5	**Worse:** The appearance is worse than the original condition.

- Subject's Global Aesthetic Improvement Scale

Table 15: Subject Global Aesthetic Improvement Scale

Rating	Description
1	**Very Much Improved:** Optimal cosmetic result.
2	**Much Improved:** Marked improvement in appearance from the initial condition, but not completely optimal.
3	**Improved:** Obvious improvement in appearance from initial condition.
4	**No Change:** The appearance is essentially the same as the original condition.
5	**Worse:** The appearance is worse than the original condition.

- Patient Satisfaction Questionnaire

  Subjects completed a Sponsor-provided questionnaire regarding improvement in wrinkles, satisfaction with the treatment and willingness to recommend the treatment to friends and family members.

Results:

Safety:

a. What side effects were seen in the clinical study?

Common Treatment Responses on the face and neck:

Common Treatment responses of dryness, redness, burning sensation and itchiness which lasted the duration of 1-3 days. Reactions of tenderness and peeling/flaking occurred for the duration of 1-7 days.

The following common treatment responses were reported in the subject safety diaries which were sent home with the subject:

- Dryness in 7/32 (22%) subjects lasting from 1-3 days
  - These responses were reported by 6 subjects with FST II, 1 subject with FST IV
- Redness in 2/32 (6%) subjects lasting from 1-3 days
  - These responses were reported by 2 subjects, 1 subject with FST II, 1 subject with FST IV
- Itching in 1/32 (3%) subjects with FST II, lasting from 1-2 days
- Peeling was reported in 8/32 (22%) of subjects lasting 1-3 days
  - These responses were reported by 8 subjects, 5 subjects with FST II, 1 subject with FST III, 2 subjects with FST IV
- Tenderness that lasted 1-4 days in 1/32 (3%) of Subjects , with FST II
- Burning in 2/32 (6%) of subjects lasting 1-3 days
  - These responses were reported by 2 subjects with FST IV

b. What adverse events were seen in the clinical study?

At the 3-month post-treatment visit, no adverse events were seen.

No adverse events related to the SkinPen Precision treatment were observed on the face or neck during the study.

c. What are other possible adverse events?

Although not seen in the clinical study, patients may experience red and flushed skin, skin tightness and mild sensitivity to touch (such as itching, burning, stinging, tingling), scaling/dryness, redness, edema and tenderness/discomfort.

Benefits:

What will a SkinPen Precision Treatment accomplish, and what did the clinical study show?

The study doctors reported using the G. Lemperle Wrinkle Scale:

Results of the photo grading indicated a significant improvement in wrinkles on the neck area assessment at 3 months post- treatment.

Table 16: Results of Photo Grading of G. Lemperle Wrinkle Scale for SkinPen Precision System

Detail	Time Point	N	Mean	Standard Deviation	Min	Median	Max
Neck	Day 1	32	3.31	0.74	2.00	3.25	5.00
	3 Mo. Post-Treatment	32	2.45	0.93	1.00	2.00	4.50

Table 17: Change from Baseline for Photo Grading of G. Lemperle Wrinkle Scale for SkinPen Precision System

Detail	Time Point	N	Subjects graded as having a ≥1 grade improvement
Neck	3 Mo. Post-Treatment	32	16 (50%)

Clinician's Global Aesthetic Improvement Assessment:

Treatment with SkinPen Precision produced an improvement in CGAIS scores at 3 months post-treatment. At three-months post-treatment evaluation, 31.5% of subjects received a '3: improved' grading and 57% received a grading of '4: no change' relative to pre-treatment. Four subjects (11.5%) received a grading of '2: much improved'.

Subjects reported using the Subject Global Aesthetic Improvement Scale:

Treatment with SkinPen Precision produced an improvement in Subject GAIS scores at 3-months post-treatment. At 3-months post-treatment, 22 (68.8%) subjects reported some percentage of improvement in the appearance of their wrinkles, with 10 (31.3%) subjects reporting no change.

Subjects reported using the Patient Satisfaction Questionnaire:

The results of the patient satisfaction questionnaire for all subjects indicated that a greater number of subjects selected favorable responses regarding treatments at 1 month and 3 months post-treatment for the following inquiries

- Question 1: Do you notice any improvement in how your fine lines and wrinkles look in the treated area?

Table 18: Results of Patient Satisfaction Questionnaire - Question 1

Time Point	Yes [N (%)]	No [N, (%)]
1-Month Post-Treatment	30 (93.8)	2 (6.3)
3-Months Post-Treatment	23 (71.9)	9(28.1)

- Question 2: How would you characterize your satisfaction with the treatment?

Table 19: Results of Patient Satisfaction Questionnaire – Question 2

Time Point	N	Favorable (+) N (%)	Unfavorable (-) N (%)	Neutral N (%)
1 Month Post-Treatment	32	28 (87.5)	3 (9.4)	1 (3.1)
3 Months Post-Treatment	32	24 (75.0)	6 (18.8)	2 (6.3)

- Question 3: Would you recommend this treatment to your friends and family members?

Table 20: Results of Patient Satisfaction Questionnaire – Question 3

Time Point	Yes [N (%)]	No [N, (%)]
1-Month Post-Treatment	25 (80.6)	6 (19.4)
3-Months Post-Treatment	21 (65.6)	11 (34.4)

Subjects were informed of the following potential common treatment responses in the informed consent process: skin will be red and flushed similar to a moderate sunburn, skin tightness and mild sensitivity to the touch, redness, burning, tingling, stinging, itching, and/or scaling/dryness, edema (swelling), tenderness/ discomfort, a possibility of developing an infection (an increase in redness, warmth, itching, or pus formation). The diaries included space for daily recording of observations for the 30 days in between treatment visits. Adverse events were assessed by the investigator at each subsequent visit.

SYMBOL LEGEND

Manufacturer's trade name and address		Manufacturer's catalogue code	REF
Serial Number	SN	Batch code	LOT
Authorized Representative in the European Community	EC REP	CE mark	CE
Do not re-sterilize	STERILIZE	Do not re-use	
Sterilized using ethylene oxide	STERILE EO	Consult Instructions for Use	
Caution		Do not use if package is damaged	
Temperature shipment limits	-18 °C 60	Humidity limitation	30 % 75
Keep dry		Not for general waste	
This device includes RF transmitters		Direct Current	
Positive Polarity	− +	Use-by date	
Date of Manufacture		Type BF applied part	

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