

Industry Bulletin – 8/4/15 – Skin Care Machines/Devices

The Board of Barbering and Cosmetology (Board) does not approve or regulate equipment or products used in the barbering and beauty industry. Consequently, the Board provides no opinion on the contemplated use of any machine a licensee is considering purchasing.

The Barbering and Cosmetology Act (Act) defines the scope of practice of cosmetology and its specialty branch of skin care. (California Business and Professions Code, section 7316 (b) and (c).) A person licensed as a cosmetologist or esthetician is required to limit their practice and services rendered to the public to only those areas for which they are licensed. (California Business and Professions Code, section 7317.) The Act confers no authority to practice medicine or surgery. (California Business and Professions Code, section 7320.) The Board's regulations specifically prohibit invasive procedures which results in the removal, destruction, incision, or piercing of a client's skin beyond the epidermis or the application of electricity which visibly contracts the muscle (Title 16, California Code of Regulations, section 991.) Licensed cosmetologists and estheticians are cautioned not to engage in any invasive procedures.

The use of electrical stimulation in providing skin care services falls within the practice of an esthetician under certain conditions. So long as the machines providing the electrical stimulation do not deliver an electrical current that will visibly contract the muscle of the body or face and/or result in the destruction or removal of the skin below the client's epidermis. The machines parameters must be set to stimulate the muscle not to contract the muscle.

The Board understands that the following machines/devices while used in a proper current range may not constitute an invasive procedure:

- Galvanic Current
- Microcurrent
- High Frequency Current
- Ultrasonic (low frequency, low powered, topical devices intended for skin cleansing, exfoliation and product application)
- LED devices (410 nm – 945 nm. (nm = nanometers))

The following services may be **considered invasive** or practice of medicine:

- Radio Frequency (except for electrolysis licensees)
- Electrical Muscle Stimulators (EMS) - Faradic type devices
- Intense Pulsed Light (IPL) Therapies (photo facials)
- X-rays
- Ultrasound (Facial Lifting)

- Photo Light Therapy
- Endermology/Endermologie
- Injections of any sort
- Derma rolling or derma planing
- Removal of moles, age spots, skin tags and/or freckles

If the machine produces any of the following, you are working out of your scope of practice:

- Bleeding
- Bruising
- Edema
- Inflammation
- Oozing
- Excoriation
- Scabbing
- Removal of skin below the epidermis
- Piercing of skin
- Heating or burning of the skin

Questions to consider in determining if you are working within your scope of practice:

Is my intent of service to beautify the skin?
Am I treating a disease or illness?

Intended Use

Intended use can be established in a number of ways. For example:

How is the product being advertised? Is the product being marketed as a cosmetic for beautification or does the advertising claim to treat, or cure an ailment?

A skin cream can advertise that it smooth's and beautifies your skin (cosmetic use), however, if it advertises that it will cure or treat acne it could be considered practice of medicine.

What is the consumer's perception of the product/machine? Why is the consumer purchasing the service and what does the consumer expect out of the service?

A machine could advertise that it assists in the penetration of hydrating moisturizers for the beautification of your skin (cosmetic use) however, if it claims to reduce cellulite or manage pain, it could be considered practice of medicine.

Do the ingredients cause the product to be considered practice of medicine?

A skin peeling agent could advertise that its use will remove unwanted dead skin cells and promote vibrant, glowing skin, (cosmetic use) however, if the skin peeling agent claims to remove brown spots or scarring, it could be considered practice of medicine.

For additional consideration of how to establish a product's or machine's intended use, please see the U.S. Food and Drug Administration (FDA) publication, "Is It a Cosmetic, a Drug, or Both? (Or is It Soap?)"

http://www.fda.gov/cosmetics/guidanceregulation/lawsregulations/ucm074201.htm#Intended_use

Consumer Notice

The Board does not approve or regulate the sale of skin care machinery. Every year thousands of skin care machines are manufactured and brought into the United States. These machines may or may not have gone through proper testing and/or FDA approvals. Be diligent - make sure you know what you are buying. The Board does not have regulatory authority over the manufacturing and/or selling of machinery. It is the licensee's responsibility to know if they can use the purchased machine within their respective scope of practice.

Items to consider before purchasing skin care equipment

- Is the machine registered with the FDA and compliant with FDA requirements?
- Make sure you know the machines intent of use, claims of the machine, and FDA classification (select FDA class 2 devices and all Class 3 devices are out of scope for our licensees)
- Does the machine have any safety certifications? Does it carry the UL, CSA or CE listed mark on the device and power cord?
- Is the manufacturer ISO 13485 certified?
- Does the manufacturer maintain liability insurance on the machine?
- Have you been provided with instructions on how to properly clean/disinfect the machine?
- Are there any associated contraindications associated with the use of the machine?

If you are unsure of the answers to these questions, ask the manufacturer prior to purchasing the machine.

NOTE: The Board recommends licensees maintain an Equipment Evaluation Binder on site for questions that may arise regarding the machine during a Board inspection. For information on how assemble an Equipment Evaluation Binder, see the Board's website www.barbercosmo.ca.gov under CA Safe Salon.