FOREO ESPADA Range User Manual

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GETTING STARTED

This booklet contains all essential instructions; for additional product resources, visit foreo.com.

WARNING: No modification of this equipment is allowed.
Please READ ALL INSTRUCTIONS BEFORE USE. Use this product only for its intended use as described in this manual.

INTENDED USE

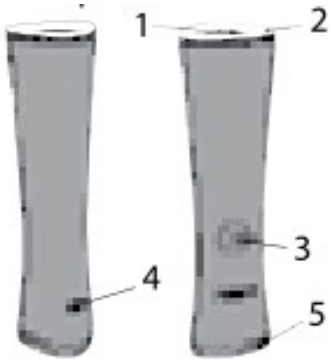
ESPADA™ has been developed to be used as an at-home device for the treatment of mild to moderate inflammatory acne on the facial area. The device is safe to use on all skin tones. ESPADA™ quickly, noninvasively and effectively eliminates acne-causing bacteria.

Suitable for:

- Mild acne (whiteheads, blackheads and papules)
- Moderate inflammatory acne (inflamed, sensitive bumps filled with pus)

ESPADA™ FEATURES

1. Treatment surface
2. Antibacterial silicone
3. Start/stop button
4. Charging port
5. Indication light



- Blue (LED) light – For killing acne bacteria. Activates when device touches the skin. Flashes 3 times to indicate the start of each routine. Each time ESPADA™ is switched on, it performsa self-check to ensure blue LED

emissions remain at the appropriate level for use. If moved from the skin the light will automatically turn off.

- T-Sonic™ pulsations – when the device is turned on, its pulsations will be in a lower intensity and when it touches the skin, the intensity will increase so more blue light can penetrate the pores for increased effectiveness. After the device is moved from the skin, the pulsations will return to a lower intensity setting automatically.
- Targeting light (red cross-shaped light) – Targets the exact spot you wish to apply the treatment. Activates when device is away from the skin and turns off when the device touches the skin.
- Built-in timer – Every 30 seconds the device will pause its pulsations and flash to indicate the end of each routine. After indication, the device should be moved to the next treatment spot.
- If the device does not make contact with the skin when it is turned on, it will automatically switch off after 3 minutes.

USING YOUR ESPADA

Cleanse and dry your face before using the device. Press the universal
button once to activate. Direct it over the blemish you wish to treat with the targeting light for ultimate precision. Gently place the device onto the blemish and hold it there for 30 seconds and wait for the built-in timer to indicate when the treatment is finished. Blemishes can be subjected to more than one 30 second routine, depending on severity. For mild acne, apply two 30 second routines. For moderate acne, 3 to 4 routines. Move the device to another blemish you wish to treat, if any, and repeat the procedure. There is no need to switch off the device between treatments.
NOTE: SKIN WARMTH: The skin may feel warm during treatment, which is normal and not cause for any concern. TEMPORARY SKIN REDNESS: The skin may develop a slight redness that fades within 24 hours. TEMPORARY SKIN DISCOLORATION: If the skin develops a slight discoloration that lasts more than 24 hours, stop using ESPADA™.
Before your 1st treatment perform a simple compatibility test. Test the device on a less sensitive area of the skin, such as the inner arm, before beginning treatment on the face following the HOW TO USE instructions exactly. Wait 24 hours and check the treated area. If you don’t notice any difference (redness, discoloration or irritation) between the treated and untreated skin, you may begin the Blue Light Acne Treatment.

RISKS

Hazards	Effects to user	Caution
Overheating	May cause injury, discomfort or interrupted treatment	Stop use immediately, allow device to cool.
Inadvertent light contact with eyes	May cause discomfort and possibly headache	Use caution to prevent light source from shining directly into the eyes.
Photosensitivity	May cause redness, inflammation and irritation	Contact your physician if you think you may be having a photosensitive reaction.
Adverse reaction with certain medications or supplements	May cause redness, inflammation and irritation	Please read Contraindications before use.
Contact with neck in users with thyroid conditions	Possible stimulation of growth	Please read Contraindications before use.
Incorrect identification of “mild to moderate inflammatory acne”	Attempting to use on more severe forms of acne or other skin conditions may cause adverse results	Please read Intended Use before starting

WARNINGS

- Consult your dermatologist prior to using ESPADA™ if you have medical concerns.
- **Do NOT** use the device for severe, nodular or cystic acne.
- **Do NOT** use the device on or come in contact with injured skin or skin that has undergone surgery.
- **Do NOT** use the device on beauty spots/moles, warts, ingrown hairs or irritated skin.
- **Do NOT** use device in and around the eye and lip area.
- **Do NOT** use the device if you are particularly sensitive to light.
- **Do NOT** use the device if you have had sunburn within the past 2 weeks.
- **Do NOT** apply the treatment to a spot more than 3 times daily. Any more often than this could lead to skin burns or injuries. Leave a minimum time of 4 hours between each treatment.
- **Do NOT** use device longer than 2 minutes on one blemish. Overuse can lead to skin injury.
- Excessive use beyond the recommended treatment time may cause the device to become warm. The device’s temperature will not go beyond 40°C if used at room temperature, but may cause discomfort or prolonged redness.
- If after using device you experience a worsening of the skin (skin feels tense, uncomfortable, irritated, red, burning, etc.), undesired side effects or prolonged redness, stop using the device and consult your doctor. However, a temporary, mild reddening after application is normal.
- Never look directly at the blue light as this could lead to eye injury.
- **Do NOT** let children use or play with ESPADA™. ESPADA™ has not been tested on children and may cause skin injury such as temporary redness or pigment changes (hypo- and hyperpigmentation) or affect their eyes.
- Proper supervision and instructions for safe use should be given to those with reduced physical and mental

abilities.

- **Do NOT** share ESPADA™ with other people. Sharing the device could transfer bacteria from one person to another.
- **Do NOT** use the device if it is visibly damaged, and never attempt to open or repair the device.
  Doing this could result in damage or malfunction to the device, serious eye or skin injury, fire, or possibly fatal electric shock.
- Pregnant or breastfeeding women should not use this device.
- Those who have had a migraine in the past two years should not use this device.
- **Do NOT** use over a thyroid gland as it may result in growth stimulation.
- If you are taking drugs or steroids for pain or skin conditions that cause light sensitivity, using this device may result in a photosensitive reaction.
- Do not use over or near a steroid injection received within the last six months. Doing so may result in a photosensitive reaction.
- In order to prevent fire or serious burns, immediately turn off device if it begins to overheat.
  Keep away from aerosol products.

Contraindications

- **Do NOT** use if you have a history of light triggered seizures.
- **Do NOT** use this device over a suspicious or cancerous lesion as it can delay proper medical treatment

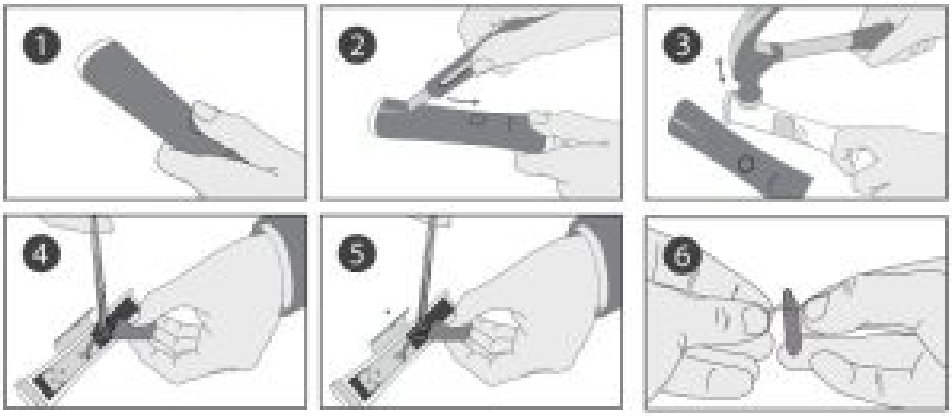
Typical characteristics of potentially cancerous lesions include:

- Asymmetry: one half of the abnormal skin area is different than the other half
- Borders: irregular borders
- Color: varies from one area to another with shades of tan, brown, or black (sometimes white, red, blue)
- Diameter: usually (but not always) larger than 6 mm in size (diameter of a pencil eraser)
- Bleeding: Any skin growth that bleeds or will not heal

Emissions test	Emissions test	Emissions test
Actinic UV	Risk Group 2	UV emitted from this device May result in eye or skin irritation
Near UV	Risk Group 2	UV emitted from this device May result in eye irritation
Blue-light	Risk Group 1	Not required
Retinal Thermal	Exempt Group	Not required
Retinal Thermal, weak visual sti mulus	Exempt Group	Not required
Corneal/ Lens IR	Exempt Group	Not required

Spectral irradiance: 0.5lm. Maximum output of optical radiation: 75mW

ASSEMBLY INSTRUCTIONS



CHARGING

Your FOREO device is rechargeable with its included USB cable. It is recommended that IEC60950 standard power suppliers are used to charge the ESPADA™. 1.5 hours of charging delivers a full charge that will provide up to 50 30-second treatments.

While charging, the indicator will flash repeatedly. When the battery is full, the indicator will emit a steady glow. When the battery is low, the indicator will start to flash repeatedly.
CAUTION: Before charging, make sure the charging port and charger are free from water. Do NOT use your FOREO device while charging, and do NOT charge for more than 24 hours. Never use the device or charger if they are damaged, and only use the charger supplied by FOREO with the device. To reduce risk of electric shock, do not place the device where it can fall into water or other liquid. If device accidentally falls into water when charging, unplug immediately.
The charging chord should be kept away from all heated surfaces. Never insert any object into any openings of the device. Never operate this device if its chord or plug has been damaged or is working improperly.

MAINTENANCE AND SAFETY

To keep your FOREO device in optimum condition, we recommend cleaning ESPADA™'s treatment surface after each use. Clean the device with soap, rinse with warm water and dry with a soft, lint-free cloth. We recommend spraying the device with FOREO's Silicone Cleaning Spray for optimal results. NEVER use cleaning products that are silicone-based or containing alcohol, petrol or acetone as they may damage silicone.

ENVIRONMENTAL REQUIREMENTS

Emissions test	**Operation**	**Storage and Transport**
Temperature	5 to 40 °C	-10 to 50 °C
Humidity	15 to 93% RH, non-condensing	<=93% RH, non-condensing
Pressure	Storage and Transport	700 – 1060hPa

WARRANTY TERMS AND CONDITIONS

REGISTER WARRANTY: To activate your 2-Year Limited Warranty, register the number provided on the FOREO Magnetic Card at **www.foreo.com/support**.

2-YEAR LIMITED WARRANTY: FOREO warrants this device for a period of TWO (2) YEARS after the original date of purchase against defects due to faulty workmanship or materials arising from Normal Use of the device. The warranty covers working parts that affect the function of the device. It does NOT cover cosmetic deterioration caused by fair wear and tear, or damage caused by accident, misuse or neglect. Any attempt to open or take apart the device (or its accessories) will void the warranty. If you discover a defect and notify FOREO during the warranty period, FOREO will, at its discretion, replace the device free of charge. Claims under warranty must be supported by reasonable evidence that the date of the claim is within the warranty period. To validate your warranty, please keep your original purchase receipt together with these warranty conditions for the duration of the warranty period. To claim your warranty, you must log in to your account at **www.foreo.com** then select the option to make a warranty claim. Shipping costs are nonrefundable. This undertaking is in addition to your statutory rights as a consumer and does not affect those rights in any way.

FOR AUSTRALIA-BASED CUSTOMERS ONLY: Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and for compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure. Australia Office, FOREO Oceania, Level 1, Suite 10, 1014 Doncaster Road, Doncaster East, VIC, 3109, Australia. **TEL** +61 (0) 448 885 779

DISPOSAL INFORMATION: Battery must be recycled or disposed of properly. Disposal of old electronic equipment (applicable in the EU and other European countries with separate waste collection systems). The crossed-out dustbin symbol indicates that this device should not be treated as household waste, but rather be brought to the appropriate collection point for recycling of electrical and electronic equipment. Please see back

page for instructions on
how to remove the battery.

BATTERY CARE: It is recommended to regularly use the device to ensure proper performance. ESPADA™ should be fully charged at least every 3 months to maintain the battery.

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSIONS & IMMUNITY: Medical electrical equipment requires special precautions regarding EMC and must be installed and put into service according to EMC information provided in this document. Portable and mobile RF communications equipment can affect the medical electrical equipment. This declaration currently applies to ESPADA™ device

GUIDANCE AND MANUFACTURER'S DECLARATION: ELECTROMAGNETIC EMISSIONS: The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment

Emissions test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 15	Group 1	The device is supplied by very low voltage Li-on batte ry. Therefore, its RF emissions are very low and are not l ikely to cause any interference in nearby electronic e quipment.
RF emissions CISPR 11	Group 2	The device does not need to use an AC adapter to ch arge, so it's radiated power is very low.

WARNINGS:

- This device should not be used adjacent to other high field equipment or areas. If adjacent use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.
- This device should not be used adjacent to high-frequency equipment. If the device is adjacent to a short wave device or microwave device, the device's output may be unstable.
- The use of accessories other than those specified for the device is not recommended as it may result in increased emissions or decreased immunity of the device.
- The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that the device is used in such an environment.

Immunity test	IEC60601-1-2 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge(ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electromagnetic field susceptibility IEC 61000-4-3	3V/m	3V/m	Because it is not life-supporting equipment, it does not use only shield location.
Power frequency (50/60 HZ Magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated emission	40 dBμV/M (3M) 30MHZ ~ 230MHZ 47 dBμV/M (3M) 230 MHZ~ 1000MHZ	40 dBμV/M (3M) 30MHZ ~ 230MHZ 47 dBμV/M (3M) 230MHZ~ 1000MHZ	In all frequencies, the radiated strength is less than limited value.

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 ESPADA™ device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

Notes: These guidelines may not apply in all situations. Electromagnetic propagation is affected.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE DEVICE

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

Rated maximum output Power of transmitter (w)	**Separation distance according to frequency of transmitter (m)**		
	30MHZ to 80MHZ	**80MHZ to 800MHZ** **d = 1.2√p**	**800MHZ to 1000MHZ** **d = 2.3√p**
0.01	d = 1.2√p	0.12	0.23
0.1	d = 1.2√p	0.38	0.73
1	d = 2.3√p	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

ESPADA™ complies with regulatory requirements of the following European Directive 93/42/EEC concerning medical devices and all the latest standards listed below.

N60601-1/IEC60601-1, EN60601-1-2/IEC60601-1-2, IEC60601-1-11, EN60601-2-57/IEC60601-2-57, EN62471/IEC62471, EN ISO10993-5, EN ISO10993-10

SUPPORT

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Documents / Resources

	FOREO ESPADA Range [pdf] User Manual ESPADA Range