

Quadra Q4

PHOTOAGING & SKIN THERAPY GUIDE

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USA FDA 510K CLEARANCE K071883

Quadra Q4® intense pulsed light is indicated for use in Dermatological and Plastic Surgery applications and specifically for long term stable, or permanent, hair reduction. In addition, Quadra Q4® is indicated for the treatment of benign cutaneous vascular lesions and the treatment of benign pigmented lesions. Quadra Q4® is indicated for the treatment of mild to moderate inflammatory acne vulgaris.

WARNING

The information provided in this document is intended for general guidance in the use of the Quadra Q4® IPL device for photoaging and skin therapy indications. It is not intended as an expert protocol or medical advice. The treatment parameters suggested here are those reported by experienced users in published literature or reported directly to DermaMed Solutions, LLC. However, the user alone bears full responsibility for choosing treatment parameters, operation of the device, and appropriate patient care.

TRAINING

Training is a key factor in consistently achieving successful treatment outcomes. At a minimum, all operators should receive basic training in light science, light-based treatment, and the safe use of laser/IPL devices. No two devices are identical in the way they deliver light energy, so it is vital to obtain training. Contact DermaMed Solutions for training opportunities.

ACCESSORIES

An IPL treatment room must be fully equipped with all necessary accessories to ensure successful and efficient treatments. Requirements include refrigerated cooling packs or the equivalent for skin cooling.

For optimal diagnosis before treatment, operators are encouraged to use advanced skin analysis including detailed evaluation of melanin, erythema, hydration, and lipid levels. Use of skin scanners and digital cameras is also encouraged.

INTRODUCTION

Lasers and intense pulsed light (IPL) devices have been used in aesthetic applications now for more than ten years. In that time, both the technology and treatment practices have improved. Today, people with almost all skin types can take advantage of light-based treatments for photoaging and skin therapy.

IPL devices emit a broad band of visible and near-infrared wavelengths of light energy that can penetrate at various depths of the skin to target hair follicles, vascular lesions, and pigmented lesions. Because of their multiple wavelengths, IPL devices also have the ability to produce non-specific dermal remodeling of collagen.

Quadra Q4® IPL systems generate a unique square pulse, constant spectrum output that produces clinically effective responses with lower, safer applied energy. Higher efficiency means Quadra Q4® systems are smaller, more portable, and substantially more affordable to own and operate than conventional IPLs. Lower energy also makes treatment more comfortable for patients.

With Quadra Q4® technology, a single system can provide a wide range of therapies.

Applications covered in this treatment guide include:

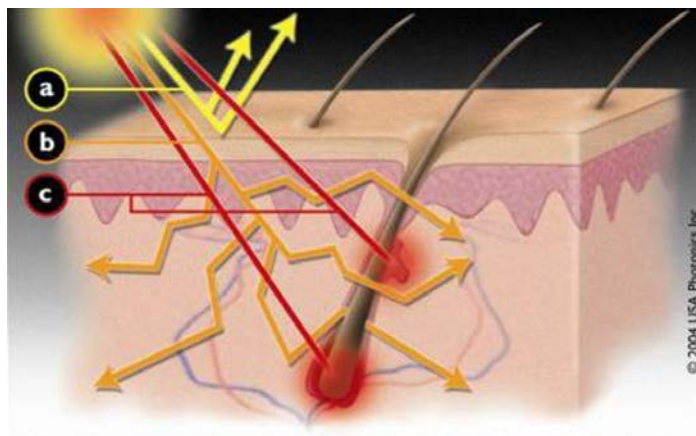
- Treatment of pigmented and vascular lesions
- Skin therapy and treatment of photoaging
- Treatment of acne vulgaris

THE INTERACTION BETWEEN LIGHT AND SKIN

Light Absorption by Chromophores

The skin has three primary targets that absorb light: melanin, blood, and water. These targets are called chromophores. Light energy absorbed by chromophores is converted to heat energy.

Skin therapy using Quadra Q4® light therapy consists primarily of creating sufficient heat in the red or brown sun-damaged structures of the skin to reduce their appearance or to eliminate them completely. This result is achieved by light absorption in the melanin of the mottled pigmentation and the oxyhemoglobin in fine blood vessels.

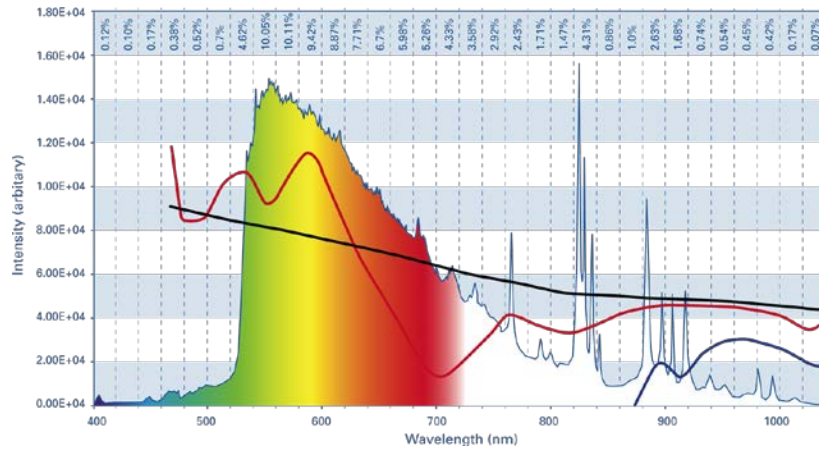


Light that isn't reflected (a) scatters beneath the skin's surface (b) and is then absorbed by melanin and blood. The melanin is coagulated by the absorbed heat energy, and heat absorbed by the blood is conducted to the delicate vessel walls (vascular endothelium), which causes treated vessels to collapse or completely coagulate.

Characteristics of Light that Affect Absorption

The amount of radiant energy that will be absorbed by a tissue also depends on characteristics of the light source, specifically energy level applied, the wavelengths of the light, the spot size of the delivery device, and the duration of each pulse of light.

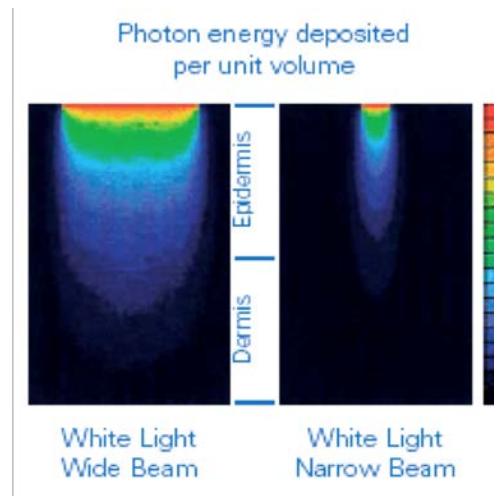
Wavelength. The wavelength of the light energy is a key parameter that affects the interaction between a light and the tissue. IPL devices produce mostly visible broad-band wavelengths of light. Potentially harmful, short wave UV light (<400 nm) is filtered out by the lamp itself, and hardly any long-wave infrared light is produced. The remaining wavelengths between 500 nm and 1000 nm are well absorbed by melanin and blood and are well suited for skin therapy.



IPL wavelengths and absorption. The spectral distribution of a typical xenon lamp IPL overlaid with absorption curves for blood (red), melanin (black), and water (blue).

Spot size. The spot size of the light source's delivery device can also affect the depth of penetration of the energy. In a highly scattering medium such as skin, light diffusion at the edges of the beam causes spreading of the energy as it penetrates into the tissue. As a consequence, a larger spot size delivers more energy at a given depth.

Unlike traditional IPL devices, the Quadra Q4® uses twin flash lamps to produce a large rectangular spot size of 8.9 cm², which ensures that the light energy penetrates deeper into the skin. With the Quadra Q4®, there is no need to overlap spots, and the large spot size ensures faster and more comfortable treatment.



Depth of penetration by spot size. Large spot sizes increase depth of penetration.

Pulse duration. The total amount of energy applied to a tissue in a single pulse is determined by the energy level (or fluence) and the duration of the pulse.

The pulse duration is not only important in determining energy applied; it is also important in the selective destruction of target tissues. Generally, the pulse of IPL light used will be longer for hair removal than for skin therapy. By choosing long pulses of light for hair removal, the operator will avoid collateral damage to epidermal melanin as the tiny particles of melanin in the skin have time to lose absorbed heat during a long pulse (compared with, say, a much larger hair follicle structure which will hold its heat longer).

When targeting melanin in the epidermis as part of treatment for skin therapy or photoaging, great care must be taken to avoid over-treatment side effects.

Technology Differences

Some traditional IPL suppliers use colored glass filters in the applicator to reduce epidermal absorption side effects. By using the Quadra Q4® IPL devices with the latest square pulse and constant spectral output technology, multiple applicators may not be required, and effective treatments can be performed more simply with a single, user-changeable flash lamp.

Energy Required for Successful Skin Therapy

Several factors determine the appropriate energy level for skin therapy. The overall objective is to find the optimal therapeutic window where energy is sufficient to damage the blood vessels and/or the melanin in the skin blemish while avoiding collateral damage to surrounding tissue. Normally, the skin will only feel warm temporarily after treatment and any redness will disappear within minutes or a few hours.

Darker skin (including suntanned or spray-tanned skin) absorbs larger amounts of light energy than lighter skin, so that side effects appear with lower applied energy. This threshold varies from person to person and body area to body area.

The constant spectral output of the Quadra Q4® IPL device produces the lowest possible intensity for a given energy level thus minimizing discomfort and other side effects such as redness, pain, and skin burns.

GENERAL CONSIDERATIONS IN PHOTOAGING AND SKIN THERAPY

Changes in Skin as it Ages

Skin aging is a complex biological process consisting of two independent components:

- **Intrinsic aging**, or “biological clock” aging, which affects skin by slow irreversible tissue degeneration
- **Extrinsic aging**, or photoaging, the result of exposure to outdoor elements, primarily ultraviolet (UV) irradiation

As a result of these processes, major aging changes are seen in the extracellular matrix components of the dermis, ie, the collagen meshwork and the elastic fiber system. As part of intrinsic aging, the rate of synthesis of collagen and elastin is reduced, which can explain the noticeable thinning and visible loss of elasticity of the skin in the elderly.

At the same time as the collagen matrix deteriorates and the skin becomes rough and wrinkled, pigmentation changes, telangiectasias, and sometimes, actinic keratoses and epidermal malignancies occur.



Examples of photoaging of the skin. From left to right: forearm sunspots (Courtesy of USA Photonics), seborrheic keratosis (Courtesy of Dr. S. McCoy, Adelaide), and a pigmented lesion.

Photoaged skin is characterized by:

- Rough skin texture
- Mottled pigmentation

- Telangiectasia
- Mild to moderate rhytides (wrinkles)
- Enlarged pores
- Acne scarring
- Skin laxity

The exact mix of these elements will depend upon age, sex, and ethnic background (eg, Asians predominantly exhibit pigmented dischromia while many Caucasians have telangiectasia as the primary component of photoaging).

Therefore, several differently targeted treatments may be required to deal with all of the elements of photoaging. More aggressive device settings will result in more downtime for the patient and more side effects such as erythema, edema (swelling), bruising, and crusting of pigmented lesions while less aggressive treatments will mean more treatments will be required.

In a comprehensive treatment program, the first step is to treat epidermal pigmented lesions. Reduction of superficial pigmented blemishes allows deeper penetration of light energy at subsequent treatments.

The second step is to treat vascular lesions. These treatments (typically 4-6 weeks apart) may also improve appearance of acne lesions, help clear infected hair follicles, and stimulate collagen neo-genesis.

Over several months, the end result should be enhanced skin texture and pore size, better skin hydration and elasticity, and improved skin translucence. Reduction in the appearance of fine lines and wrinkles in the skin has also been reported using IPL devices as part of a comprehensive treatment regime.

Skin Analysis – Fitzpatrick Skin Typing

Skin type is one of the most important factors in identifying whether patients are appropriate candidates for light-based treatment and in determining initial treatment parameters.

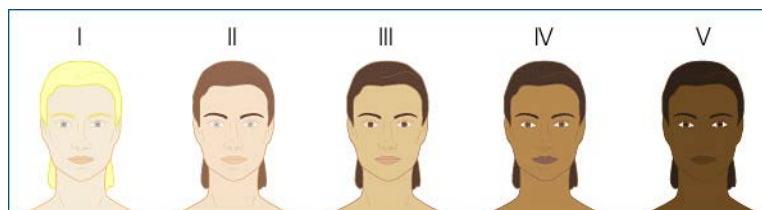
Skin is most often classified based on the Fitzpatrick Skin Classification Scale. The scale classifies skin based on complexion (pigmentation) and tendency to burn. According to Fitzpatrick, skin can be classified according to six types, as shown in the table and figure.

The most difficult patients to treat are those with Fitzpatrick skin type 1 who have a long history of sun exposure. In these patients, connective tissue is so fragile that typical IPL settings may damage the skin, with higher incidence of bruising, swelling, and blistering. In such cases, low energy settings must be used in early treatments until the supporting dermal connective tissue is strengthened and the redness is reduced. A standard five-treatment program is usually extended in this patient group. Very dark

skin types, particularly Afro-Caribbean, are also problematic because of high levels of melanin in the epidermis absorbing light energy in competition with the melanin in the targeted pigmentation or blood in any broken capillaries. Darker Asian skin on the other hand, occurs largely in regions of the world with intense sunlight and features a naturally higher level of epidermal melanin and treatment has to be modified to take these characteristics into account. The Quadra Q4 is only indicated for Skin Types I - IV.

Fitzpatrick Skin Classification Scale

Skin Type	Skin Color	Characteristics
1	<ul style="list-style-type: none"> • Caucasian • Very light complexion • Light eyes • Freckles • Usually blond or reddish hair color 	Always burns; never tans
2	<ul style="list-style-type: none"> • Caucasian • Light complexion • Light eyes • Occasional to frequent freckles • Blond, reddish, light brown hair color 	Usually burns; tans with difficulty
3	<ul style="list-style-type: none"> • Darker Caucasian; light Asian • Medium complexion • Light to dark eyes • Hair color usually brown to dark 	Sometimes mild burn; gradually tans
4	<ul style="list-style-type: none"> • Mediterranean; Asian; Hispanic • Darker complexion • Dark eyes • Dark brown to black hair color 	Rarely burns; tans with ease
5	<ul style="list-style-type: none"> • Middle Eastern; Latin American; light-skinned black; Indian • Dark complexion • Dark eyes • Dark brown to black hair color 	Very rarely burns; tans very easily
6	<ul style="list-style-type: none"> • Dark-skinned black • Black complexion • Black eyes • Black hair color 	Never burns; tans very easily

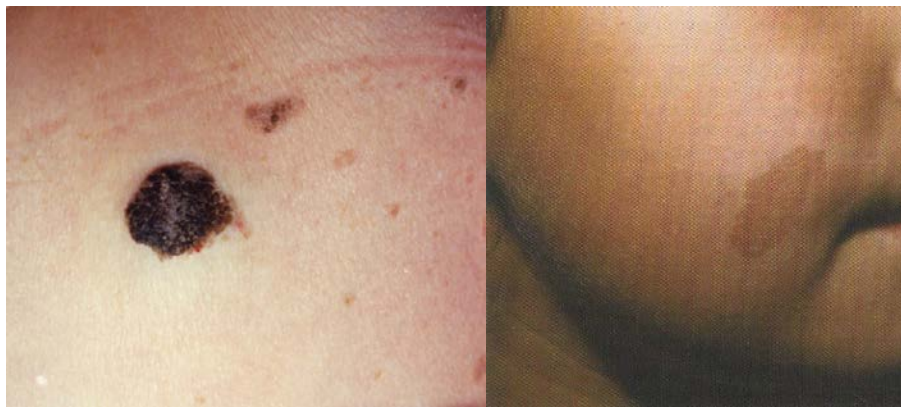


Visual representation of the Fitzpatrick Skin Classification Scale.

Conditions that Shouldn't Be Treated with IPL

Patients with certain skin conditions should not be treated with any IPL device. These conditions include raised benign melanocytic lesions such as:

- Naevi or moles
- Pigmented skin tags
- Seborrheic keratosis
- Favre-Racouchot (solar comedones)



Benign mole (left; courtesy of Dr. S. McCoy, Adelaide) **and nevus of Ito** (right).

These and similar skin lesions should be removed by ablation or thermal coagulation, not IPL.

In addition, patients with clearly identifiable medical conditions such as eczema, rosacea, port wine stain, birthmark, suspicious mole, nevus spilus, seborrheic dermatitis, warts, etc., should be referred to a dermatologist first for diagnosis and treatment.

Conditions that Should Be Treated Before Skin Therapy

Although specific macro vascular and pigmented conditions, such as pikiloderma of Civate, spider nevi, large telangiectasia, venus lakes, etc., are often the result of age and sun damage, they should be treated separately before undertaking a general treatment program of skin therapy.

SKIN CONDITIONS THAT CAN BE TREATED EFFECTIVELY WITH QUADRA Q4® SYSTEMS

Treatment with Quadra Q4® IPL has been effective in the following applications:

- Superficial epidermal pigmented lesions
- Vascular lesions
- Mild-to-moderate rhytides (static wrinkles)
- Mild-to-moderate acne

Superficial Epidermal Pigmented Lesions

Mottled pigmentation (eg, freckles, sun spots, etc.) can be treated effectively with IPL, especially in cases with high contrast in the pigmentation between the lesion and the surrounding skin.



Forearm epidermal pigmentation treated with Quadra Q4®, before and after a single treatment at one week and eight weeks.

Most successful IPL treatments of mottled blemishes are of epidermal pigmentation. However, combined treatments with topical antioxidants, polyphenols, or other pigment lightening creams or peels are often necessary for good results.

In the published literature, the evidence of success in post-inflammatory pigmented lesions with a deeper pigment component (in the papillary layer of the dermis and usually caused by chemical or physical trauma) is either anecdotal or based on single or small-number case studies. Recurrence in 4-6 months is also common.

Topical treatments used together with Quadra Q4® include: bleaching agents such as topical tretinoin and azelaic acid or chemical peels such as TCA, glycolic acid and Jessner's solution. Q-switched ruby and Nd:YAG lasers have also been reported as delivering moderately good results although with an increased incidence of post-inflammatory hyper-pigmentation.

Only with proper diagnosis (or a great deal of diagnostic experience and skill) can a user determine how much superficial epidermal pigment there is in a lesion and how much is the more difficult dermal pigmentation. The optimal successful endpoint of IPL pigment treatment is peri-lesional erythema (redness around the treated blemish) and/or some darkening of the pigmented area within 20 minutes. This is followed by further darkening over 24-48 hours and exfoliation of the darkened areas over the next 7-21 days leaving lightly hypopigmented areas which even-out to normal skin color during subsequent weeks. High-factor protective sunscreens, use of a parasol or sun shade and the wearing of hats and gloves (walking, driving, and gardening) are necessary to protect the sensitive 'new' skin.



Close-up photography showing before, immediately after and 7 days after Quadra Q4® treatment for facial pigmentation.



Age spots, before and after treatment.

Generally good clearance of superficial epidermal pigmentation in most skin types (1-4) including freckles (ephelides) and age spots (solar and senile lentigos) is achieved using Quadra Q4® devices. If there is high contrast between underlying skin color and the pigmented blemish, the treatment usually results in immediate darkening of the pigment with further darkening over the next 24-48 hrs.

If there is poor contrast between the pigmented blemish (eg, age spots) and normal skin, the pigment may not fully coagulate and may only lighten over the following 14-21 days. This means that high contrast blemishes may only require 1-2 treatments to resolve satisfactorily while low contrast blemishes may require 3-6 treatments. These coagulated epidermal blemishes usually slough-off (peel) in normal washing in 7-21 days depending on age, sex, and skin condition. Normally the underlying skin appears pink or hypopigmented, but the normal uniform skin color returns over subsequent weeks. Patients should be counseled not to pick at crusts to avoid scarring. It is also important to protect the skin from sun-exposure with sunscreen or gloves until the normal skin color returns.

Pressure technique. A number of recently published clinical studies confirm that a pressure technique (ie, pressing the glass transmission block firmly on the skin surface through the cooling gel) when treating epidermal pigmented blemishes will improve treatment results by compressing capillaries to express blood and thereby removing competitive absorption of light energy by oxyhemoglobin. The logic is easily demonstrated by applying thumb-pressure to the skin for a second and removing it, leaving a blanched thumb-print for a brief period before the peripheral blood supply returns the skin color to its normal mixture of melanin and blood.

Pigmentation in darker skin types. Treating skin types 3 and 4 can be problematic as the increased level of naturally occurring epidermal melanin competes with the

pigmented lesion (typically seborrheic keratoses, sun and age spots), which may lead to either no improvement or increased risk of hyper- or even hypo-pigmentation.

The therapeutic window for successful Quadra Q4® treatment of darker skin types will always be small and must be established carefully with test areas and steadily increased fluence to avoid hyperpigmentation.

Melasma. One of the commonly presenting cases for IPL and laser treatment among patients with darker skin types is melasma. Melasma is nine times more common in females than males and includes dermal hyperpigmentation, epidermal hyperpigmentation and mixed variants. Typically, melasma presents as light-to-dark brown symmetrical hyperpigmentation of the central face and cheeks, but it may also occur just on the bridge of nose, forehead, or upper lip.

The precise cause of melasma is unknown. Melasma is often common within the same family and a change in hormonal status may trigger it. Melasma is frequently associated with pregnancy (also known as chloasma or mask of pregnancy). Birth control pills may also cause melasma; however, hormone replacement therapy used after menopause has not been shown to cause the condition. Melasma is not associated with any internal diseases or organ malfunction.

Sunscreens are essential in the treatment of melasma. They should be broad spectrum, protecting against both UVA and UVB. An SPF 30+ or higher formulation should be selected.

If epidermal and mixed variants of melasma hyperpigmentation are present in the skin, it is likely that at least transient improvement (ie, lightening) will be achieved with Quadra Q4® treatment of the more superficial pigmentation however, it is unclear whether the effect on the dermal component will be lasting.

The successful endpoint of Quadra Q4® treatment of melasma may not include any immediate color change in such deeper-located pigment but only mild-to-moderate erythema at the margins of the pigmented lesions. Lightening may then occur over the succeeding weeks. High-factor protective sunscreens, use of a parasole, and wearing hats or gloves (when driving or gardening) are required to protect the sensitive treated skin areas. Multiple treatments (6-8) are usually required.

Improvement in melasma using intense pulsed light has been reported but results can vary from good clearance to only a modest lightening. It is therefore important to record good before and after photographs as patients often forget their appearance before treatment.



Moderate improvement in melasma following Quadra Q4® treatment. (Clinical photography courtesy of Dr. M. Vedamurthy, Chennai, India)

Post inflammatory hyperpigmentation / Café au lait macules. Pigmented blemishes with a deep epidermal or dermal component will be difficult to treat with any IPL. Even powerful and deeply penetrating wavelength lasers have had mixed results with this type of lesion. As these blemishes contain pigment at varying depths and concentrations, it is difficult for any operator to determine pigment location. Even the use of magnification, cross-polarized light and/or a Woods Lamp (UV diagnostic lamp) does not give a complete picture of pigment location.



An example of post-inflammatory hyperpigmentation with pigment at variable depths in the epidermis.

Vascular Lesions

Vascular lesions can be treated effectively with IPL. Good results after one treatment in Fitzpatrick Skin Types 1-3 can be achieved for diffuse redness (eg, acne rosacea) or telangiectatic matting of fine vessels. Small cherry angiomas (Campbell de Morgan spots) may also respond well to Quadra Q4® treatment.

Several studies have demonstrated IPL efficacy in the treatment of Class I and II Portwine stain birthmarks.



Facial thread veins/broken capillaries. (Photo courtesy of Dr S. McCoy, Adelaide.

Very large vessels (>1 mm) cannot be treated successfully by IPL (and require either sclerosing or treatment with a deeply penetrating Nd:YAG laser). Very fine vessels (<0.1 mm) are generally not cleared completely by IPL and require the use of a wavelength-specific laser such as the pulsed dye or KTP laser. Vessel size is notoriously difficult for the therapist to determine (even with a transparent mm ruler, skin scanner, magnification, or a Woods Lamp) and the hemoglobin target itself is moving as the blood flows along the vessels. The most likely range of vessel sizes for effective treatment with IPL is 0.1 mm – 0.3 mm.



General redness (erythema).

Typically, higher fluences and multi-pulsing are used to achieve vessel attenuation while allowing the epidermis to cool during inter-pulse delay times. Significant pre- and post-cooling of the skin is necessary.

Wrinkles

Fine lines found at the periphery of laughter lines may be improved with IPL treatment, but underlying muscles determine the skin and large wrinkles.

Collagen stimulation following light-based therapy results from damage to the microvasculature and the resultant release of inflammatory and cytokine mediators leading to collagen neogenesis. It has also been suggested that there may be some direct stimulation of certain cytochromes in the fibroblasts of the mitochondria to increase collagen production.

In any event, increased collagen production in the skin leading to the improvement in the appearance of fine lines and wrinkles takes weeks and months to develop. Patients must be prepared to see only a subtle improvement at best.

Laughter lines and frown lines are unlikely to show significant improvement as they are largely due to the underlying musculature and nose/cheek folds. Marionette lines are only likely to respond to ablative laser resurfacing techniques or the use of injectable collagen-based or hyaluronic acid fillers and/or Botox®.

The results of Quadra Q4® treatment of photoaging are most noticeable in the early improvement of pigmented and vascular dyschromia, but later-emerging subtle enhancements in skin tone and texture resulting in enhancements of the appearance of fine lines and wrinkles are also an important component in the overall treatment.



Before and after skin therapy plus botulinum toxin-right eye area. (Clinical photos courtesy of Dr Jesus. Valdez, Mexico)

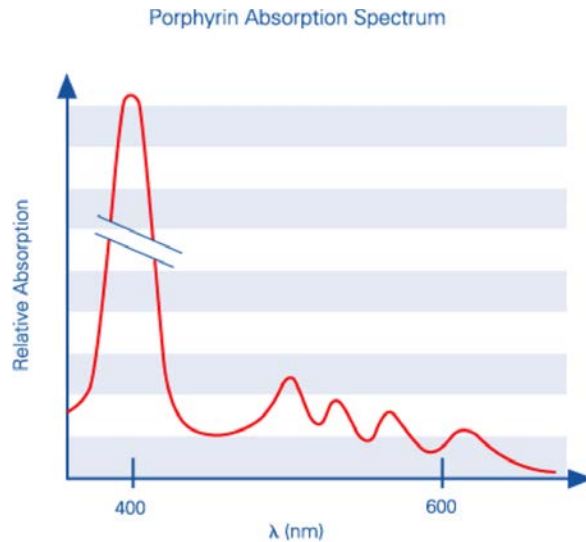


Before and after 5 Quadra Q4® treatments only every 2 weeks, showing shortening of peri-orbital wrinkles. (Clinical photos courtesy of Dr Jesus. Valdez, Mexico)

Acne

Although mild-to-moderate inflammatory acne is a medical condition, patients often present with the side effects of acne seeking skin therapy treatment. Broad-band IPL can relieve many of the symptoms of this type of acne and help in its management to avoid subsequent acne scarring.

Early inflammatory acne outbreaks are characterized by infection of the pilosebaceous duct by *Propionibacterium*. These bacteria are capable of spontaneously producing high concentrations of porphyrins, which are complex light-sensitive compounds that are normally used in the body as a component of hemoglobin. Porphyrins can absorb energy from light and transfer this energy to surrounding oxygen molecules. Subsequently, toxic oxygen species such as singlet oxygen and free radicals are thus formed that can destroy the acne bacteria. The improvement of acne in individuals after exposure to sunlight is explained by the photosensitivity of the *P. acnes* bacterium.



Typical UV-visible absorption spectrum of a porphyrin.

Clinical research has established protoporphyrin as the chromophore responsible for this photosensitivity. The absorption characteristics for protoporphyrin IX (PpIX) include significant absorption peaks at 508 nm, 542 nm, 577 nm and 635 nm (the Q-band), and several of these are covered by the high-energy output of broadband light (530 – 950 nm) and are sufficient to stimulate a beneficial response.

Longer laser wavelengths (630 nm, 670 nm, 810 nm) have also been successful in the treatment of acne, it is reasonable to assume that the more deeply penetrating longer wavelengths of broadband light also achieve greater penetration depth to include acne bacteria in the pilosebaceous duct.

With Quadra Q4®, appropriate long single or triple pulses ensure delivery of sufficient light energy to provide optimum effectiveness in stimulating the body's own immune system response to fight the bacteria. Typically 5-6 treatments, 1-2 weeks apart, are required. Quadra Q4® treatment of acne should be considered an additional acne management tool that will reduce excessive use of antibiotics. Acne and post-acne pigmentation in darker skin types may also be treated successfully using Quadra Q4®.

Photodynamic therapy. Q-band wavelengths (508 nm, 542 nm, 577 nm, and 635 nm) alone stimulate natural body porphyrins. A solution of 20% 5 amino-levulinic acid (5-ALA) stimulates fluorescence artificially. Methyl aminolevulinate and 1% non-occluded liposome-encapsulated 5-ALA also provide similar results but with lower post-treatment toxicity. (See the reference section at the end of this guide for further reading on acne treated with lasers and IPL.)



Acne before and 13 months after a single IPL+PDT treatment. (Clinical photos courtesy of Dr D. Fleming, Brisbane)

PRE-TREATMENT ASSESSMENT, DOCUMENTATION, AND COUNSELING

Patients considering any IPL indication should go through a pre-treatment assessment and documentation process. The process includes:

- Taking a complete medical history to elicit any special circumstances, photo-sensitizing medication or potential contraindications.
- Providing detailed information about the procedure and its risks and noting any special circumstances applicable to the patient.
- Asking the patient about each contraindication individually and recording each response. If the patient answers yes to any of the listed contraindications, document it in full on the consent form and follow the directions listed for that condition.
- Determining the patient's response to sun exposure, eye color, and ethnicity to confirm skin type (Fitzpatrick Scale). Consider performing a full skin analysis using appropriate skin evaluation tools (eg, Wood's Lamp, skin analyzers for hydration, lipid level, erythema, and melanin).
- Answering any questions the patient may have in full.
- Helping set realistic patient expectations about the outcome of the treatment.
- Obtaining informed consent. Review with the patient to ensure they have read it. Sign and date the General Medical History Questionnaire and Consent to Treatment Form. Counter-sign and date the consent form and give the patient a copy if requested.
- Performing a test treatment (for suitable patients) to establish predicted treatment parameters. A test area must be performed on or as near as possible to the area to be treated at least 3 to 7 days prior to any course of treatment (Skin Type 4 should be tested at least 2 weeks prior to treatment).
- Carefully recording all relevant information gathered.
- Setting a follow-up appointment to evaluate the test and begin treatment.
- Sending the patient home with instructions for pre-treatment skin care. (As found in back of manual).



Number of Treatments

Typically, skin therapy requires at least 6-8 treatments at 4 – 6 week intervals.

Normally, after a significant improvement in skin discoloration (vascular and pigmented blemishes) improvements in skin texture (which are much more subtle) take many weeks to develop fully.

Contraindications

Patients with any of the following contraindications should not be treated with IPL unless a letter from the patient's primary care physician is available confirming that the patient can be treated safely.

- Tanned skin (active tan) through sun exposure or tanning bed use in the previous 30 days (because of increased risk of hyperpigmentation)
- Waxing, plucking, sugaring, or threading depilation treatment of the area in the previous 4-6 weeks (because the follicle has been removed)
- Hypopigmentation (eg, vitiligo)
- Any inflammatory skin condition (eg, eczema, active Herpes Simplex, etc. at the treatment site because it may aggravate the condition)
- Presence of cancer or current cancer drug therapy
- History of keloid scarring (because any IPL burn may produce a keloid scar)
- Epilepsy (because repeated consecutive flashes may induce seizures)
- Use of St. John's Wort (herbal remedy) in the past 3 months for depression (due to photosensitivity)

- Use of oral isotretinoin, accutane, or tretinoin in the previous 3-6 months for the treatment of acne or other dermatological conditions
- Pregnancy; until periods return and breastfeeding is stopped (because hormonal imbalance may reduce treatment effectiveness)
- Use of drugs for diabetes (due to possible photosensitivity and poor wound healing)
- Use of anti-coagulant drugs (eg, for heart disease)
- Presence of a pacemaker unless the pacemaker manufacturer confirms in writing that it is safe to treat the patient
- Use of any topical medication, perfumes, deodorants, sun block, essential oils, or other skin lotions (which could cause photosensitivity)
- Presence of surgical metal pins or plates under the tissue to be treated
- Age under 18 years if the establishment is not registered to treat children or if parental permission is withheld

A doctor's letter should also be obtained before treating patients who are reportedly using quinidine, any anti-psychotic medication, or large combinations of cardiac/diuretic drug or topical steroid creams in the area to be treated, general anesthesia in the last 3 months, local anesthetic treated areas in the past month, and any cases in which you are uncertain about any reported medical condition or medication.

Treat with caution and obtain a doctor's letter if you are uncertain about anyone who has:

- Fake tan
- Allergies
- Hormone abnormalities such as polycystic ovarian syndrome
- Cold sores in the treatment area
- Previous depilation treatments
- Reported HIV infection or hepatitis

Pre-treatment Counseling

Patients must follow a strict routine of sunscreen use and other good skin care practices for 2-4 weeks before IPL treatment. If the patient won't adopt good skin care

practices, the outcome of treatment will be compromised and short-lived at best. Therefore, effective counseling is of paramount importance.

Patients should be counseled and provided with the following take-home instructions:

- Don't expose skin to UV light (sun exposure or the use of tanning beds) or self tan for at least 4 weeks before and/or between IPL treatments.
- Don't depilate with waxing, plucking, or threading (shaving or depilatory creams are acceptable) before and/or between IPL treatments.
- Don't use bleaching creams or perfumed products (e.g. aromatherapy oils) for 24-48 hrs before treatment sessions.
- Avoid swimming in strong chlorinated water immediately before an IPL treatment session.
- Avoid exfoliating, microdermabrasion, or peels for 1 week before treatment sessions.
- Keep the area to be treated clean and dry.
- Hydrate the body by drinking plenty of water.
- Protect the skin from sun exposure with suitable clothing and use of sunscreen SPF 30+ before first treatment and between subsequent treatment sessions.

Treatment programs will often include a preliminary 2-4 week course of fruit-acid peels or microdermabrasion as well as sun protection, vitamin/moisturizing, and/or skin lightening creams depending on the degree of skin damage.

Hot and humid weather conditions can aggravate skin in the period immediately before treatment.

THE THERAPEUTIC WINDOW – CHOOSING TREATMENT PARAMETERS

IPL systems work by heating target tissues sufficiently to damage or destroy them. The overall objective is to find the optimal therapeutic window where the energy absorbed is sufficient to damage the target without causing significant damage to surrounding tissue.

Treatment Parameters

Quadra Q4® systems have two primary parameters operators can adjust to determine the therapeutic window:

- **Fluence** is a measurement of energy density; in other words, it is the amount of energy delivered (in Joules) per square centimeter. Higher fluence means more energy delivered to the tissue.
- **Pulse duration** is the length of time over which the pulse of energy is delivered. Pulse duration is usually measured in milliseconds (msec). At a given fluence, long pulse durations deliver energy more slowly; short pulse durations deliver energy more quickly.

The appropriate fluence and pulse duration depend on the patient's skin type (Fitzpatrick Scale) and the condition being treated. In general, darker skin should be treated with longer pulse durations.

Treatment Programs

Preset treatment programs available with a range of available pulse lengths and energy levels is designed to suit individual patient needs.

Treatment Parameters Are Guidelines Only

The parameters listed in this table and throughout this treatment guide are intended as guidelines only. The use of test patches is strongly advised as patient-to-patient variation may affect the treatment outcome and the possible incidence of side effects.

How to Choose Treatment Parameters – General Guidelines

To choose the initial treatment parameters:

- Exclude all unsuitable subjects (eg, those with pre-existing medical conditions such as cancer, those taking contraindicated drugs, those with suntans, etc.)

- Determine the subject's underlying Fitzpatrick Skin Type AND the skin type of the area to be treated. A subject's general Fitzpatrick Skin Type is assessed on a body area not normally exposed to the sun. The area to be treated may appear different from the underlying skin type due to sun damage, age, or specific local skin tone that must be taken into account.
- Use the list of treatment program options in the User Manual for the system being used to identify starting programs.
- Undertake test areas at several increasing energy density levels until a suitable starting energy level is determined.
- The starting energy is that which will produce a heat response in the skin, which feels hot or like a prickle to the patient but is tolerable. In addition, some redness may develop in the treatment area within a few minutes. Should a strong histamine-like (allergic) reaction occur with swelling immediately around the hair follicles with general raw redness around the area, the energy level is too high.
- Normally, the skin will feel warm temporarily after treatment, and any redness will disappear within minutes or a few hours.

Typical Treatment Parameters – Pigmented Component

Pigmented blemishes are the first target of skin therapy as epidermal pigment will at least partially block the penetration of deeper penetrating light energy intended to treat the vascular component, stimulate collagen production, or to tackle acne bacteria in the deeper lying sebaceous ducts.

Light skin

Clinical data have shown that for lighter skin types (Fitzpatrick Skin Types 1-3) single pulses of 20-25 msec (Programs 3-4) with energy ranges of 14-17 J/cm² have proven to be effective to treat mottled pigmentation.

Treatment Ranges for Pigmented Blemishes on Light Skin

PIGMENTED LESIONS					
SKIN TYPE	PULSE	TIME-ON (msec)	TIME-OFF (msec)	ENERGY RANGE (J/cm ²)	PROGRAM
I	Single	20	13.0 to 15.0 J/cm ²	A
	Single	25	13.0 to 17.0 J/cm ²	B
II	Single	20	13.0 to 15.0 J/cm ²	A
	Single	25	13.0 to 17.0 J/cm ²	B
	Single	30	12.0 to 19.0 J/cm ²	C
III	Single	30	11.0 to 16.0 J/cm ²	A
	Single	40	12.0 to 15.0 J/cm ²	B
	Multiple	15	20	12.0 to 18.0 J/cm ²	C

Treatment Parameters for Pigmented Blemishes on Light Skin

Fitzpatrick Skin Type	Pigment Color	Joules/cm ²
1	Light	14-17
1	Medium	14-17
1	Dark	14-17
2	Light	14-17
2	Medium	14-17
2	Dark	14-17
3	Light	14-17
3	Medium	14-17
3	Dark	14-17
3	Light	14-17
3	Medium	14-17
3	Dark	14-17

Dark skin

Darker skin can react to light treatment by hyper- or hypo-pigmenting so it is best treated with a longer pulse duration to spread out the energy and make the treatment safer and more comfortable. This means using a multi-pulsing program.

Treatment Ranges for Pigmented Blemishes on Dark Skin

PIGMENTED LESIONS					
SKIN TYPE	PULSE	TIME-ON (msec)	TIME-OFF (msec)	ENERGY RANGE (J/cm ²)	PROGRAM
IV	Multiple	15	20	12.0 to 18.0 J/cm ²	A
	Multiple	20	25	12.0 to 18.0 J/cm ²	B

Treatment Parameters for Pigmented Blemishes on Dark Skin

Fitzpatrick Skin Type	Pigment Color	Joules/cm ²
3b	Dark	14-17
4a	Light	13-17
4a	Medium	13-17
4a	Dark	12-17
4b	Light	13-16
4b	Medium	12-16
4b	Dark	12-16

Typical Treatment Parameters – Vascular Component

After superficial pigmented dischromia has been treated, vascular elements can be more easily reached by deeper penetrating wavelengths of light. Vascular dischromia and vascular blemishes are common in lighter skin types (Fitzpatrick Skin Types 1-3) and are much less common in darker skin.

When treating vascular abnormalities with IPL, the skin color is more important than the vessel size (which is notoriously difficult to determine). Darker skin can react to light treatment by hyper- or hypo-pigmenting so it is best treated with a longer pulse duration to spread out the energy and make the treatment safer. This means using a longer pulse or multi-pulsing if available. Multi-pulsing programs have the added advantage of having gaps between the pulses that allow the epidermis to cool. The total amount of energy delivered should remain the same.

Since many vascular blemishes are localized areas of vascularity (eg, cherry angiomas and spider nevi), these are best isolated using white card cut-out skin masks to protect adjacent skin. Treatment is usually achieved with a single high-energy shot as the skin over the blemish will blanch making pulse stacking inappropriate.

Light skin

Clinical data have shown that for lighter skin types (Fitzpatrick Skin Types 1-3) single pulses of 20-25 msec with energy ranges of 14-17 J/cm² have proven to be effective to treat mottled pigmentation.

Treatment Ranges for Vascular Blemishes on Light Skin

VASCULAR LESIONS					
SKIN TYPE	PULSE	TIME-ON (msec)	TIME-OFF (msec)	ENERGY RANGE (J/cm ²)	PROGRAM
I	Single	20	12.0 to 15.0 J/cm ²	A
	Single	25	13.0 to 17.0 J/cm ²	B
II	Single	25	13.0 to 17.0 J/cm ²	A
	Single	30	13.0 to 18.0 J/cm ²	B
III	Single	25	12.0 to 15.0 J/cm ²	A
	Multiple	10	20	12.0 to 18.0 J/cm ²	B

Treatment Parameters for Vascular Blemishes on Light Skin

Fitzpatrick Skin Type	Blood Vessel Size	Joules/cm ²
1	Thin	16-17
1	Medium	16-17
1	Thick	16-17
2	Thin	16-18
2	Medium	16-18
2	Thick	16-18
3	Thin	16-18
3	Medium	16-18
3	Thick	16-18

Dark skin

A smaller range of parameters is suggested for vascular blemishes in darker skin because they are much less common.

Treatment Ranges for Vascular Blemishes on Dark Skin

VASCULAR LESIONS					
SKIN TYPE	PULSE	TIME-ON (msec)	TIME-OFF (msec)	ENERGY RANGE (J/cm ²)	PROGRAM
IV	Multiple	10	20	11.0 to 14.0 J/cm ²	A
	Multiple	20	25	11.0 to 15.0 J/cm ²	B

Treatment Parameters for Vascular Blemishes on Dark Skin

Fitzpatrick Skin Type	Blood Vessel Size	Joules/cm ²
4	Thin	16-18
4	Medium	16-18
4	Thick	16-18

Typical Treatment Parameters – Wrinkles

Normally, skin therapy treatments will follow in sequence: pigmented, then vascular elements. In so doing, the process of collagen stimulation for wrinkle reduction will already be underway. When treating patients for skin texture improvement only, it is only necessary to repeat treatments using the same settings as for fine blood vessels.



Skin therapy including reduced pigmentary dischromia and wrinkles showing a subtle improvement post-treatment.

Typical Treatment Parameters – Acne

IPL treatment of acne is intended as an acne management option to allow relief from continued use of antibiotics or where isotretinoin therapy is contraindicated. The broadband light produced by Quadra Q4® includes light energy at all four peaks of absorption by protoporphyrin 9 (PpIX) in the Q-band of wavelengths. IPL does not cure acne but assists the production of natural porphyrins to fight the acne bacteria by producing singlet oxygen which destroys the bacteria in situ.

Unlike blue light acne therapy where wavelengths used only penetrate the uppermost layers of the skin, the longer wavelengths of Quadra Q4® will penetrate to the sebaceous duct and sebaceous gland where the bacteria propagates.

The treatment of acne is similar for most skin types. The objective is to deliver only moderate energy over a long pulse (or multiple pulses for very dark skin) to stimulate protoporphyrin 9 production. Clinical experience indicates that a total of 30 J/cm² is required for optimal stimulation of PpIX and this can be achieved with multiple passes (if necessary cooling between passes).

ACNE LESIONS					
SKIN TYPE	PULSE	TIME-ON (msec)	TIME-OFF (msec)	ENERGY RANGE (J/cm ²)	PROGRAM
I	Multiple	20	25	8.0 to 12.0 J/cm ²	A
II	Multiple	20	25	8.0 to 12.0 J/cm ²	A
III	Multiple	20	25	8.0 to 11.0 J/cm ²	A
IV	Multiple	20	25	8.0 to 10.0 J/cm ²	A

Note: If acne is inflamed and sensitive, use a lower fluence.

Usually 5-8 treatments are required at 2-3 week intervals to provide relief from mild to moderate inflammatory acne.

TEST TREATMENTS

Testing is required to establish the best starting IPL energy level and to reduce the risk of unwanted side effects from over-treatment.

Test areas should be evaluated on or near the treatment site using the lowest recommended fluence for the skin type, increasing the fluence if necessary until the patient feels a ping, heat, or mild discomfort (according to the individual's pain tolerance). Testing should be ceased immediately if any side effects occur.

When performing the first test area on a new patient you have only 1-3 chances to establish the energy level. For larger areas such as facial areas, décolleté, forearms, etc, it is easy to establish a test area. However, for small areas such as specific pigmented blemishes, spider nevi, etc, only one shot can be made. In that case, it should be the best estimated shot.

On Lighter Skin (Types 1-3), use this sequence:

- One shot at the lowest energy level predicted by skin type
- One shot 1 J/cm² above the lowest predicted energy level
- One shot 2 J/cm² higher than the lowest predicted energy level to evaluate tissue response

Example: According to "Typical Treatment Parameters for Pigmented Blemishes" (section above) a Skin Type 2 patient with a medium pigmented blemish would need Program 4 predicting a start energy of 14.0 J/cm² so, you choose energy levels: 14.0 J/cm², 15.0 J/cm² and 16.0 J/cm² for the test area.

On Darker Skin (Type 4), use this sequence:

- One shot 0.5 J/cm² below the lowest energy level predicted by skin type
- One shot at the lowest energy level predicted by skin type
- One shot 0.5 J/cm² above than the lowest predicted energy level to evaluate tissue response

The choice to go higher with the second and third test shots will be based upon a number of factors including:

- Did the patient experience the sensation of a ping or heat?
- Is the area in question tanned?

- What has been the patient's response to treatment on other body areas (for patients who have been treated previously)?

Additional Considerations with Testing

The following points should also be observed when performing testing:

- Testing should be carried out on all patients before a full treatment.
- The area to be treated needs to be clean, free of cosmetics and creams.
- The aim of test shots is to determine the most effective fluence settings for the patient skin type and size of area without causing any adverse reactions.
- Only a small area (3 or 4 shots in darker skin types, a few more in fair skinned patients) should be treated. If possible this should be in an area that is not too obvious but representative of the proposed treatment area.
- Usually 3 settings are required.
- Patient, operator, and anyone else in the treatment room must wear appropriate IPL safety eye-wear before treatment commences.
- The applicator's contact crystal (light guide) must be held flat on the surface being treated with the contact crystal touching (but not compressing) the skin tissue.
- Test area treatment should be ceased immediately if side effects occur.
- Patients must be given clear instructions on post Quadra Q4® skin care, in particular sun avoidance and avoidance of injury to the skin.

Post-testing Instructions

After testing, patients should be given clear instructions on post-treatment skin care, in particular sun avoidance and avoidance of injury to the skin.

Recording

Details of the test treatment performed should be recorded in the patient's record, including:

- Treatment area
- Quadra Q4® type
- Program
- Pulse width
- Fluence
- Number of shots

The entry should be signed, timed, and dated. The Quadra Q4® treatment register (log book) must be completed recording treatment in the same way.

Follow-up

Patients with skin types 1-3 should return in 3-7 days for final evaluation and treatment. Patients with skin type 4 should wait for 14 days to be sure no late emerging side effects occur.

PERFORMING TREATMENT WITH THE QUADRA Q4®

Treatment Room Set-up Check List

- Make sure any required IPL hazard warning notices are in place at entrances.
- Close window blinds and cover any mirror surfaces to reduce reflection hazard.
- Check fire extinguisher location (suitable for electrical fires).
- Make sure all Local Rules, Treatment Protocols, and patient documentation is available for reference.
- Check availability of all required supplies: couch roll, razors, gloves, tissues, refrigerated clear ultrasound gel, wooden spatulas, skin cooling gel packs, white marker pencils, wipes, post-treatment skin calming lotion such as derma renewal gel.
- Close the entrance door to prevent unauthorized entry and to protect the privacy and dignity of the patient by suitable means e.g. use towels during intimate area treatment, eye safety, etc.
- Check ventilation (extractor fan, air conditioning, etc).

[Contact your Laser Protection Advisor for further assistance on safety issues.]

Patient Preparation Check List

- Ensure all patient questionnaires (general medical history) and consent forms are completed and signed by the patient and the operator. Consent Forms should ideally be signed each time before an IPL treatment.
- Ask patient to remove all jewelry, make up, deodorant, etc in the treatment area.
- The area should be cleaned with water only; any creams may leave a residue, which could affect the efficiency of the treatment.
- Mark the extent of the skin area to be treated with a white eye liner pencil.
- In the area to be treated, 'white-out' small lesions, moles, etc. and cover any sensitive areas (tattoos, lips, etc) with cut-out adhesive white labels to protect them from absorbing light energy.



Cover sensitive areas.

- Give the patient and any assistant or observer present in the room suitable protective safety glasses (eg, broadband shade 5).
- Disposable adhesive ocular shields should be placed over the eyes of the patient if treating facial areas near to the eyes where safety glasses would allow light penetration under the rim. Ocular shields are available for purchase through DermaMed Solutions Item #31-9300 IPL Eye Shields - \$75.00 for a 50 pack.
- Set up the Quadra Q4® program and predicted energy setting (based on skin type, size of vessels, location of pigment, etc).
- Cool the area with ice (recommended) or if you will be using a cold pack change frequently to ensure temperature is effective enough to cool the skin.



Cold packs – change frequently during treatment

If Using Gel

- If you choose to use **clear** gel, either dispense sufficient ultrasound gel into a small container or deposit blobs of clear ultrasound gel directly onto the skin from the dispenser bottle and using a clean wooden spatula, spread a layer of gel over the skin approximately 2 – 3 mm thick. The gel must be kept cold (but not frozen) in a fridge.



Mixing and applying ultrasound gel.

- Do not overwork the gel on the skin, as it will heat up. Do not reuse the gel (infection risk).
- The operator must wear suitable safety glasses during Quadra Q4® treatment and blink during the flash to limit light entering the operator's eyes and thereby improve visibility of the treatment area after the flash.

Using the Quadra Q4® Applicator

- Place the light guide (crystal) flat to the skin.
- The light guide should NOT be pressed into the gel firmly but should float just on the skin surface (to avoid compressing the fine blood vessels).



The light guide should be flat against the skin but not pressed into the ultrasound gel; allow it to contact the skin only lightly.

- Place the treatment spots directly next to one another with minimal overlap.
- Make sure there are no gaps between the treatment spots.

Beware If:

- The light guide overlaps a previous treated area (over-treatment risk).
- The light guide treats skin with hair (may permanently remove hair), over tattoos or tanned skin (over-treatment risk).
- The light guide leans to one side (insufficient energy delivered to the target).
- Part of the light guide is not in contact with the skin (insufficient energy delivered to the target).

After Using the Quadra Q4® Applicator

- Ensure that the skin area is completely treated (no obvious gaps).
- Put the Quadra Q4® into STANDBY.
- Remove safety eyewear.
- If using gel, once the area has been treated, remove the ultrasound gel using a spatula and then tissues.
- Check the area for redness and record in patient notes.
- Apply a cooling gel pack to any sensitive areas if required.
- Apply a calming lotion such as dmSkincare's derma renewal gel or D20 solution.
- Always use a sunscreen of SPF 30 or higher. We recommend dmSkincare's daily eclipse SPF 30 physical sunscreen.
- Complete the patient treatment notes and record any unusual occurrence.
- Provide post-treatment advice and take-home information sheet (found at the end of the manual).
- Book your patient's next treatment.
- Switch-off the Quadra Q4®, clean the crystal treatment guide with a moist tissue or an isopropyl wipe and prepare the room for the next patient.

PRACTICAL TIPS BY BODY AREA

All areas of the body can be treated except inside the orbit of the eye (eg, underneath the eyebrows) or on mucous membranes (eg, inside nostrils, ears, etc.).

Facial Area

For whole-face therapy, make a line of treatment spots down the face along the jaw line and add rows above as necessary where skin therapy is needed until all required cheek areas are covered. Then repeat the process on the forehead and chin areas.

Pay particular attention to the following points:

- Avoid accidentally treating the scalp hair by using a white hair band.
- Use a piece of white Fibrella cloth, white card, or white adhesive label to shield areas if required.

Upper lip

When treating the upper lip (moustache area), remember that the central area below the nostrils (nasal alia) is particularly sensitive. Mostly the upper lip area can be treated with 2-3 shots (depending on spot size).

Following multiple treatments of the upper lip (moustache area) resulting in increased collagen in the skin tissue, it may be possible to observe an improvement in the lip line (Cupid's Bow) with more lip vermilion newly exposed to give a fuller look to the lip.

- Remember to remove all lip gloss, lip salve, or make up.
- Apply white pencil to mask any semi permanent lip liner on the lip margin.
- Shield the lips with damp cotton wool or white adhesive label before treating.
- Use gel sparingly as it can easily obstruct the nostrils, which is unpleasant for the patient.

To identify whether pigmentation is epidermal (eg, freckles, age spots, epidermal melasma, etc.) or dermal (post-inflammatory hyperpigmentation, dermal melasma, etc.), the skin in the area to be treated can be stretched between the fingers. If the pigmentation lightens significantly on stretching, the pigmentation is mostly epidermal. If there is little color change, the pigmentation is deeper.

Treatment of poikiloderma of Civatte (mostly found on the lateral lower third of the neck) should be undertaken carefully starting with lower fluences as the neck skin in this area is particularly delicate.

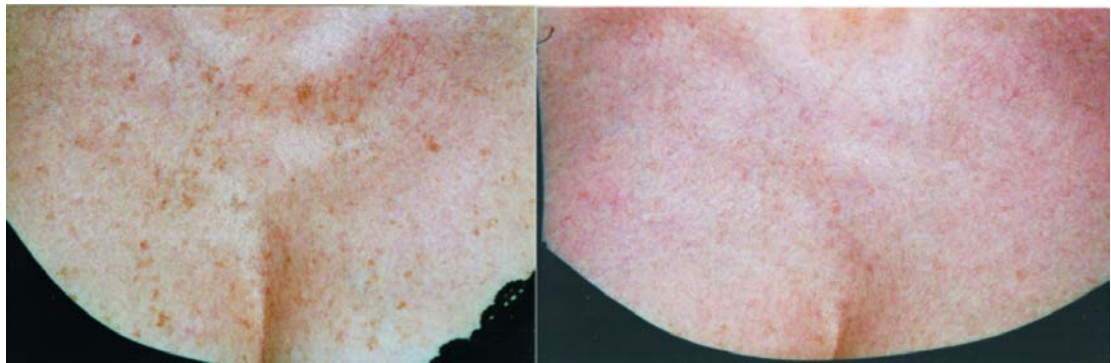
Remember, fine lines and wrinkles will require multiple treatments and only improve fully over several months.

Facial treatments should be kept outside the orbital canthus (outer bony rim of the eye socket).

Individual small pigmented blemishes may be treated easily using a paper mask made from a small sheet of white folded paper (or white self-adhesive label) with the corner cut-off.

Décolleté

The upper chest in female patients (between and above the breasts) can be treated taking care with energy settings as the chest bone (sternum) is close to the body surface in this area and may be sensitive. Moreover, the décolleté is often heavily tanned and sun-damaged and does not heal easily if over-treated. Therefore, treat with caution, starting with lower fluence levels.



Nipple Pigment

Post-breast feeding, some women experience significant darkening of the areola and seek skin lightening treatment. Care should be taken when treating this sensitive intimate area.

Forearms

The forearms may be covered with mottled pigmentation (freckles) from sun exposure. Care should be taken to eliminate active tan in advance of Quadra Q4® treatment (particularly with the driving-side arm) through the use of high-factor sun lotion for at least two weeks before treatment commences.

- Mark out the sub-divided area to be treated using a white pencil.
- It is preferable to treat around sections of the arm rather than along the length of the arm. If required you can treat around the elbow or wrist.



HANDLING TREATMENT-RELATED PROBLEMS

After treatment, the skin may be red and feel warm. These normal transient changes should disappear within minutes or a few hours – 24 hours at the most. More severe treatment-related side effects may also occur with overtreatment. They may appear immediately or shortly post treatment (0 – 24 hrs); in rare cases, late emerging side effects (typically 24 – 72 hrs) may occur.

Management of Treatment-related Side Effects

Timing	Side Effect	Management
Immediate	Excessive pain	<ul style="list-style-type: none"> Stop treatment Cool the skin and moisturize Review after 24 hr and restart treatments at lower fluence
	Excessive persistent heat and redness	<ul style="list-style-type: none"> Normally resolves in 24 hrs If a burn-associated reaction is expected, a one-time application of a local steroid ointment may be indicated (medical prescription) Cool the area regularly using cloth-wrapped ice packs or cooling gel Advise the patient to use pure aloe vera and skin protection as for a mild sunburn until the sensation disappears If the reaction persists, have the patient consult a doctor
	Damage to natural skin texture (crust, blister, burn)	<ul style="list-style-type: none"> Cool area thoroughly for pain relief If already blistered or burn, recommend burn sprays and creams from the pharmacy Have the patient consult a doctor Follow the adverse incident procedure
	Edema, fragile skin, purpura	<ul style="list-style-type: none"> Cool area throughout for pain relief Have the patient consult a doctor Follow the adverse incident procedure
Late Emerging	Change in pigmentation (hyper- and hypo-pigmentation)	<ul style="list-style-type: none"> Advise the patient to moisturize and protect the skin from sun exposure and further injury Instruct the patient to leave the skin alone and not to rub it Have the patient consult a doctor if the condition persists
	Excessive hypo-pigmentation or scarring	<ul style="list-style-type: none"> Advise the patient to avoid skin exposure and use a sun block for six months Have the patient consult a doctor Follow the adverse incident procedure
	Prolonged itching in the treatment area	<ul style="list-style-type: none"> Advise the patient to keep the area cool and to apply pure aloe vera gel Have the patient consult a doctor if the itching persists
	Ineffective skin therapy	<ul style="list-style-type: none"> Reassess the patient's history and increase fluence depending on skin reaction

Only retreat areas that have experienced treatment-related side effects when the areas have healed fully and only after testing is repeated.

Adverse Incident Procedure

If anything goes wrong during treatment, such as serious skin reaction, excessive pain, patient taken ill, etc., treatment should be stopped immediately. Appropriate information should be recorded in the patient notes, including the extent of the partially completed treatment and details of any untoward side effects.

Serious skin damage should be referred immediately to the Emergency Department of the nearest hospital or via the patient's doctor to an appropriate medical specialist if necessary.

In all cases of eye damage or suspected eye over-exposure to the Quadra Q4® flash, an immediate eye test by an ophthalmic specialist should be arranged through a doctor or the Emergency Department of the nearest hospital.

Adverse Event Reporting

Adverse event reporting requirements vary by country. Serious adverse events are those involving death, life-threatening injury, hospitalization, disability, or congenital abnormality as well as those that require intervention to prevent permanent impairment or damage. In general, serious adverse events must be reported to regulatory authorities in a timely manner.

For example, the registered person in England and Wales is required to notify the Healthcare Commission within 24 hours of any death or serious injury to a patient as a consequence of treatment, either in the establishment or within seven days of treatment. Similarly, any allegation of misconduct resulting in actual or potential harm to a patient by the registered person or any person employed by the registered person must also be reported to the Healthcare Commission (Regulation 28). Any such injury following laser or IPL treatment should also be reported to the Laser protection Adviser.

Procedure in the Event of Equipment Failure

In the event of equipment failure, treatment should be abandoned immediately and the emergency stop button pressed and/or the key removed to prevent any risk of further emission of energy. Remove the mains plug.

Appropriate details should be recorded in the patient notes, including the extent of the partially completed treatment and details of any untoward side effects.

The Quadra Q4® factory service engineer should be informed immediately of the circumstances of the equipment failure and an Incident Report completed.

POST-IPL TREATMENT INSTRUCTIONS

Patients should be instructed in post-treatment skin care and should be provided with written take-home instructions recommending they:

- Don't expose skin to UV light (sun exposure or the use of tanning beds) or self tan for at least 2 weeks.
- Don't shave for 48-72 hrs after facial treatment.
- Don't use bleaching creams, or perfumed products for 24-48 hrs.
- Don't pick or scratch the treated area.
- Avoid rough handling of the area treated.
- Leave any skin responses alone (they are temporary and will subside).
- Avoid very hot baths / showers / steam baths / sauna for 1 week.
- Avoid swimming in strong chlorinated water for 1 week.
- Avoid exfoliating or peels for 1 week.
- Avoid rough sports for 24-48 hrs.
- Avoid wearing tight clothing.
- Keep the area clean and dry.
- Hydrate the body by drinking plenty of water/
- Use sunscreen (min SPF 30+) and consider using protective cotton gloves for driving, a hat to protect facial areas.

Immediately post-treatment, effective skin cooling of the epidermis can be helpful. The use of ice or cooling gel packs, aloe vera gel, etc., can improve patient comfort and reduce post-operative erythema.

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R. Rox Anderson, et al reported moderate improvement in acne in an eleven patient study with a moderate decrease in sebum measurements for at least one month post-treatment using a 532nm laser. *Lasers in Medical Science Abstracts, Joint International Laser Conference, 21-23 September 2003, Edinburgh, Scotland. Vol 18, Supplement 1 2003.*

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