

High Speed

LIGHT *Sheer*® DUET™



Clinical In-Service Training

UPDATE v.24 March 2010

PB-1076090_A

- Laser Safety
- Laser Tissue Interaction
- Laser Operations - Platform & Handpieces
- Clinical Protocols - LHR & PFB
- Lumenis & You - A Partnership for Success
- Questions?

Laser Safety



ANSI Laser Classification	Description	Examples
Class I	Generally do not pose a hazard	(i.e., CD, DVD)
Class II	Generally do not pose a hazard unless viewed directly for extended period of time	(i.e., checkout scanners)
Class IIIa	Generally pose low hazard risk	(i.e., laser pointers)
Class IIIb	Can produce hazard if viewed directly	(i.e., low wattage eye lasers)
Class IV	Can produce hazard from direct or specular reflection - also pose skin hazards	(i.e., most medical lasers)

ANSI: American National Standards Institute.

- Every facility must have a Laser Safety Officer (LSO) appointed
- Administrative Controls
 - Documentation, training programs, etc.
- Procedural Controls
 - Policies, Safety Glasses, Signs, etc.
- Engineering Controls (by Mfg)
 - Interlocks, standby, emission indicators



LSO: Laser Safety Officer

Facility LSO is responsible for Laser Log, to include (not limited to):

- ❑ System and Equipment Audits
- ❑ Laser Maintenance Records
- ❑ Safety Audits
- ❑ Education - Initial and On-going
- ❑ Competency - Skills Check Lists

- NHz is the actual area (boundary) where someone could be injured by the laser beam
- ANSI Laser Standards state that the entire room is the NHz
- NHz depends on factors such as:
 - Wavelength
 - Power
 - Spot Size and Divergence Angles
 - Exposure Time
 - MPE (maximum permissible exposure)

- ❑ Ensure all persons in treatment room are wearing protective eyewear
 - ❑ OD \geq 5, wavelength 790-830 nm
- ❑ If patient's face is treated they must wear opaque or metal eye goggles or shields
 - ❑ Laser beam can cause severe retinal injury
- ❑ Do not treat within bony orbit of eye
 - ❑ Do not treat eyebrows or eyelashes
- ❑ Ocular Hazard Zone:
 - ❑ 164 feet / 50 m
 - ❑ Laser light focused by the lens of the eye onto retina has a high fluence

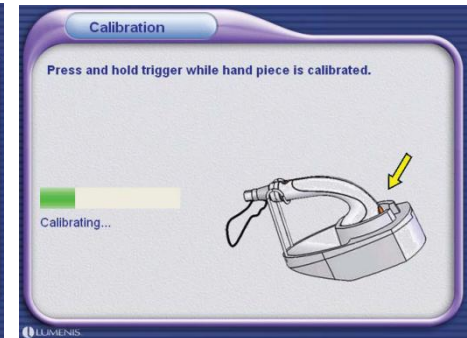
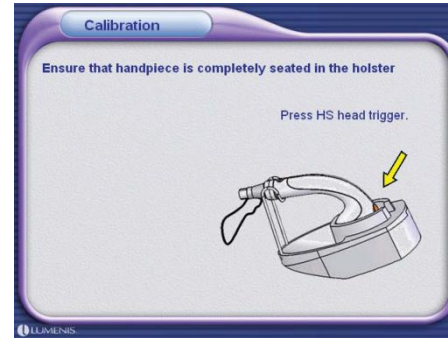
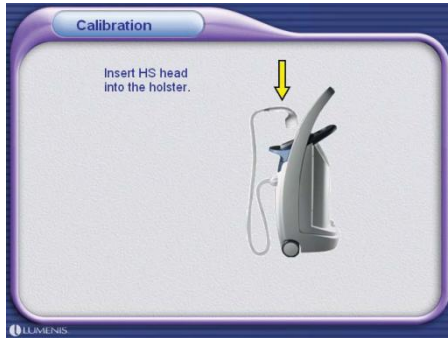
Operator Glasses:
 $OD \geq 5$ for 800 nm
wavelength



Patient Goggles
or Shields:

Opaque or metal

- Calibration is required:
 - At start up, when system is first turned on
 - When new handpiece is attached
 - After 25,000 pulses in one 'power on' session
- Calibration is recommended prior to the start of each treatment
- Verify port is clean and handpiece is properly seated prior to calibration
 - To ensure accuracy of calibration
 - To avoid damage to calibration port

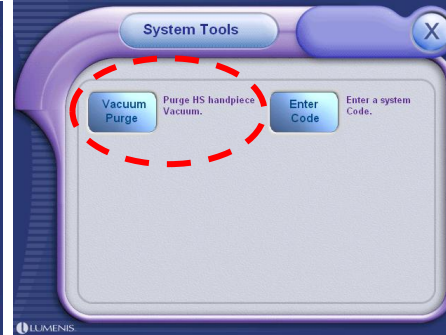
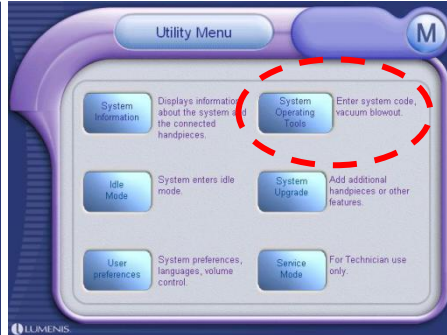


- ❑ Remove the handpiece and reinsert into the calibration port
 - ❑ *Verify hp is perpendicular to port and not seated at an angle; improves accuracy, avoids damage*
- ❑ Touch screen prompts, follow each step
- ❑ Press enable button on handpiece
- ❑ Press and hold trigger until calibration complete

- Vacuum Purge is required:
 - At start up and before any treatments
 - To ensure proper function of vacuum assist technology
- Vacuum Purge is also recommended as needed between treatments
 - To clear system and prevent build up of debris



Upgrade planned for Q2 2010 will include a reminder screen for system operators.



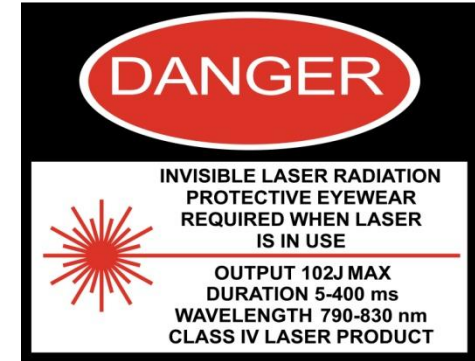
■ Select

- 'Utility' on Main Screen
- 'System Operating Tools' on Utility Menu
- 'Vacuum Purge' on System Tools Screen
- Follow on screen instructions until purge is complete.



- 'Laser in Use' warning sign on door
- Pair of operator glasses outside of door
- Enclosed room with opaque fire resistant window coverings
- Allow any flammable liquids used for cleaning the skin to fully evaporate before treatment
- Have a fire extinguisher available
- Water must be available (e.g., running or in bowl)

- LightSheer Duet classification
 - Class IV laser by Center for Devices and Radiological Health (CDRH)
 - Class 4 laser by European Standard (EN 60825-1)
- Follow ANSI, OSHA, European standards
 - Contact Laser Institute of America (LIA) (800) 34LASER for current ANSI and OSHA standards
 - <http://www.laserinstitute.org>
 - i.e., ANSI Z136.3, ANSI Z136.1 and EN 207
 - ANSI: American National Standards Institute



Laser Tissue Interaction



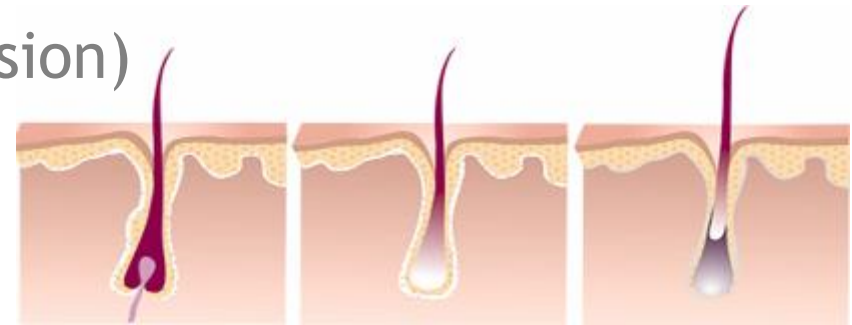
- Hair growth has three phases

- Anagen (active/growth)
- Catagen (transition/regression)
- Telogen (resting)

- Growth cycle

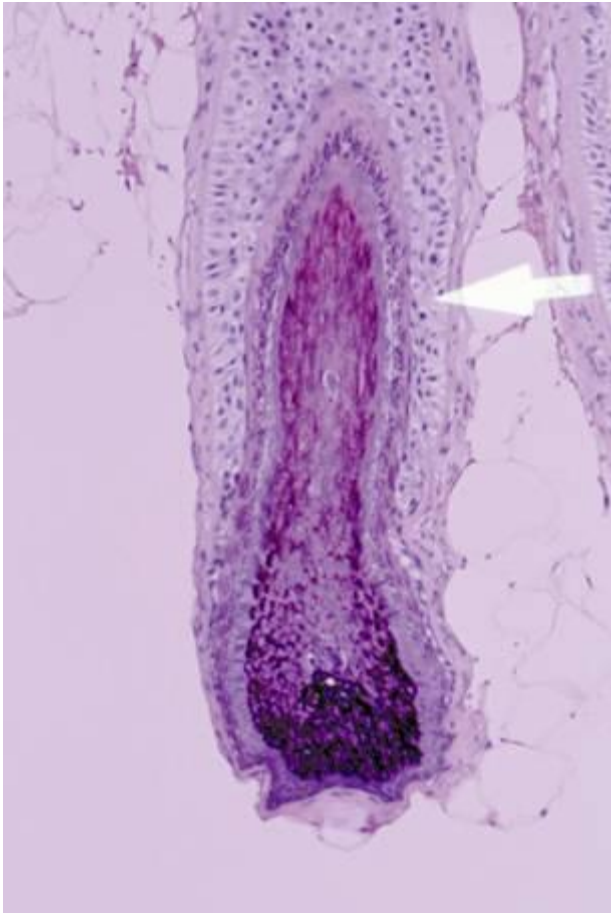
- Depends on body part
- Lasts anywhere from 4 to 12 months

- Hair reduction is considered permanent when a significant amount of hair does not return for longer than the complete growth cycle

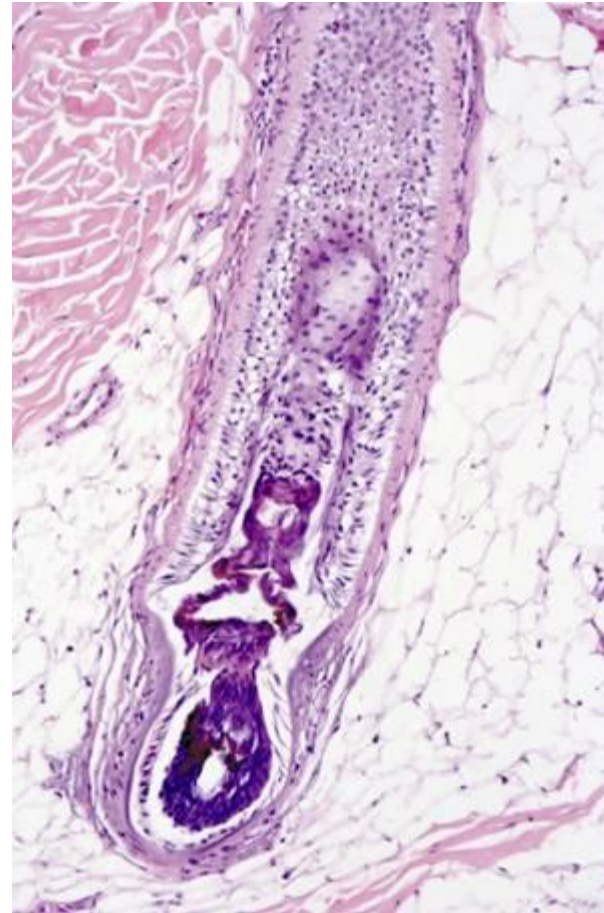


- Based on the theory of Selective Photothermolysis
- The target chromophore is melanin
 - Present in the hair shaft
 - Also present in the upper third of the follicular epithelium
- Heat generated in the hair shaft diffuses to the follicular epithelium to cause the damage that is desired






A normal follicle



A damaged follicle

- PW must be equal to or shorter than Thermal Relaxation Time (TRT) of the target (hair follicle) to confine thermal damage
 - Depends on hair diameter (i.e., fine vs. coarse)
- PW must be matched with appropriate amount of fluence to cause follicular damage while sparing surrounding tissue
 - Depends on melanin content in skin vs. surrounding tissue
 - Note: maximum tolerated fluence is generally inversely proportional to melanin content in skin for a given pulse width
- In general,
 - Treat fine/thin hair, lighter skin types with shorter pws
 - Treat coarse/dense hair, darker skin types with longer pws



Laser Operation LightSheer Duet Platform







LightSheer ET

- 9 X 9 mm treatment area
- 10 -100 J/cm²
- 5 - 400 msec pulse widths
- ChillTip cooling
- Full LS ET functionality
- Field replaceable

LightSheer HS

- 22 X 35 mm treatment area
- Up to 12 J/cm²
- 30 - 400 msec pulse widths
- Vacuum Assist technology
- Greater Speed, Comfort
- Field replaceable



LightSheer ET



LightSheer HS



ET Treatment Screen



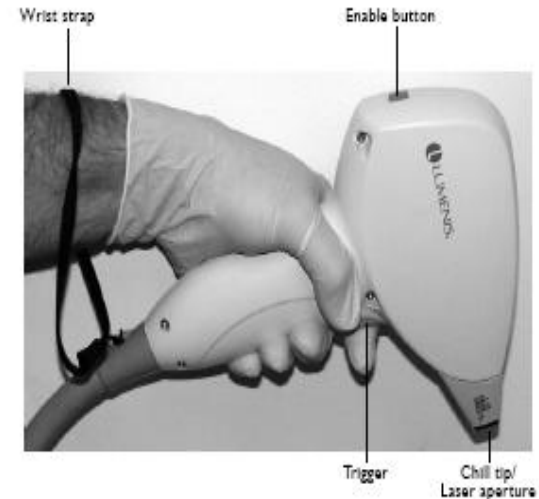
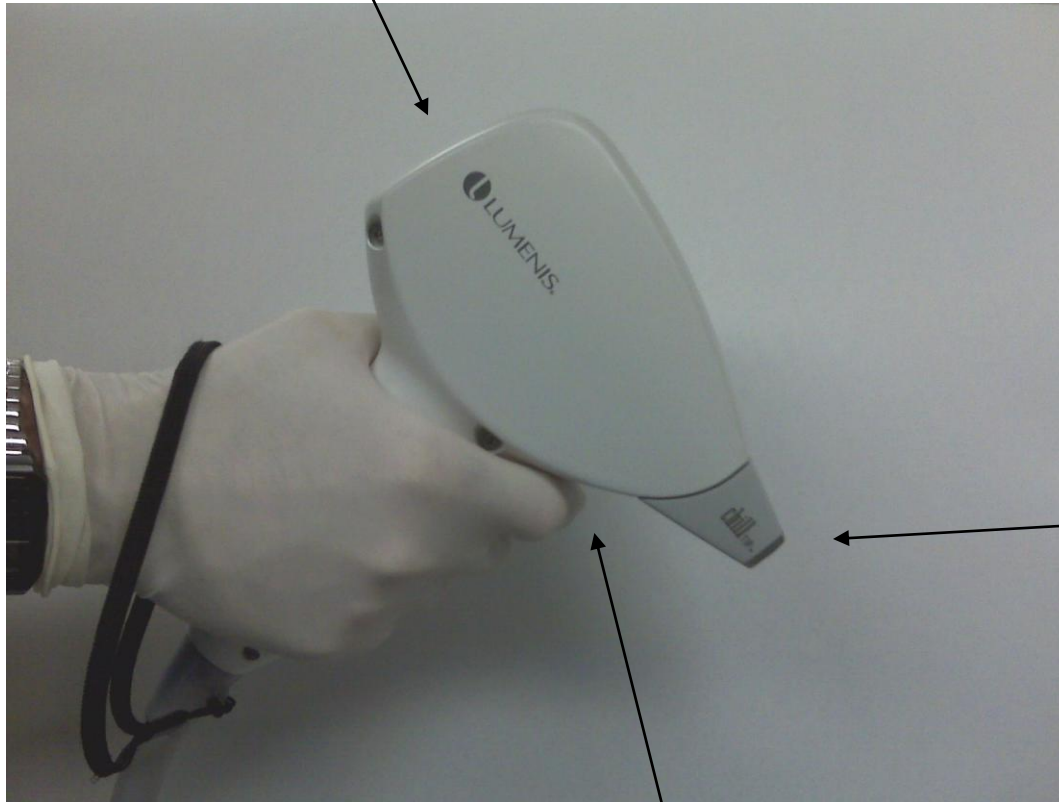
HS Treatment Screen



Laser Operation LightSheer ET Handpiece



Press enable button

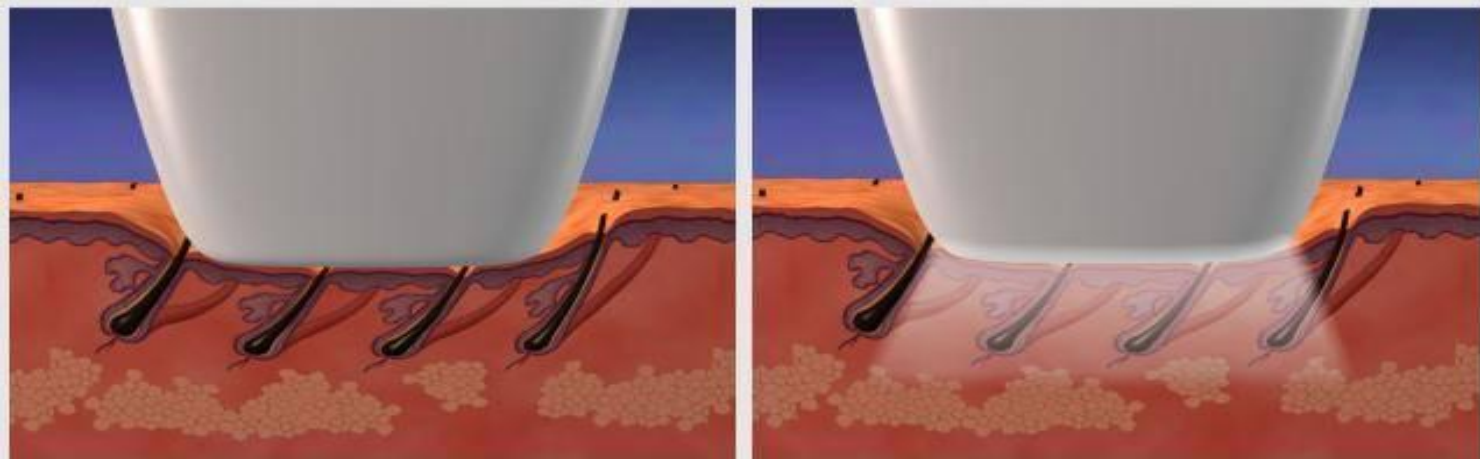


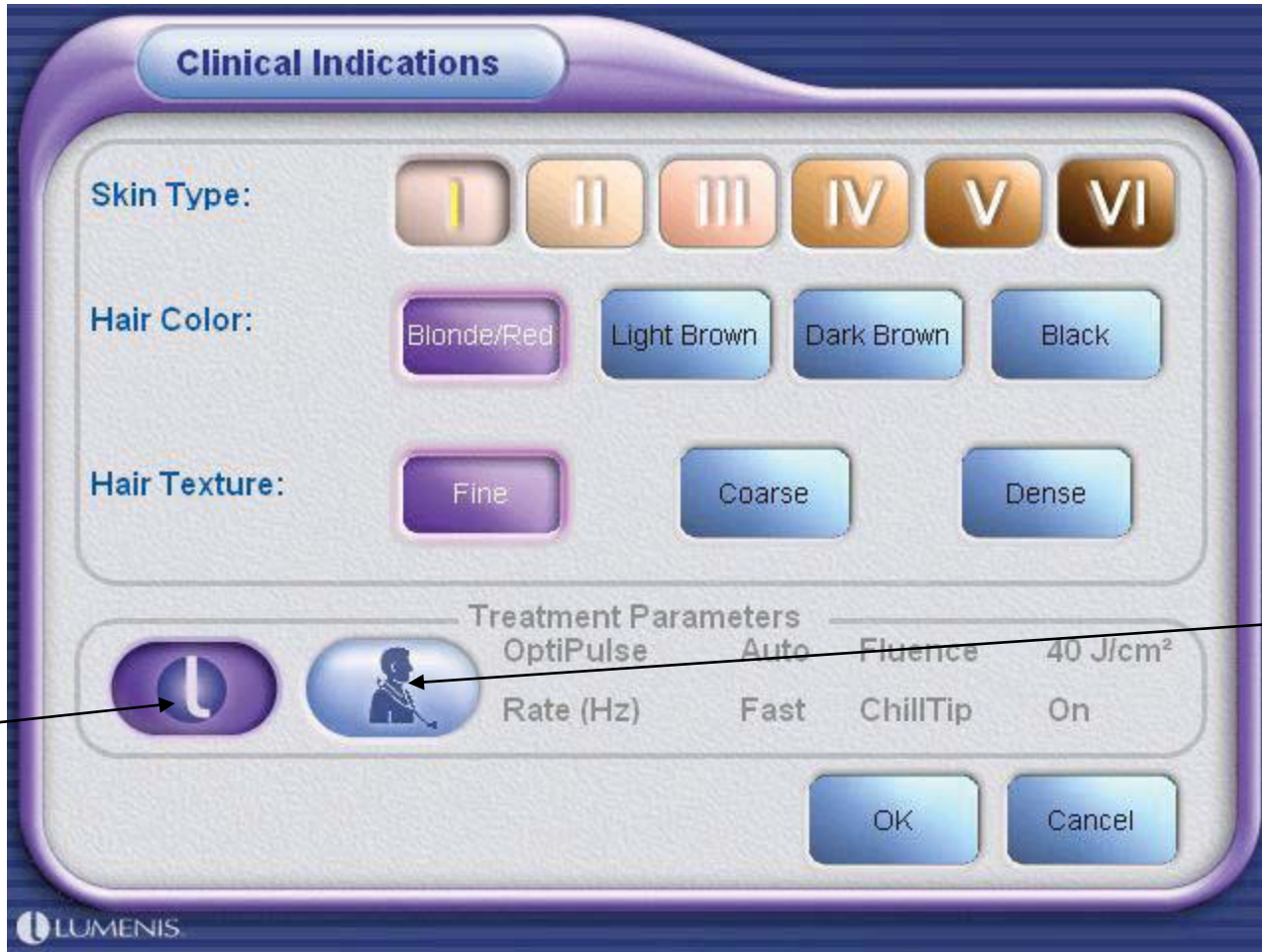
Position tip on patient's skin, apply light pressure

Depress pulse trigger to begin treatment

LightSheer ET Handpiece delivers up to 100 J/cm^2 with 5-400 ms pulse durations & Contact Cooling

- Contact Cooling with ChillTip reduces temperature
- Compression
 - Reduces competing chromophore, oxyhemoglobin
 - Blanches vessels, eliminates energy lost into this target
 - Rotates follicle closer to surface, so laser light hits broadside, penetrates deeper into the hair shaft
- Melanin in follicle is heated to point of thermal damage



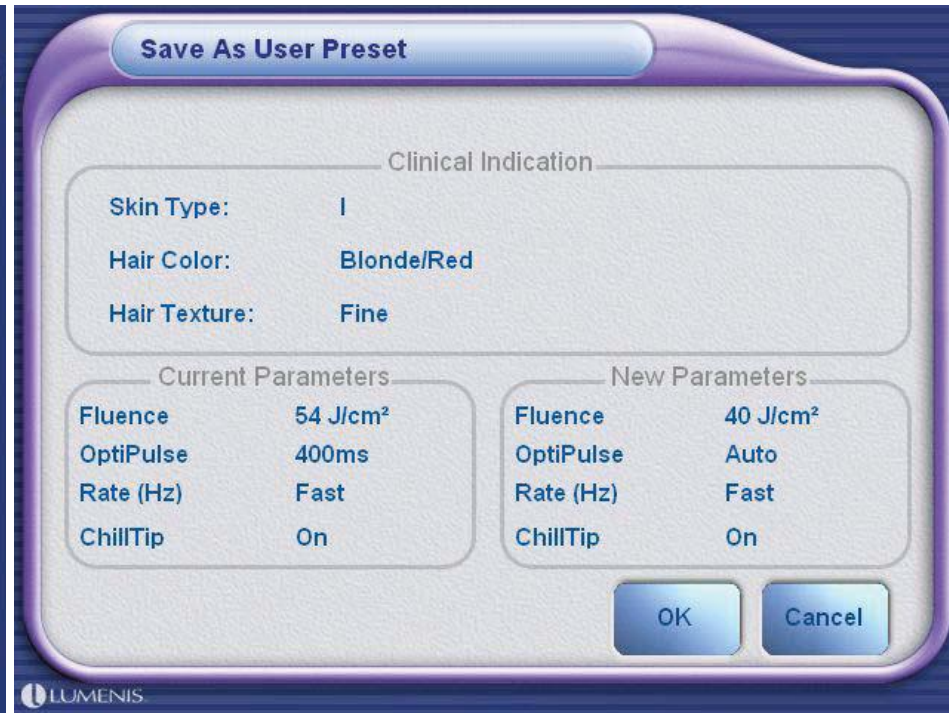


Lumenis Presets

User Presets

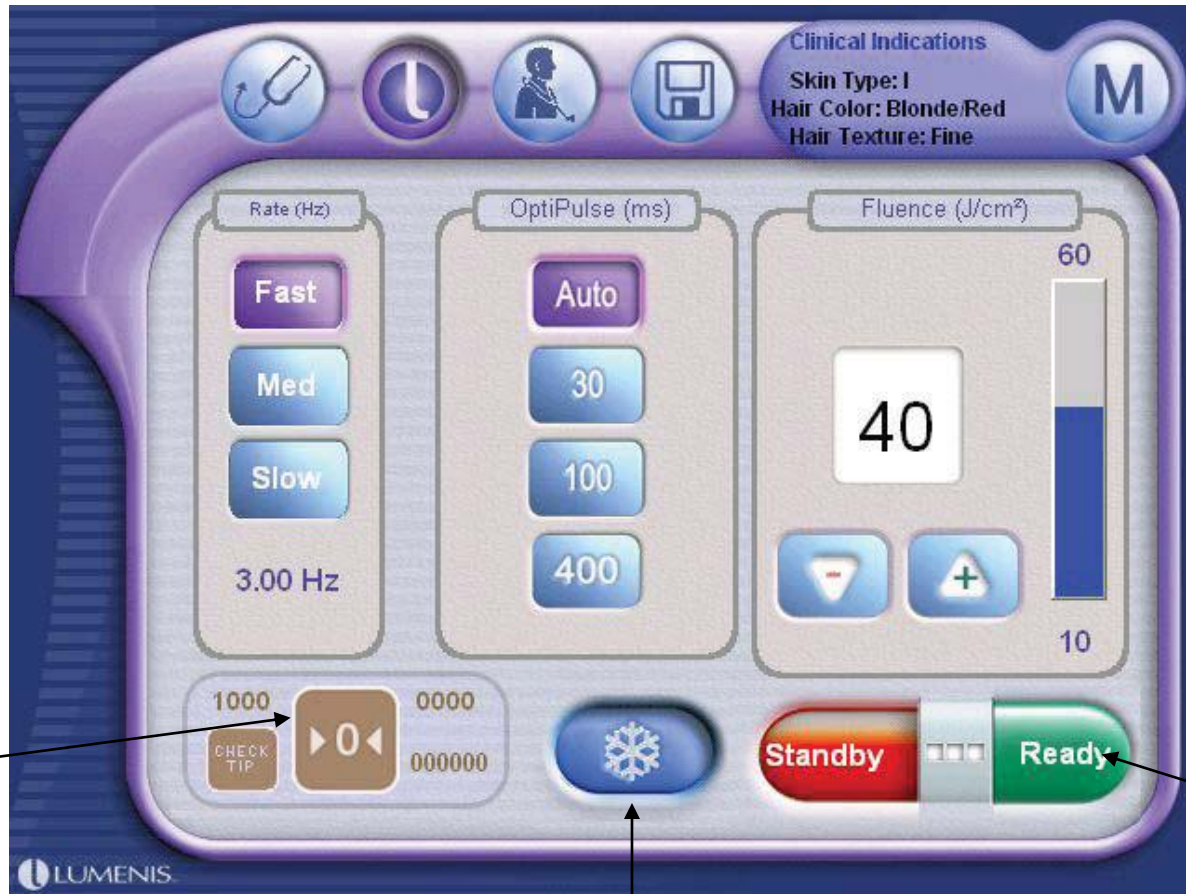
User pre-sets

Save user pre-set



Sample of Saved User Preset

Select: Rate (Hz), OptiPulse (ms), Fluence (J/cm²)



Reset
Pulse
Counter

Verify in
Ready Mode

Verify ChillTip
(Blue is ON)

NOTE: CHILLTIP MUST REMAIN ON DURING LASER HAIR REMOVAL TREATMENT.

■ Rate (Hz)

- Fast (1–3 Hz), Med (0.5–1 Hz), Slow(0.5 Hz)
- Rate will adjust based on pulse duration and fluence; maximum rate is 3 Hz

■ Fluence (J/cm^2)

- AUTO, 30 ms and 100 ms will allow up to $60 \text{ J}/\text{cm}^2$
- 400 ms pulse duration will allow up to $100 \text{ J}/\text{cm}^2$
- The highest tolerable fluence will provide the greatest efficacy
- Higher fluence = Higher risk, perform test spots and titrate carefully

■ Pulse Width (ms)

- Auto: 1/2 fluence rate, 5 ms to 30 ms; provides the highest efficacy for fair skin, shallow/fine hair
- 30ms: deeper, terminal / coarse hair
- 100-400ms: darker skin types, tanned skin, dense hair

■ Tip Counter

- Counts total pulses on handpiece and per treatment
- During treatment, the system operator must visually check tip every 50-100 pulses and keep tip clean at all times
- **Pulse counter will produce a warning message after 1000 pulses to check tip and clean if necessary (a reminder only)**
 - Press 'ok' to continue treatment



- ❑ Prep skin
 - ❑ Recommend patient shave area to be treated day before procedure; clinician to verify prior to treatment
 - ❑ Apply gel if desired
 - ❑ Avoid contact between laser tip and any areas of blood from shaving
- ❑ Press enable button
- ❑ Position tip on patient's skin, apply moderate pressure
- ❑ Depress pulse trigger to begin treatment
- ❑ Perform test spot
- ❑ Wait and observe tissue response
 - ❑ See 'Clinical Protocols' for additional detail

■ “Pick and Place” Technique

- Place on skin, pulse laser, release trigger, handpiece is then picked up from skin, moved to the next treatment area, and lowered against the skin

■ “Bounce & Glide” Technique

- Place on skin, hold trigger in ON position, the tip is kept continuously in contact with the skin and bounced along skin tissue in cadence with the audible beep that signifies firing of laser
- **Do not remove laser tip from skin surface when using this technique**

- Check if ChillTip is activated
 - Physically touch the tip to check for cooling before treating patient
- **ChillTip must be cleaned often**
 - Singed hair can collect on tip causing excessive heating
 - Can occur after several pulses or up to one full run, depending on the amount of hair extrusion
 - Visually check the tip for any debris every 50-100 pulses, without looking directly into tip
 - Clean more frequently in areas of high hair density
 - ‘Warning’ after 1000 pulses only serves as a reminder

- Cleaning should be performed with gauze pads moistened with distilled water or a mild alcohol solution
 - **Caution:** While operating the LightSheer system, never look directly into the laser aperture at the distal end of the handpiece, even if you are wearing laser safety glasses. Serious eye injury or blindness could result.

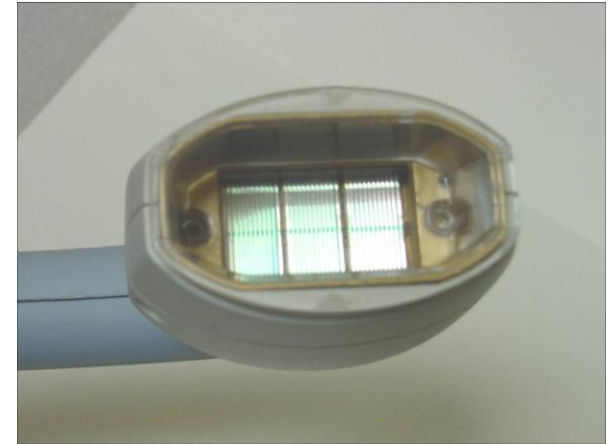


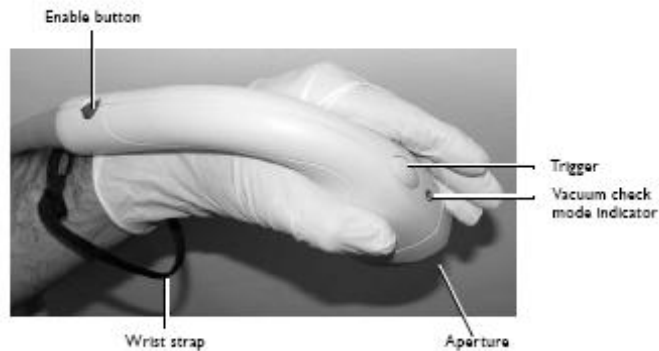
A faint, stylized world map is visible in the background of the blue header bar, composed of various geometric shapes and patterns.

Laser Operation LightSheer HS (High Speed) Handpiece



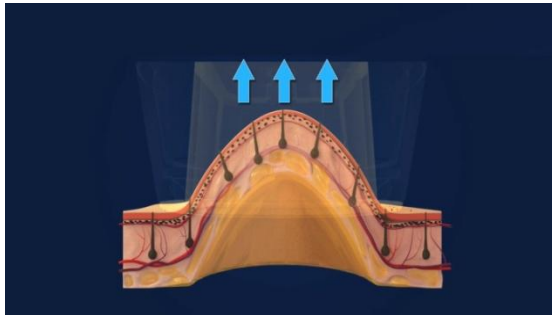
- ‘High Speed’ handpiece
 - 22 mm x 35mm spot size
- Vacuum Assist technology
 - Enhances light absorption
 - Improves treatment comfort
- Disposable tip / insert protects VA technology
 - Replace disposable insert between patients
 - Also replace during treatment if insert or filters become dirty/clogged
- Do not use treatment gel with ‘HS’ hp



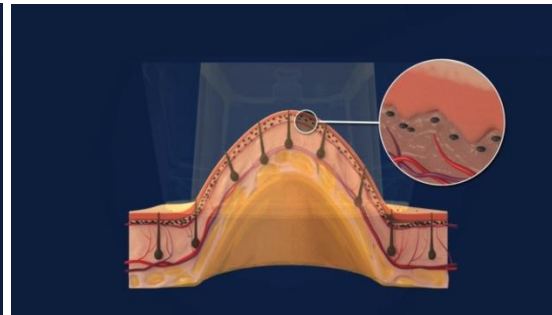


- Ensure new, clean insert in HS handpiece prior to treatment
- Press ENABLE button
- Position HS opening on patient's skin
- Obtain vacuum contact
- Press and hold trigger for desired pulses
- Move to next treatment spot
- Note: A fine mist of mineral spring water may be applied to skin prior to treatment to maximize patient comfort

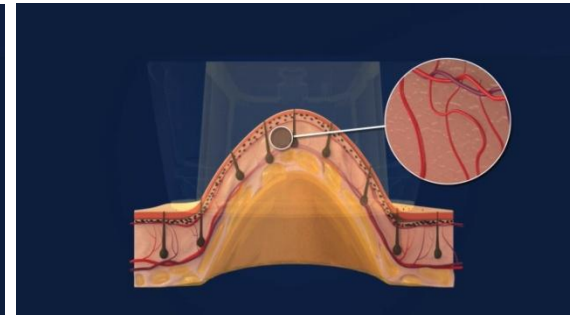
HS Handpiece delivers up to 12 J/cm² and 30-400 ms pulse durations with Vacuum Assist



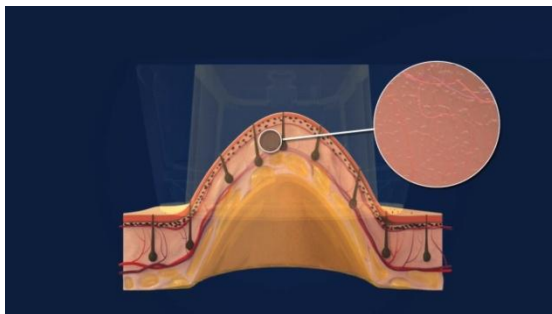
Vacuum assist technology gently pulls skin up into handpiece. Skin senses vacuum pressure instead of laser pulse.



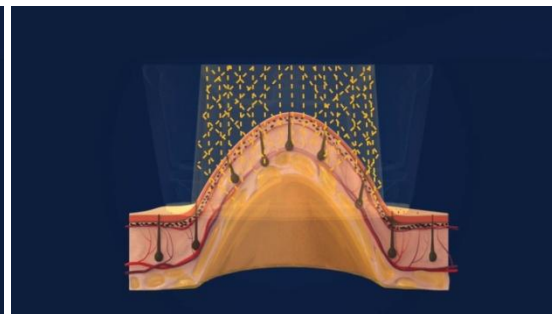
Skin is stretched thin. Hair is pulled closer to energy source. Density of melanocytes in skin is reduced. Less energy will be absorbed by the epidermis.



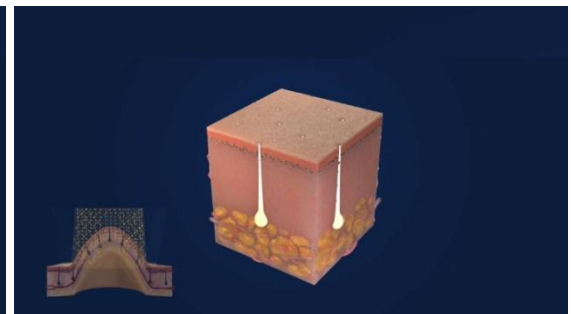
Vacuum pressure temporarily compresses tissue and surrounding vessels.



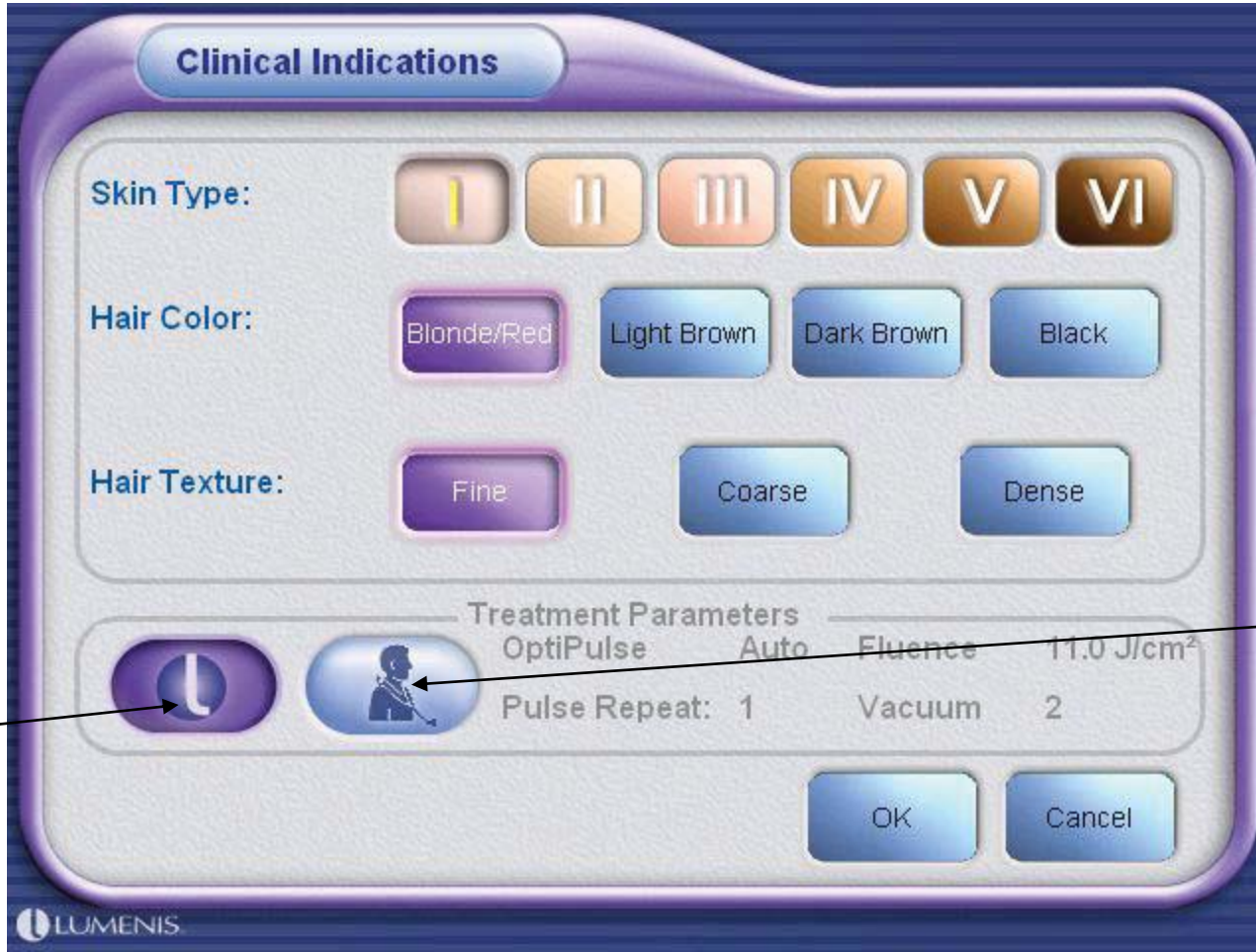
Blood is temporarily displaced. Less energy will be absorbed by oxyhemoglobin.



Less energy is lost to competing chromophores. More photons are able to reach target melanin in hair, which absorbs the energy.



Heat builds up, damages hair follicle and its ability to regrow.

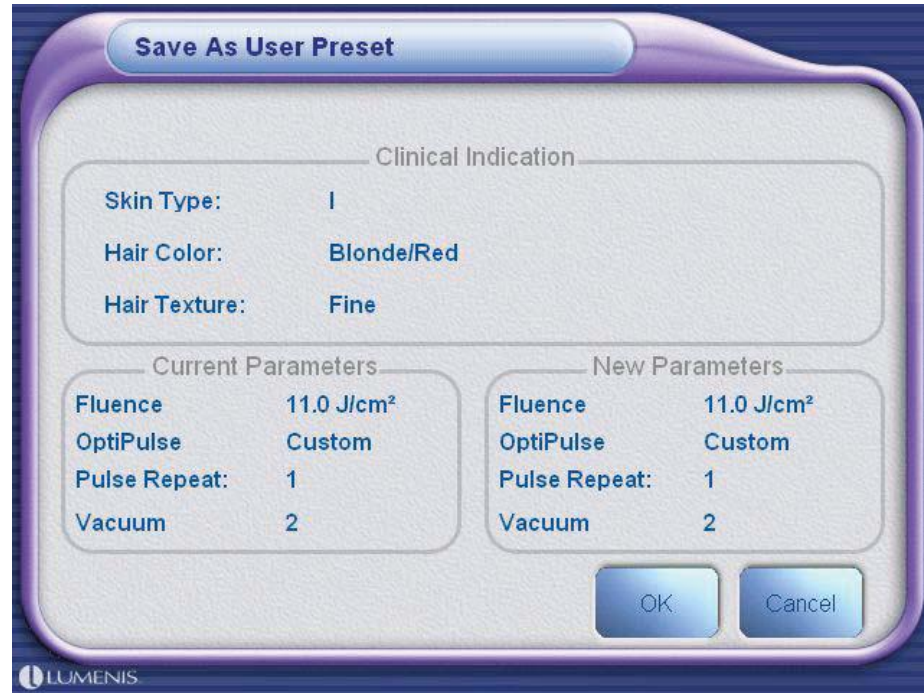


Lumenis Presets

User Presets

User pre-sets

Save user pre-set



Sample of Saved User Preset

Select: No. of Pulses, Vacuum, OptiPulse (ms), Fluence (J/cm²)



Reset
Pulse
Counter

Verify in
Ready Mode

Verify Vacuum
(Green is ON)

- **Number of Pulses** (pulse stacking)
 - User selects number of pulses emitted per trigger press
 - Recommend beginning with one pulse
 - The additional pulses will emit additional energies and should only be increased with caution
 - If desired clinical endpoints are not reached using single pulse at max. fluence, move to pulse stacking and repeat test spot procedure at fluence level 2 J/cm² lower, then titrate as needed
 - Trigger needs to be held through multiple pulses
 - Additional pulses will extend treatment time

■ Vacuum Level

- High (18 inHg)
- Medium (12 inHg)
- Low (8 inHg)

■ Pulse Duration (ms)

- 30 ms: Fastest Pulse Duration Fluence max 6 J
- Custom: Most common setting, automatic PD selection
 - 30-70 ms based on fluence level selected
 - Actual will be indicated at column bottom
- 100 ms: Darker skin types and tans
- 400 ms: Darker skin types and tans

Fluence

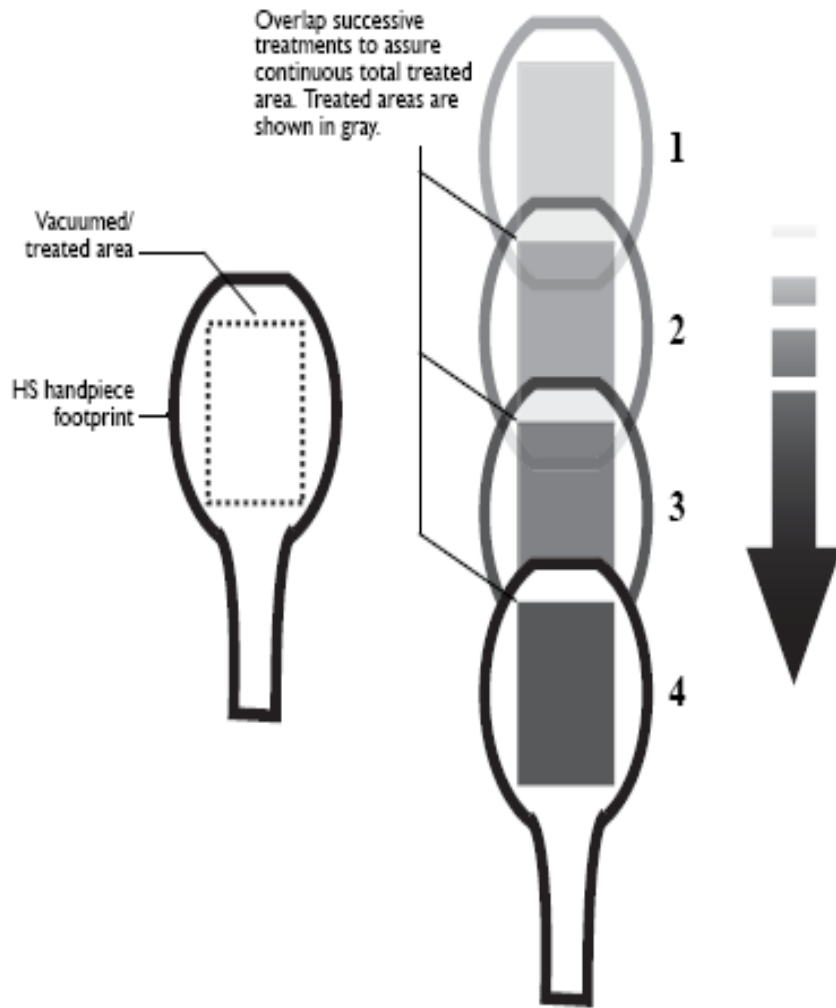
- 4.5 - 6 J/cm²
 - When 30 ms pulse duration is selected
- 4.5 - 12J/cm²
 - When Custom (30-70ms); 100 ms; 400 ms pulse durations are selected

Tip Counter

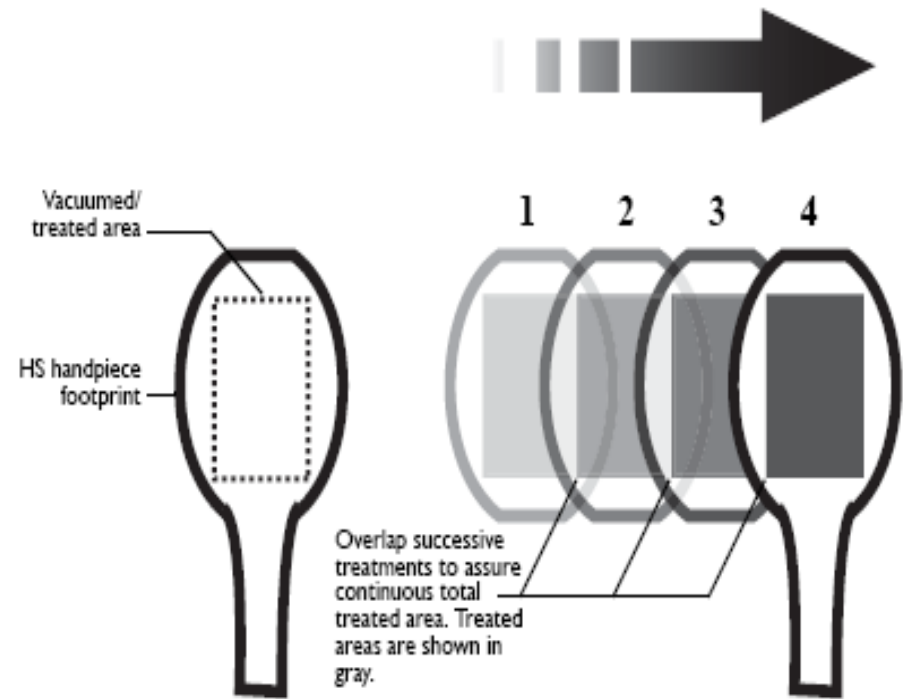
- Counts total pulses on handpiece and per treatment
- During treatment, the system operator must visually check insert frequently (e.g., every 5-10 pulses) and keep clean at all times
- Pulse counter will produce a warning message after 500 pulses to check tip/insert and clean if necessary (as a reminder only)**
 - press OK to continue treatment



- Prep skin: shave to skin surface, clean skin
- Press ENABLE button
- Position handpiece on patient's skin
- Depress pulse trigger to begin treatment
- Perform test spot
- Observe laser tissue interaction
- Wait and observe tissue response
 - See 'Clinical Protocols' for additional details



Assuring continuous end-to-tip coverage using the HS handpiece



Assuring continuous side-to-side coverage using the HS handpiece

- ❑ Keep the diode window and disposable insert clean at all times during treatment
- ❑ Whenever you see any contamination on the window surface:
 - ❑ using lint free gauze pad moistened with alcohol, clean the HS handpiece window
 - ❑ and then clean with dry gauze pad
- ❑ Frequently observe disposable insert for damage and replace it if necessary



A faint, stylized world map is visible in the background of the blue header bar, composed of various shades of blue and white.

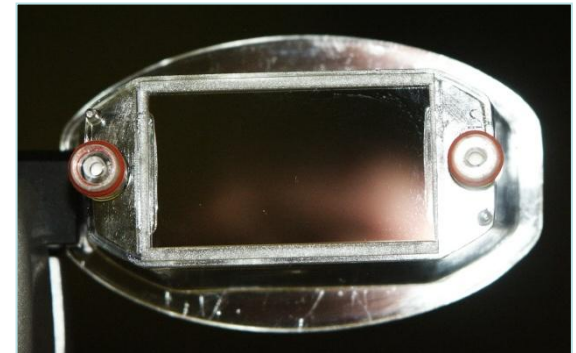
Laser Operation HS Handpiece & Disposable Insert Care Guidelines



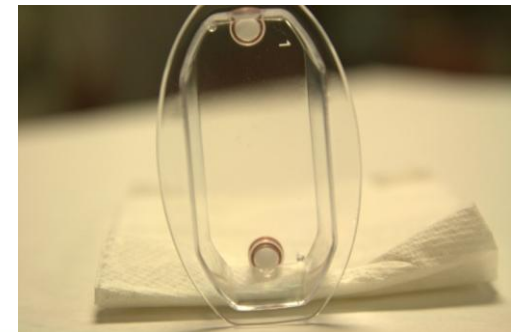
- NEW disposable insert with glass window designed to be easier to clean and last longer per treatment
 - Released in March 2010; available NOW

- FORMER disposable insert with all plastic design
 - No longer sold; replaced with NEW insert above

NEW Disposable Insert
(with glass window; available)



FORMER Disposable Insert
(all plastic; obsolete)



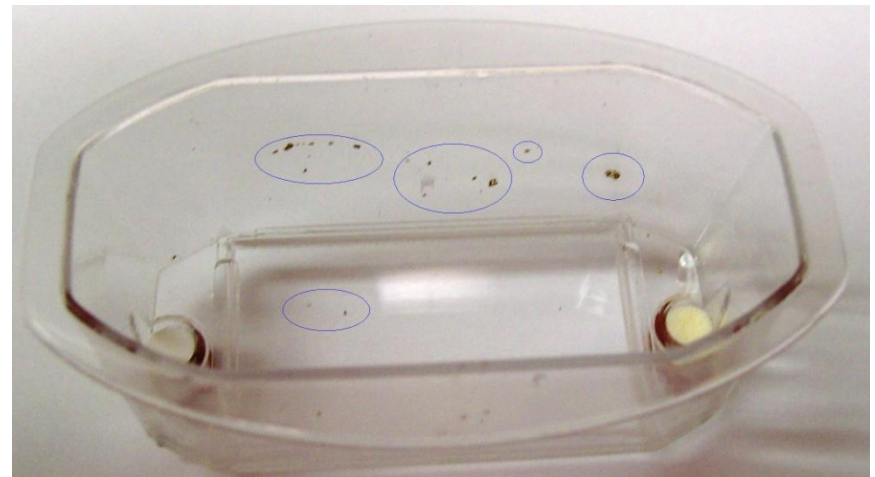
- **Debris or particles, including fingerprints, adhering to the inside of the disposable insert during application of energy could lead to absorption of light and overheating and/or burning of the disposable insert.**

FORMER Disposable w/all plastic :



This product is no longer sold; obsolete.

NEW Disposable w/glass window:



Sample after approx. 2000 laser pulses.
Easier to clean; last longer per treatment.

- Use of the LightSheer Duet with a damaged disposable insert can damage your HS handpiece and compromise treatment quality.



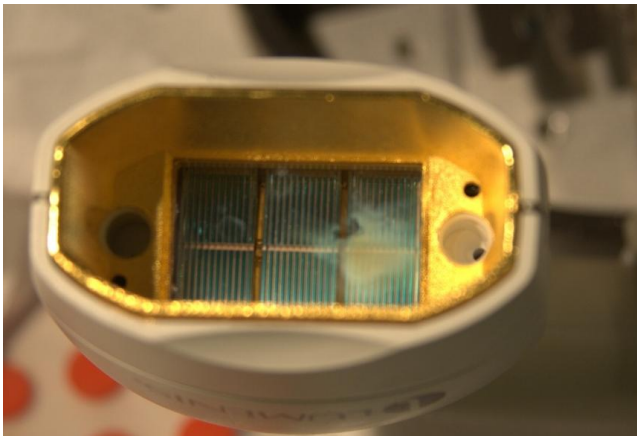
‘Damaged’ sample of former disposable w/all plastic;
no longer sold, obsolete.

- ❑ Pre-treatment Requirements
 - ❑ Thoroughly shave and clean the treatment area to remove any pieces of hair or other debris.
 - ❑ While the system is OFF, inspect the handpiece.
 - ❑ The diode window should be clean and free of debris.



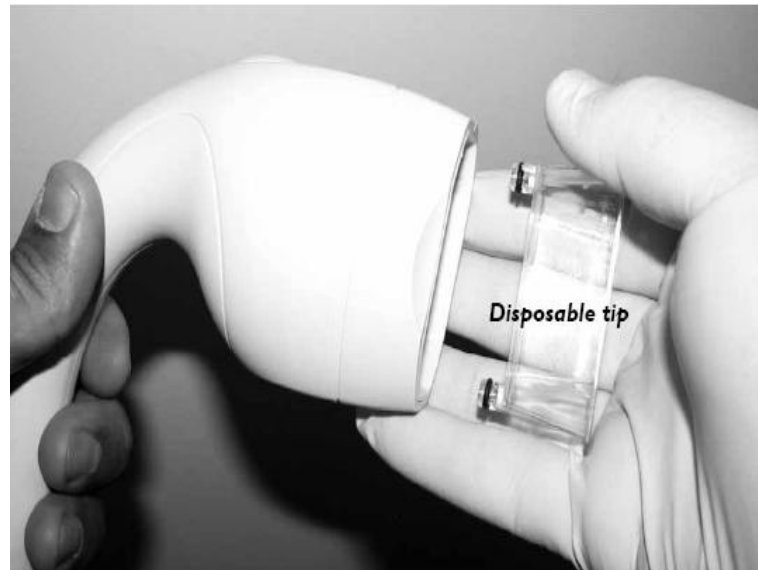
IF THE DIODE GLASS WINDOW IS NOT CLEAN

- Remove disposable insert using outer edge/lip
 - **Caution:** when removing disposable insert with glass window after firing the laser, DO NOT TOUCH the backside that faces diode window; insert bottom backside will get very HOT after firing the laser.
- Clean the diode window with lint-free gauze moistened with alcohol solution.
- Then wipe clean with a dry gauze pad to remove any fingerprints, stray hairs or debris.



- Insert a new and clean disposable insert with a **gloved hand** (note: use powder-less gloves).
- Avoid creating fingerprints or having debris contaminate the insert.

How to Insert



Note: 'Disposable tip' in photo same as 'disposable insert'.

■ During Treatment

- Frequently observe the disposable insert for debris or damage - **more often when treating coarse hair.**
- Throughout the treatment, check the disposable insert **every 5-10 pulses.** Wipe away any contamination with a dry gauze.
- If the dry gauze does not clean the insert, clean with alcohol moistened gauze.
- If any discoloration or debris is observed on the disposable insert, clean with **alcohol and then wipe with dry gauze.**



Caution: While operating the LightSheer system, never look directly into the laser aperture at the distal end of the handpiece, even if you are wearing laser safety glasses. Serious eye injury or blindness could result.

■ During Treatment (continued)

- After firing the laser, if smoke is visible, or white flash is seen, check the disposable insert and clean again or change as necessary.
- If the disposable insert cannot be completely cleaned with alcohol, discard and insert a new one.
 - **Caution:** when removing the disposable insert with glass window after firing the laser, use outer edge/lip; DO NOT TOUCH the backside that faces diode window as this will get very HOT after firing the laser.

White Flash = Stop & Replace Insert

- If during treatment the clinician sees a bright white flash from the handpiece, the disposable insert* should be replaced immediately.
 - **Caution:** when removing the disposable insert with glass window after firing the laser, use outer edge/lip; DO NOT TOUCH the backside that faces diode window as this will get very HOT after firing the laser.

A. Red Flash - NORMAL

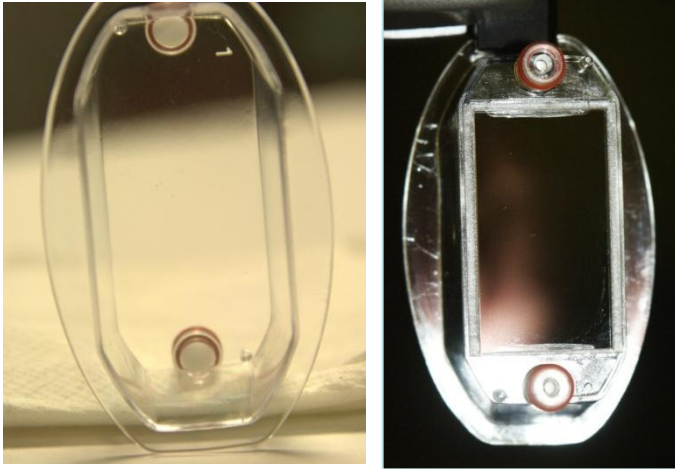


B. White Flash - REPLACE INSERT*

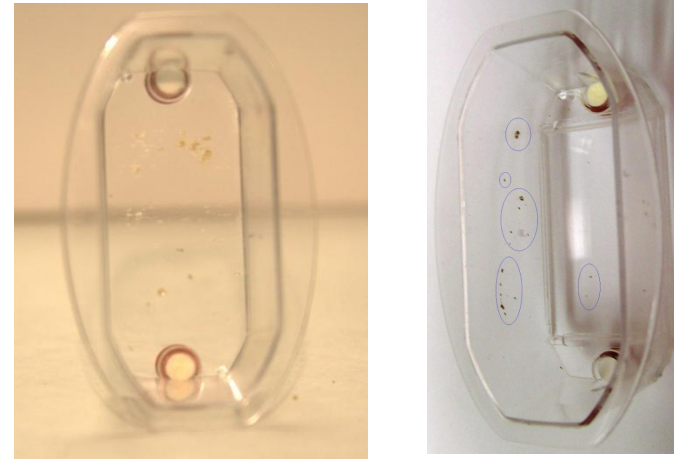


For Demonstration purposes only.
Do not attempt.

A. Clean Inserts - USE



B. Contaminated Inserts - CLEAN



C. Burned Insert - REPLACE



D. Burned Insert - REPLACE

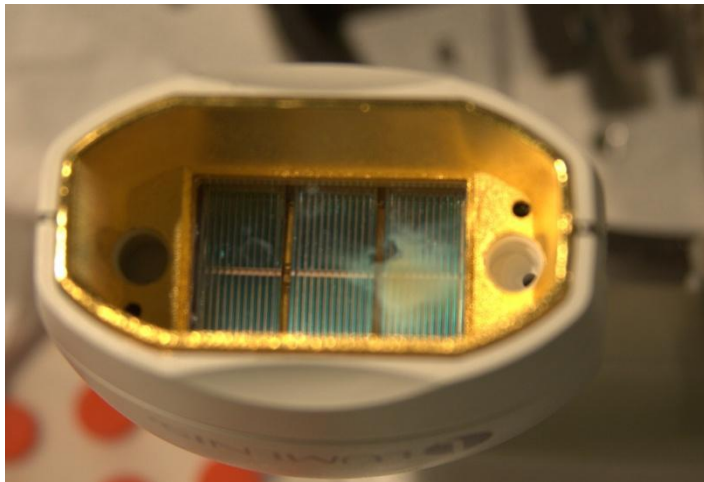


Note: C & D above are 'damaged' samples of former/obsolete disposable (all plastic); no longer sold and replaced with new disposable insert (w/glass window).

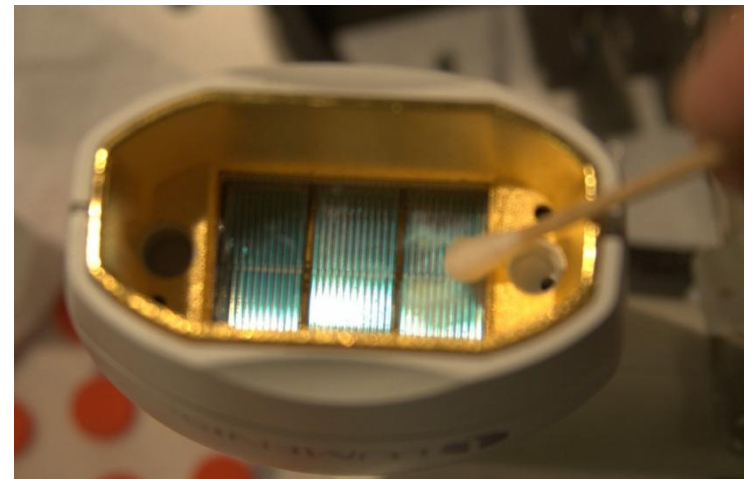
A. Diode Window is
CLEAN: Ready to Use



B. Diode Window is DIRTY:
Clean prior to Use

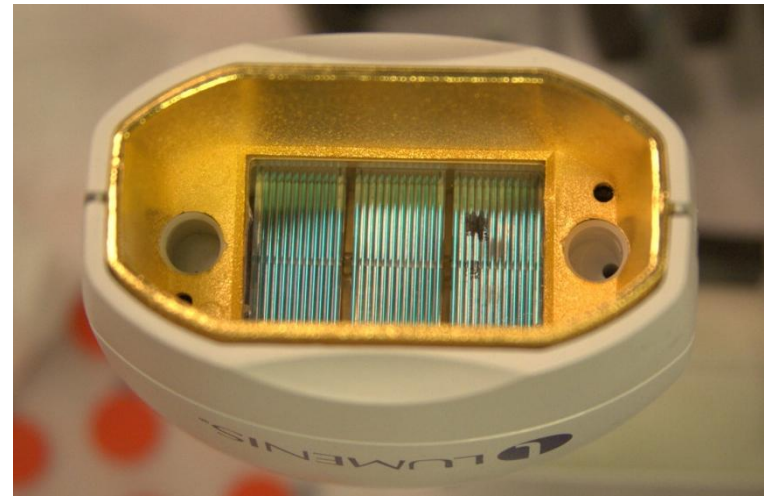
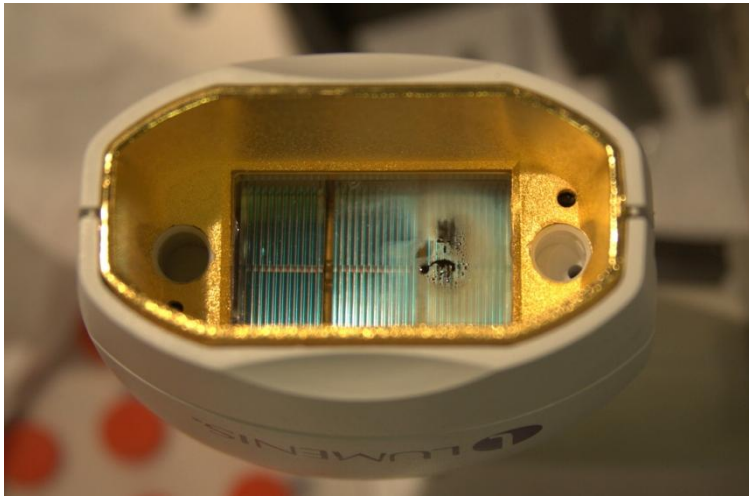


C. Clean Diode Window: with
alcohol moistened cotton



IF Diode Window Can NOT Be Cleaned

DO NOT USE



CALL Customer Service

In the US: 1-877-LUMENIS

Outside the US: contact your local service representative.

- **Post Treatment**
 - Dispose of the insert after each patient treatment.
 - **Caution:** when removing the disposable insert with glass window after firing the laser, use outer edge/lip; DO NOT TOUCH the backside that faces diode window as this will get very HOT after firing the laser.
 - Apply a new and clean insert into headpiece and place in system holster / cradle.

A. Use edge/lip to remove



B. New Insert for next treatment



Clinical Protocols Laser Hair Removal



- No two patients are alike, treatment outcome cannot always be predicted
 - Never promise 100% reduction
- Clearly define permanent hair reduction
- Describe need for multiple treatments
 - Multiple treatments are required (e.g., avg. 5-7)
 - For darker skin types IV-VI, more treatments may be needed (e.g., can be as many as 12)
 - Discuss possible side effects and obtain signed patient consent



- Take baseline photographs
- Recommend patient shave area to be treated day before procedure (clinician to verify prior to treatment)
 - Avoid contact between laser tip and any area of blood from shaving skin
- Clean skin surface to remove any hair debris
 - Note: a lint roller may be helpful to remove hair particles, debris; then wipe skin w/alcohol solution to remove tackiness
- Perform test spot, wait 15 - 30 minutes for skin types I - IV; allow AT LEAST 48 hours for skin types V-VI to observe skin response before conducting treatment
- Use topical anesthetic if desired
 - e.g., ET hp with higher fluence over longer treatments, or very sensitive areas either hp
 - Apply prior to treatment, following prescription guidelines; and completely remove before treatment
- Optional: use caution if marking area treated with pencil, avoid any pigment (i.e., use white, not black)

- Obtain complete patient history
- Manage patient's expectations
- Discuss number of treatments
- Discuss contraindications
- Discuss complications & possible side effects
- Record clinical indications
 - Skin type
 - Hair color
 - Hair density
 - Hair diameter

- LightSheer is cleared to treat all skin types (Fitzpatrick I-VI), including tanned skin
 - Refer to physician recommended treatment parameters (e.g., presets)
 - Use added caution with darker skin types
 - Avoid treating patients with recent or lengthy exposure to sun or artificial UV light
 - DO NOT TREAT patients with artificial tan on skin
 - Perform the recommended test spot protocol before treatment to verify the appropriate parameter settings

Skin Type	Genetic Disposition	Reaction to Sun, Tanning Habits
I	White; very fair; red or blond hair; blue eyes; freckles	Always burns, never tans
II	White; fair; red or blond hair; blue, hazel or green eyes	Usually burns, tans with difficulty
III	Cream white; fair with any eye or hair color; very common	Sometimes mild burn, gradually tans
IV	Brown; typical Mediterranean Caucasian skin	Rarely burns, tans with ease
V	Darker Brown; Middle Eastern skin types; (Non-Caucasian skin)	Very rarely burns, tans very easily
VI	Black	Never burns, tans very easily

Source: Fitzpatrick TB: *Soleil et peau. J Med Esthet* 1975;2:33034.

Skin Type	Genetic Disposition	Reaction to Sun, Tanning Habits
I	White; very fair; red or blond hair; blue eyes; freckles	Always burns, never tans
II	White; fair; red or blond hair; blue, hazel or green eyes	Always or Usually burns, tans with difficulty, tan fades rapidly
III	Cream white; fair with any eye or hair color; very common	Sometimes mild burn, always or usually tans, tan stays for weeks
IV	Brown; typical Mediterranean Caucasian skin; moderately pigmented and may include Asian, Middle Eastern, Indian, Hispanic	Rarely burns, tans with ease, tan stays for months
V	Darker Brown; Middle Eastern skin types; darker skin type and may include Asian, Middle Eastern, Indian, Hispanic, Mediterranean (Non Caucasian)	Very rarely burns, tans very easily
VI	Darkest Brown, Black; (Non Caucasian)	Never burns, tans very easily

**Note: Lumenis recommends conservative approach to darker skin types IV-VI; perform test spots & wait; then adjust parameters to optimize treatment. If uncertain about skin type IV, approach as if skin type V for test spots to verify.*

■ Pigmented Hair

- Black, brown, red, dark blonde can achieve long lasting results
- Light blonde or white can experience temporary loss for up to 3 months
- Recommend electrolysis as a treatment for permanent removal of discrete white hair
- Terminal hair, not vellous (short, fine light colored hairs)
- Lumenis does not recommend treating hair that is lighter than surrounding tissue

Richards-Meharg Table

AREA OF BODY	ANAGEN	TELOGEN
Scalp	2-6 Years	3-4 Months
Beard/Chin	52 weeks	10 Weeks
Upper Lip	16 Weeks	6 Weeks
Eyebrows	4-8 Weeks	3 Months
Ear	4-8 Weeks	3 Months
Legs	24 Weeks	16 Weeks
Arms	18 Weeks	13 Weeks
Axilla	4 Months	3 Months
Pubic	3 Months	4 Months

Note: Other hair cycle duration tables are in use and vary, but show similar variance per anatomical site.

- ❑ Active infection in the treatment area
- ❑ Active infection or a history of herpes simplex in the area to be treated
- ❑ Use of oral Isotretinoin (e.g., Accutane, others) within the preceding 6 months
- ❑ History of keloid formations
- ❑ History of livedo reticularis, an autoimmune vascular disease
- ❑ Hypersensitivity at the treatment site to any agents, solutions, or gel used in the treatment, if no alternative exists
- ❑ Use of anticoagulants before the washout period, per package insert, and at the physician's discretion
- ❑ Patient with personal history of melanoma must first pass a skin screen (of area to be treated) by a licensed dermatologist prior to treatment

- ❑ Dysplastic nevi in the area to be treated
- ❑ History of bleeding disorders
- ❑ History of collagen, vascular or immunosuppression disorders
- ❑ Tattoos at the treatment sites: stay more than ¼ inch away from tattoo border
- ❑ Significant concurrent skin conditions affecting areas to be treated or any inflammatory skin conditions
- ❑ Active cold sores, open lacerations or abrasions on the area to be treated
- ❑ History of immune deficiency (including HIV infection or AIDS)

- History of erythema ab igne; an acquired persistent reticulated erythematous and pigmented rash of the skin produced by prolonged or repeated exposure to moderately intense heat of infrared radiation
- Use of depilatories or other hair removal treatments (i.e., waxing, plucking, tweezing, or electrolysis) in the treatment area within the preceding 6 weeks
- Chronic or cutaneous viral, fungal, or bacterial infections in the treatment area
- Photosensitivity disorder that can be exacerbated by infrared light
- History of skin cancer or pre-cancerous lesions at the treatment sites
- Use of medications, herbal supplements, perfumes or cosmetics that may affect sensitivity to light

- Erythema, edema and perifollicular edema may occur immediately after treatment and typically resolve in a few days
- Hypo- or Hyperpigmentation rare and usually transient; usually resolves in a few months; fluence and skin type dependent
- Irritation, itching, burning sensation or discomfort during or following treatment may occur
- Superficial erosions of the treated area may be visible after laser treatment
- Burns, crusting and blistering of the treated area
- Transient exacerbation of hair growth
- Purpura confined to the exposure area may be evident for several days following treatment

- Erythema ab igne, which is the development of an acquired persistent reticulated erythematous and pigmented rash of the skin produced by prolonged or repeated exposure to moderately intense heat of infrared radiation
- Pruritis may occur in rare cases
- Contact dermatitis or irritant dermatitis may occur in some cases
- Infection at the treatment site
- Mild to moderate pain may occur during or after treatment
- As with the use of any laser scarring is a possibility, but rare

- CAUTION is advised when treating patients with any of the listed contraindications.
- In the event of adverse outcomes, CONTACT LUMENIS
 - In the US @ 1-877-LUMENIS (586-3647)
 - Outside the US, contact your local Customer Support, Sales, and Service representative

- Smell or visualize singed hair
 - Hair from follicle ejected or vaporized
 - Singed hair on skin or in disposable tip (HS only)
 - Gel becomes brownish from singed hairs (ET only)
 - Odor of singed hair present

- Perifollicular edema and erythema
 - May be Mild (HS hp) to Moderate (ET hp)

- Perifollicular erythema
- Initial redness from ChillTip and pressure
- Erythema around treated hair increases after a few minutes



Courtesy Robert M. Adrian, M.D. & Linda Griffin, R.N., Center For Laser Surgery

- Perifollicular edema
- Swelling around the follicle (bumps) several minutes after treatment



Courtesy Robert M. Adrien, M.D. & Linda Griffin, R.N., Center For Laser Surgery

Courtesy C. Dierickx, M.D.

- When using LightSheer HS hp, lower fluence is used and laser energy lost to competing chromophores is minimized
- Therefore, LightSheer HS tissue response (i.e., edema and erythema) may be mild in comparison to the patient's previous experience
- Proactively counsel patients to expect milder response to minimize any potential concern

Immediate Reaction

LightSheer HS hp
(8-11 j/cm², custom)

LightSheer ET hp
(34-38j/cm², auto-30ms)

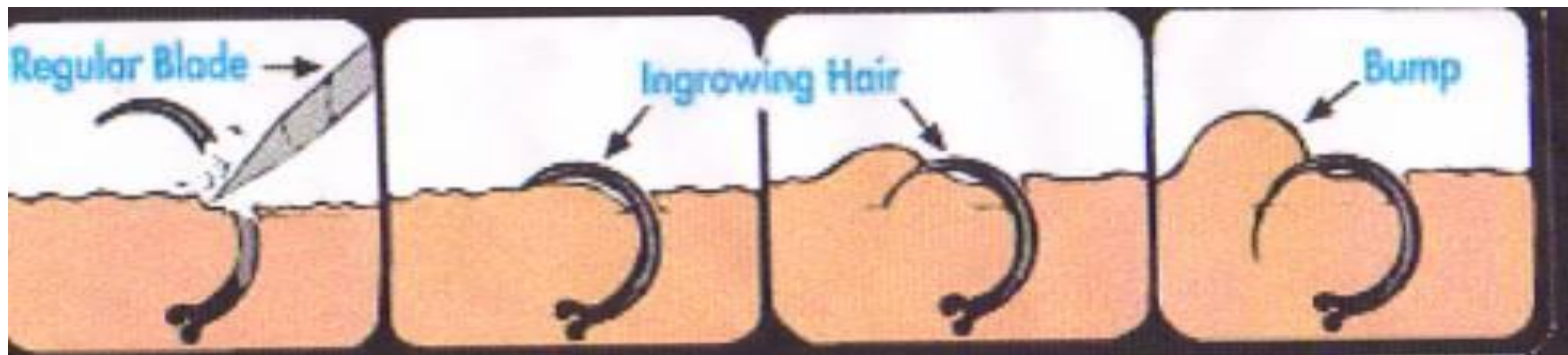
- Monitor laser-tissue interaction throughout treatment, adjust if and as needed
- Since no two patients are exactly alike, do not rely solely on written parameters
- Clinical end-points that indicate fluence and/or pulse width must be changed include:
 - Skin graying
 - Skin separation

- Sunburned sensation is common
- Suggest cool compresses, soothing cream or gel (i.e., aloe vera)
- Crusty spots may occur
- Clean area 2 x daily with mild soap
- Sunscreen for 6 weeks on treatment area
- May experience singed hair and shedding process in days following

The Treatment of Pseudofolliculitis Barbae



- Commonly referred to as ‘razor bumps’
- Medical term for persistent irritation due to shaving
- Problematic for men of African descent, others with curly hair
- Inflammatory foreign body response to a sharp hair shaft



LightSheer ET Results Shown



Before Treatment



After Treatment

Photos courtesy of Fran E. Cook-Bolden, MD

A blue horizontal banner with a faint world map background. The map is composed of various shades of blue, and the Lumenis logo is overlaid on the map in a semi-transparent manner.

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FDA Clearance 510(k) K053628, 7 April 2006

■ Skin Types

- Fitzpatrick I-VI, including tanned skin

■ Primary Procedures

- Hair removal, permanent hair reduction

■ Secondary Procedures

- Treatment of benign vascular lesions, leg veins
- Treatment of pseudofolliculitis barbae (PFB)
- Treatment of benign pigmented lesions