Warnings and Contraindications

All persons involved with the operation of the Photonica Professional (also marketed as "UltraSlim Professional") device should be trained to carry out the indicated treatment and should have fully read and understood the contents of the user manual.

Warnings

WARNING: The Photonica Professional Device is a medical device and should only be operated by QUALIFIED MEDICAL PROFESSIONALS in accordance with the instructions and specifications described in this and related device manuals.

WARNING: Read this Device Operating Manual and related device manuals before using the Photonica Professional Device.

WARNING: Keep hair and clothing away from moving parts to avoid injury.

WARNING: Never use the Photonica Professional or its accessories in a manner other than that indicated.

WARNING: Ensure that the system is connected with the supplied hospital grade power cord directly to a suitable grounded power receptacle that provides voltage and current within the specified rating for the system (i.e. 100-120V/60Hz). Connection to an incompatible power receptacle may produce electrical shock and fire hazards.

WARNING: Do not cut or modify the power cable and plug ends as this causes instrument damage and a shock hazard.

WARNING: To avoid electrical shock, do not open or disassemble the controller console, the LED light fixture of the PHOTONICA PROFESSIONAL Device after assembly. There are no serviceable parts. Device inoperability should be reported to the PHOTONICA PROFESSIONAL Service Technician in your area.

WARNING: Should the device cease functioning or function differently from the description in this manual contact your local PHOTONICA PROFESSIONAL Service Technician for further instruction or advice.

WARNING: This device has been tested in accordance with International Electromagnetic Compatibility requirements for medical devices (IEC60601-1&2). It is recommended that operators and patients avoid the use of cell phones within 3 metres of the PHOTONICA PROFESSIONAL Device during operation. In the event interference of treatment is observed, cease operation immediately and contact your local PHOTONICA PROFESSIONAL Service Technician for further instruction or advice.

WARNING: The PHOTONICA PROFESSIONAL Device should not be operated in the presence of flammable anaesthetics, volatile substances, or other explosive gases, liquids or atmospheres.

WARNING: In the case of impact to any surface of the PHOTONICA PROFESSIONAL LED light fixture or mechanical damage to any part of the PHOTONICA PROFESSIONAL system, cease use immediately. Refer the PHOTONICA PROFESSIONAL Device to be checked by a qualified PHOTONICA PROFESSIONAL Technician prior to resuming use.

WARNING: Due to the potential of lipolysis resulting from exposure to 635nm light, Photonica Professional may reduce the size of subcutaneous fat accumulations exposed to the lights. Do not expose breasts or any area of the body where a reduction in size of subcutaneous fat accumulations would be an undesirable outcome.

WARNING: Do not attempt to repair the PHOTONICA PROFESSIONAL Device. The device contains no user serviceable parts. Only technically qualified PHOTONICA PROFESSIONAL Technicians should perform troubleshooting and service procedures on internal components. Unauthorized access to internal components will void the warranty.

WARNING: Do not use the PHOTONICA PROFESSIONAL Device on a patient if the device has not been serviced in accordance with the periodic maintenance provisions specified in this manual.

WARNING: Only the components packaged with the PHOTONICA PROFESSIONAL Device should be connected to the PHOTONICA PROFESSIONAL Device.

WARNING: Do not stare at the lights due to the presence of some infrared light.

WARNING: Avoid long term use, the long term effects of prolonged use of light exposure are unknown.

Cautions

General

Use your Photonica Professional only as directed.

Operator/Patient Related

- Light therapy should not be applied over, or in proximity to, cancerous lesions, as conclusive tests have not been conducted.
- It is important to follow the instructions for proper use of the Photonica and maintain a minimum of 1" separation from the glass on the light fixture and the skin. If direct contact is applied to the skin for an extended period of time, which should never occur, a person with normal heat sensing capabilities would likely move away from the lamp due to heat build-up. However, a person with a diminished sensation of heat may not feel this heat "build-up."
- One should not stare directly at the illuminated light fixture due to the potential hazard of chronic viewing of bright lights and the presence of a minimal amount of IR and UVA light. To ensure there is no possible instance of a residual effect, disposable eye protection (IPL SmartShield) is included for the patient, to prevent direct light to the patient's pupil and retina.
- Kentek IPLSAFE eyewear is also provided for the operator's comfort and safety.

Equipment/Device Related

- Use only rated 3.15A 250V 5x20mm slow-blow glass fuses.
- Do not block the vents or cooling fans on the lights. If the air flow is blocked or diminished, the lights may overheat, resulting in permanent damage to the light fixture.
- Avoid the ingress of any liquid or exposure to the elements.
- Do not open your device. It is not user serviceable.
- Attaching the brackets higher on the pole than the specifications indicate could change the balance of the instrument and result in tipping over Refer to the Unpacking Section for further information.

If for any reason you have concerns or questions regarding proper operation of the device, please call Technical Support at +1.800.392.5950 for immediate assistance.

Contraindications

The device is intended for generally healthy individuals over the age of 18. Contraindications are pregnancy, trying to become pregnant, active cancer within the past year, and diminished ability to void waste (liver or kidneys).

For non-invasive aesthetic use for the disruption of adipocyte cells within the fat layer for the release of fat and lipids from these cells, users are advised not to use the device in areas with open wounds or lesions, active implantables (e.g., pacemakers or defibrillators), or metallic implants.

Photosensitivity

Photosensitivity is an abnormally high sensitivity to sunlight (UV) light (under 400 nm spectrum). While the Photonica Professional does not emit UVA or UVB radiation, and so does not age or harm the skin even after prolonged exposure, it is recommended that precautions should be taken. Physicians should consider photosensitivity as a potential contraindication.

Certain medical or physical conditions and medications could cause photosensitivity (also known as photosensitizers) are described below. This list should not be regarded as exhaustive or complete and care should be taken to confirm the safety of light treatment before exposure.

1. Medical or Physical Conditions include:

- Perfumes or plant materials such as St. John's Wort in contact with the skin.
- Metabolic disorders such as Porphyria and other light-induced rashes. (Porphyria is a severe light-induced allergy and treatment with Photonica Professional is NOT recommended.
- Autoimmune disease (self-allergy), such as Lupus Erythematosus.
- Albinism.
- Photo-sensitive eczema.

2. Medications – Photonica treatments cannot be administered: Gold, Auranofin, Gold 50, Ridaura

3. **Medications - Photonica treatments can be administered if these medications have not been taken in the last 8 days:** Chloropromazine, Chlorpromazine HCL, Largactil, Thorazine

4. **Medications - Photonica treatments can be administered if these medications have not been taken in the last 5 days:** Isotretinoin Accutane, Roaccutane, Sonazine, Azathioprine, Fulvicin P/G, Fulvicin U/F, Grifulvin V, Griseofulvin, Grisovin, Gris-Peg, Demecocycline, Ledermycin, Doxycycline, Cyclidox, Doryx, Doxycyl, Doxytab, Dumoxin, Minocycline, Noritet, Viacin, Vibramycin, Lymecycline, Tetrasal, Minomycin, Cyclimycin, Minomycin, Minotabs, Terramycin, Oxytetracycline Be-oxytet, Cotet, Oxypan, Quinolone Derivatives, Ciprofloxacin, Nalidixic Acid, Norfloxacin, Oflaxacin, Tetracycline Group, Achromycin, Acromysin V, Actisite, Bristacycline, Ciprofloxacin, Helidac, Hostacycline, Lymercycline, Sumycin, Terra-Cortril, Tetracycline, Tetracycline HcL, or Tetrex.

5. **Medications - Photonica treatments can be administered if these medications have not been taken in the last 3 days:** Methotrexate, Folex, Ledertrexate, LPF, Methotrexate Sodium, Mexate AQ, PF, or Trexall.

6. **Medications - Photonica treatments can be administered at the physician's discretion:** Amioderone, Aratac, Codarone X, or Pacerone.

Unpacking and Inspection

Follow standard receiving practices upon receipt of the device:

1. Check the shipping carton for damage.
2. If damage is found, stop unpacking the instrument.
3. Notify the freight carrier and ask for an agent to be present while the instrument is unpacked.
4. Retain all packing materials in their original condition.
5. Should there be damage to the device, immediately file a claim.
6. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. No assembly is required as the device ships fully assembled.
7. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

Box and the Contents list

The Photonica Professional package is comprised of:

- Photonica Professional system as described below and shown in Figure 1.
- (1) box of Kentek disposable patient protective eyewear (IPL SmartShield).
- (1) pair of Kentek IPLSAFE eyewear for the operator's comfort and safety.
- (1) Hospital – grade Power Cord plugged into the isolation transformer.
- Photonica Professional User's Manual (this guide).

Figure 1 Fully Assembled System With Lights On