# Quadra Q4<sup>™</sup>

# Platinum Series User Manual

# QUADRA Q4™ PLATINUM

# INTENSE PULSED LIGHT SYSTEM



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# 1. Safety Warnings

# **CAUTION**

Use of controls or adjustments, or performance of procedures other than those specified herein may result in hazardous optical radiation exposure.

No attempt should be made to operate this equipment until the User Manual has been read and fully understood. In addition, a clear understanding of the biological effects of the interaction of light with tissue should be prerequisite to use of this equipment.

When not in use, the equipment should be protected from unqualified use by removal of the key from the key-switch.

IT IS STRONGLY RECOMMENDED THAT ALL OPERATORS OF THIS EQUIPMENT ATTEND THE SUPPLIERS APPROVED TRAINING COURSE PRIOR TO USE.

### 1.1 Optical Safety

Suitable protective eyewear is required to be used during operation of the system. In addition, it is the responsibility of the User to ensure that the client is supplied with suitable protective eyewear during treatment.

The optical hazard warning label (Figure 1) is located on the side of the Quadra Q4 Platinum Unit.



Figure 1: Optical Hazard Warning Label

# 1.2 Optical Safety – Label Placement

(Figure 2) shows the placement on the Quadra Q4 Platinum of the warning labels.



Figure 2: Warning Label Placement

#### 1.4 Safety Warnings - Electrical Safety

ONLY MANUFACTURER RECOMMENDED ACCESSORIES SHOULD BE USED WITH THE SYSTEM. NON STANDARD COMPONENTS AND ACCESSORIES MAY DEGRADE PERFORMANCE OR CREATE SAFETY HAZARDS.

The manufacturer of the Quadra Q4 Platinum has made every effort to provide as many safety features as possible to assure personal safety. To be effective, these safety features have to be utilized and not ignored.

<u>HIGH VOLTAGE WARNING – NO USER SERVICABLE PARTS INSIDE THE QUADRA Q4 PLATINUM</u> UNIT. NO ATTEMPT SHOULD BE MADE TO REMOVE THE OUTER COVER.

Electrical hazards within the Quadra Q4 Platinum system are clearly indicated with the hazard warning label shown in (Figure 3).



Figure 3: Electrical Hazard Warning Labels (Example)

A personal injury hazard is accessible as you read the marking. Do not work near or touch any related electrical connections. These areas marked may have line voltage or very high voltages exposed.

This product is grounded through the grounding conductor of the power cord. To avoid electrical shock, plug the power cord into a properly wired receptacle (including ground) before using this product. A protective ground connection by way of the grounding in the power cord is essential for safe operation.

To avoid fire hazards, always replace fuses with ceramic types complying with IEC 127.

The use of flammable anaesthetics or oxidizing gases such as nitrous oxide and oxygen should be avoided. Some materials, for example cotton and wool, when saturated with oxygen, may be ignited by high temperatures produced in NORMAL USE of the equipment. The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the equipment is used.

The electrical requirements for the Quadra Q4 Platinum system are clearly indicated on the Product Identification label located on the rear of the equipment. The product is also CE marked on the rear. (Figure 4).

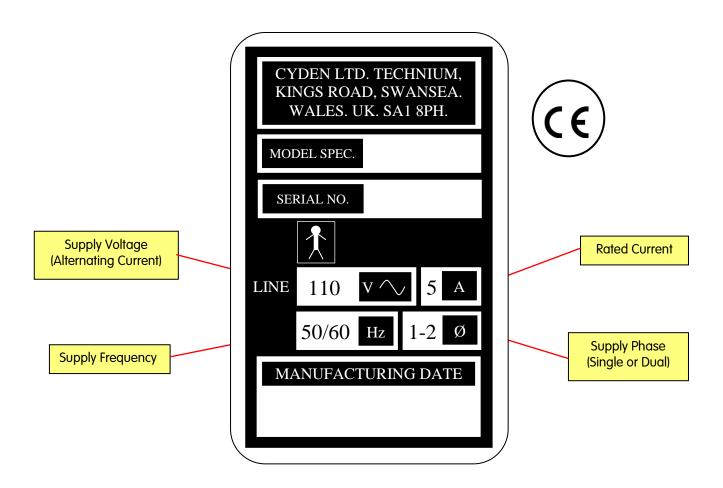


Figure 4: Product Identification Labels

# Use of the Top Tray

The Quadra Q4 Platinum top tray can be used temporarily for storing equipment e.g. glasses. However, no liquids e.g. coffee cups, should be placed in this area.

## 2. Product Description

The Quadra Q4 Platinum system is an intense pulsed light device which produces non-coherent optical output in the 530-1200nm region of the spectrum. The optical output is produced by the electrical excitation of xenon flashlamps, the intensity and duration of the optical pulse being governed by the flashlamp drive current. The energy is delivered directly to the treatment site from the flashlamps via a suitable cut-off filter which removes unwanted wavelengths from the output spectra.

The Quadra Q4 Platinum system is a self-contained unit consisting of the following functional sub-systems.

- User interface and control system;
- Flashlamp driver circuit;
- Umbilical lead from base unit to handpiece;
- Handpiece.

Mains electricity and an optional remote interlock are the only external connections.



Figure 5: Quadra Q4 Platinum Unit

The Quadra Q4 Platinum represents the state of the art in medical equipment technology. This equipment offers significant advantages over other systems:

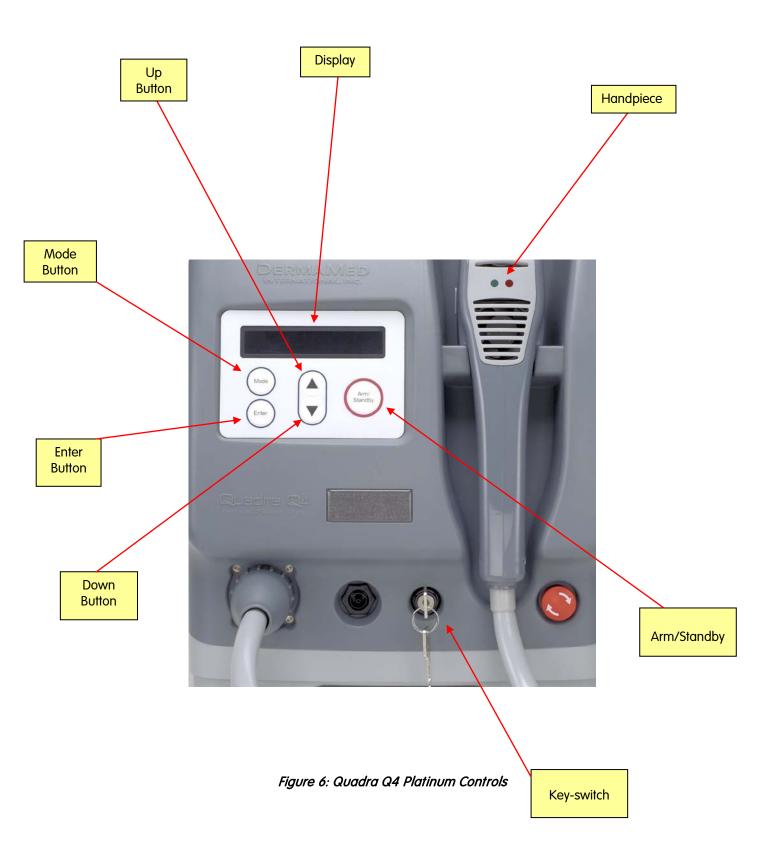
- Aesthetic, ergonomic design
- Increased repetition rate
- Full self- diagnostics
- Quick change lamp system

In addition, the equipment has been designed with ease of maintenance in mind. The system utilizes a modular design, which coupled with the computer controlled diagnostic capability, makes a robust, reliable & safe system.

The Quadra Q4 Platinum is an advanced optical system based on a unique disposable flashlamp design. The light is delivered to tissue via an ergonomically designed handpiece. The spot size of the optical energy to tissue has been fixed to 33mm x 27mm (9.0cm²).

To ensure maximum safety the onboard computer executes an automatic self-test routine every time the system is switched on. This routine checks the equipment system parameters prior to any treatment. In addition, the system software continues to check all equipment functions throughout the period of use.

# 2.1 List of Controls



# 2.2 Specification

Wavelength:	530 – 1200nm
Energy:	Up to 20 J/cm <sup>2</sup>
Pulse Duration:	Computer controlled pulse Single Pulse 10ms – 50ms Triple Pulse up to 110ms (Multiple Pulse Pattern Configurations)
Spot Size:	33mm x 27mm (9.0 cm²)
Maximum pulse energy: (delivered to tissue).	178 J
Delivery Device:	Direct Delivery Handpiece
Energy Profile to Tissue:	Homogeneous over treatment area
Repetition Rate:	0.25 Hz average
Electrical:	Dependent on model: - 230V, 50Hz @ 5A - 110V, 60Hz @ 10A
Cooling:	Self contained fan cooled
Environmental:	10°C (68F) to 30°C (86F) Non-condensing humidity below 75% RH
Dimensions:	340mm High x 305mm Wide x 480mm Deep (13.4 Inches x 12 Inches x 18.9 Inches)
Weight:	14 kgs (31 lbs)

## 3. Transport and Installation

#### 3.1 Transport Damage

The Quadra Q4 Platinum has been carefully packed and should arrive at its destination in perfect condition. Upon delivery, please check that the external packaging is not damaged. If signs of damage are present, or the shock detector labels have been activated, please report them to the shipping carrier and the Customer Service Department within 24 Hrs.

#### 3.2 Environmental Transport & Storage Conditions

The transport and storage conditions for the Quadra Q4 Platinum were determined from specifications set by the manufacturers of critical components as follows:

Temperature  $+5^{\circ}\text{C}$  to  $+40^{\circ}\text{C}$ 

Relative Humidity 35% to 65% Non-Condensing.

Atmospheric Pressure 500 – 1060 hPa

#### 3.3 Installation

### **CAUTION**

THE QUADRA Q4 PLATINUM HANDPIECE IS A DELICATE COMPONENT AND WILL CAUSE DAMAGE TO THE UNIT AND HANDPIECE IF DROPPED. NEVER PULL THE UNIT BY THE POWER CORD OR THE HANDPIECE, EXERCISING THIS MAY RESULT IN DAMAGE TO THE HANDPIECE DELIVERY SYSTEM AND / OR HARM TO THE CLIENT OR USER.

### 3.4 Space Requirements

Sufficient space is required for the equipment. The dimensions of the equipment are 340mm High x 305mm Wide x 480mm Deep

A distance of approximately 150mm should be left clear at the rear of the equipment to allow adequate ventilation.

Ambient room temperatures should not exceed 30°C (86F).

#### 3.5 Accessories

To order additional quantities of Quadra Q4 Platinum equipment accessories, please refer to the supplied Quadra Q4 Platinum Accessories list for part number details.

# 4. System Operation

### **CAUTION**

USE OF CONTROLS OR ADJUSTMENTS OR PERFORMANCE OF PROCEDURES OTHER THAN THOSE SPECIFIED HEREIN MAY RESULT IN HAZARDOUS LIGHT EXPOSURE.

#### 4.1 Switch on Procedure

To operate the equipment system, the following procedure must be followed:

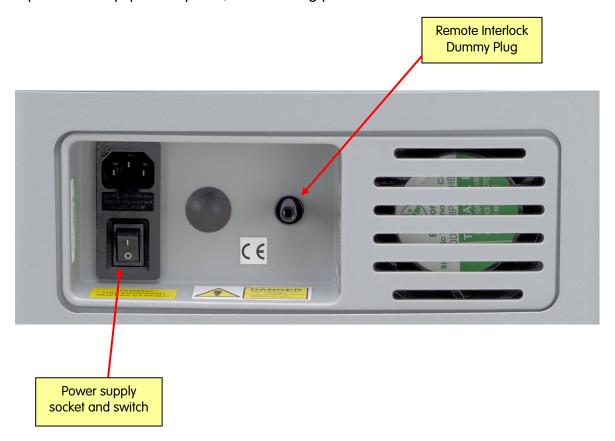


Figure 7: Quadra Q4 Platinum Unit Rear Panel

- 1. Connect Remote Interlock or Dummy Plug (rear of equipment).
- 2. Connect equipment direct to mains supply and switch ON (avoid using extension cords).
- 3. Switch mains power at the rear of the equipment to the "I" position.
- 4. Ensure the Disposable Head is in place (see Installation of Disposable Head section 4.2).
- 5. Turn the main key clockwise into the horizontal position (front of equipment).

**NOTE:** The equipment can be turned off by rotating the key anti-clockwise to the vertical position at any time. The system is only fully switched off when the mains power switch at the rear of the equipment is in the "0" position (in).

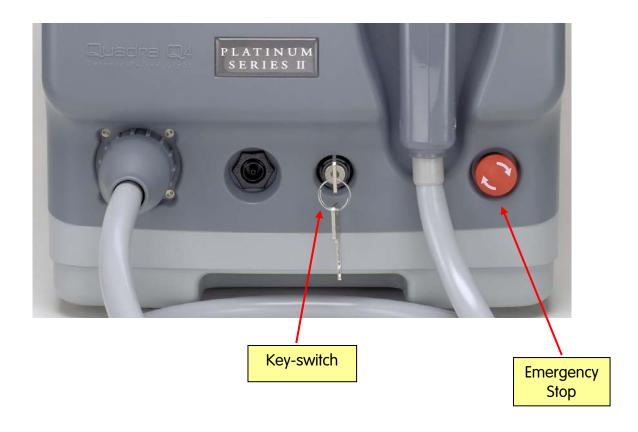


Figure 8: Quadra Q4 Key-switch

#### 4.2 Installation of the Disposable Lamp Unit

#### CAUTION

ALWAYS FOLLOW THE INSTRUCTIONS PROVIDED WITH THE REPLACEMENT DISPOSABLE HEAD.

The Disposable Lamp unit should be installed and removed using the following procedure. Failure to follow the recommendations below may result in damage to the handpiece or Disposable Lamp and / or harm to the client or user.

To remove the installed Disposable:

- 1. Ensure the Quadra Q4 Platinum unit is switched on, in 'STANDBY' and in the Mode screen. *The green light on the rear of the Handset should be ON*.
- If the unit is armed, press ARM / STANDBY, wait for the red light on the rear of the handset to turn off, and then press the Mode button.



Figure 9: Quadra Q4 Platinum Mode/Program selection screens

Light	Function	Open
Red - continuous	Handpiece charged (ready to fire)	Х
Red - flashing	Handpiece Charging or Discharging	Х
Green - continuous	Handset ready to Open	$\sqrt{}$

Figure 10: Quadra Q4 Platinum Handset LED sequence

2. When the green light on the rear of the handset is on, slide the button on the side of the handset forward. This will open the front section of the Handset.

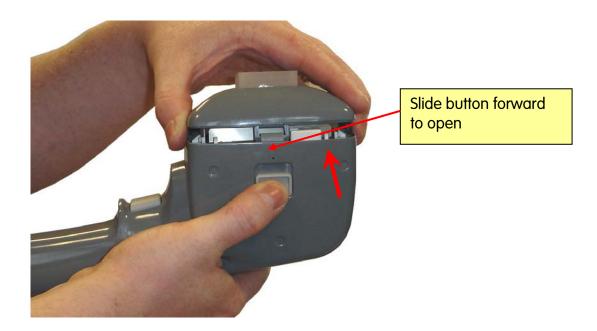


Figure 11: Handset Opening Button

3. Once the front of the handpiece has been opened, unclip the disposable retainer by sliding off the top of the disposable unit.

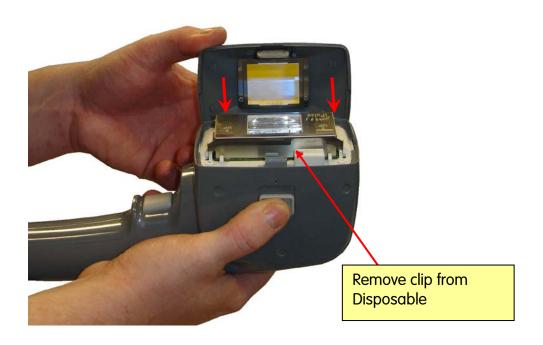


Figure 12: Disposable Retention Clip

4. Hold the sides of the disposable unit and lift upwards and away from the handpiece (do not touch the glass lamps or the rear of the glass block – if the glass block requires cleaning, follow procedure 4.3).

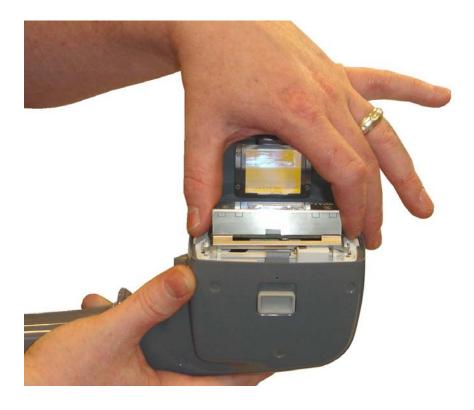


Figure 13: Disposable Unit Removal

5. Remove the 'Peel off' plastic protector from the front of the new Disposable unit (Figure 13A).



Figure 13A: New Disposable Unit

6. To fit the new Disposable Unit, ensure that the recesses at the bottom of the Disposable Unit are placed towards the Font piece hinge.

Drop the Disposable Unit into the handpiece ensuring that the recesses fit into the keyways in the handpiece plate.

Clip the Disposable Retainer over the edge of the Disposable unit (Figure 13B).

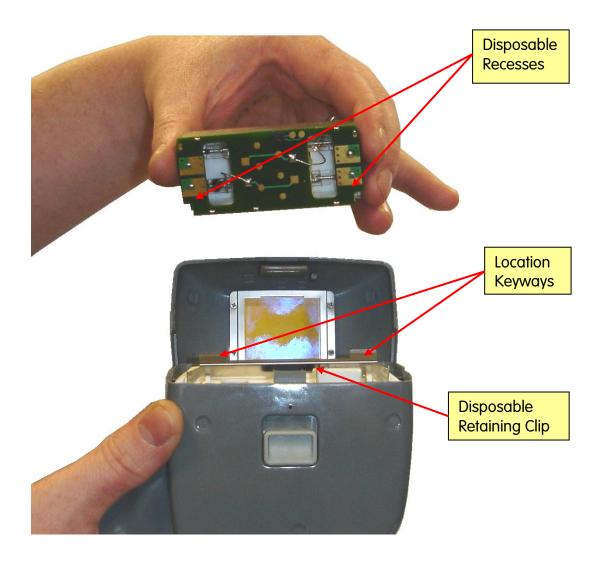


Figure 13B: Rear of Disposable Unit

- 7. Close the front of the Handset ensuring that it clicks into place.
- 8. After replacing the disposable, switch off the unit and restart. This reboots the system so that the new disposable will be recognized.

#### 4.3 Cleaning the Handset & Glass Transmission Block

#### **CAUTION**

ANY CONTAMINATION OF THE GLASS BLOCK CAN LEAD TO REDUCED PERFORMANCE OR DAMAGE TO THE INSIDE SURFACE OF THE GLASS BLOCK. CARE SHOULD BE TAKEN NOT TO SPILL ANY CLEANING FLUIDS ONTO THE UNIT.

#### 4.3.1 Outside of the Applicator & Glass Transmission Block

The front surface of the glass transmission block (area that makes contact with skin) and surrounding plastic applicator front must be kept clean using a lint free cloth. At the end of each treatment session, clean the glass transmission block, applicator head and docking cradle. The glass transmission block itself is a delicate optical component and should also be wiped with a clean soft lint-free cloth or gauze, slightly moistened with 70% isopropyl alcohol or single use 70% isopropyl alcohol prep wipes (e.g. Chemtronics 'Optic Prep' presaturated wipes) to ensure that it is "optically clean" and smear-free.

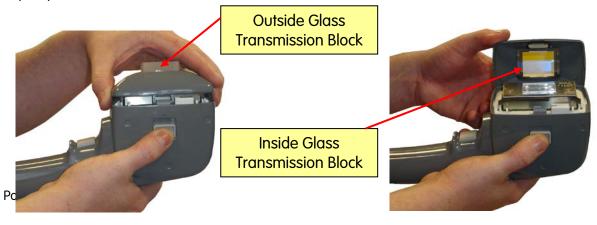
#### 4.3.2 Inside Surface of the Glass Transmission Block

The inside surface of the glass transmission block has a delicate dichroic filter optical coating to reflect unwanted wavelengths of light and must be kept "Optically Clean". To gain best access to the inside surface of the glass transmission block for cleaning please refer back to (Section 4.2 Installation of the Disposable Lamp Unit).

#### **CAUTION**

DO NOT TOUCH THE LAMP GLASS OR TRIGGER WIRE AROUND THE LAMPS WHEN INSPECTING OR UNDERTAKING CLEANING PROCEDURES.

The inside surface should be checked at least weekly for airborne dust or other debris and cleaned carefully with a clean soft lint-free cloth or gauze, slightly moistened with 70% isopropyl alcohol or single use 70% isopropyl alcohol prep wipes (e.g. Chemtronics 'Optic Prep' pre-saturated wipes) to ensure that it is "optically clean" and smear free. Wipe off and dry any excess alcohol or smears with a clean, soft lint-free cloth.



#### 4.4 Start Up

After successful installation and switch on, the main display screen should appear, showing the model and software version (e.g. CS02-1010A). This will be displayed for 2 seconds.

# SYSTEM START CS02-1010Ax.x

#### 4.5 Disposable Head Expiry

The computer will interrogate the Disposable Head prior to each shot being fired and may display the following error message.

# DISPOSABLE EXPIRED SWITCH OFF AND REPLACE

This message will occur if the disposable head pre-set number of shots has been exceeded. At this point the disposable head should be removed and replaced with the new disposable head sent by your supplier.

## 4.6 Program and Energy Selection

After the start-up screen, the system will default to the first Mode selection screen. Mode selection allows the user to choose the Treatment type, Skin Type, Program and Energy density of the system (See Section 5.6 for Quadra Q4 Platinum Treatment Programs).

The first screen enables the user to select the desired Treatment Type e.g. HAIR, VASULAR, PIGMENT, ACNE.



The required treatment program can be selected by pressing either the UP or DOWN keys as shown below.



When the desired treatment program has been selected, press the ENTER button to register the choice.



Once the ENTER key has been pressed, the display will change to Skin Type selection and the required skin type can be adjusted e.g. I, II, IV.



Again, use the UP or DOWN keys to Adjust and press ENTER to register the choice.

Once the ENTER key has been pressed, the display will change to Select Program.



The required Program: A, B or C can be selected by pressing the UP/DOWN key and then press ENTER. (To determine the appropriate treatment program refer to section 5.6 Typical Treatment Protocols).

Once the ENTER key has been pressed, the display will change to the ARMED / STANDBY screen.

Tx: HAIR SK: I SR=5000 E= 10.0 JCM2 DISCHARGED

The STANDBY screen shows both the Treatment type (e.g. Tx = HAIR), the Skin Type to be treated (e.g. SK=I) and the energy density (e.g. E = 10J/cm2).

Also, the number of pulses available on the Disposable Unit is displayed (e.g. SR = 5000 is "Shots Remaining" before replacement is required).

At this stage the ENERGY LEVEL can be adjusted by pressing the UP or DOWN keys.

#### Note:

The beginning of the Mode selection sequence can be returned to at any time by pressing the MODE button.



## 4.7 Armed / Standby Mode

#### **WARNING**

It is the responsibility of the user to ensure the client's eyes are protected during treatment.

Refer to the relevant standards for guidance.

When the ARMED / STANDBY screen is displayed, the Quadra Q4 Platinum has been set to the desired output parameters.

The unit is **NOT** ARMED and cannot produce light output at this stage.

When the operator is ready to commence treatment, press the ARMED / STANDBY key to ARM the unit.



The Red light on the back of the Handset will begin to flash. After approximately 10 seconds, the screen will indicate that the unit is ARMED and the red indicator on the back of the handset will be continuously illuminated. An audible tone will sound when the unit is ready to pulse.

Tx: HAIR SK: I SR=5000 E= 10.0 JCM2 ARMED

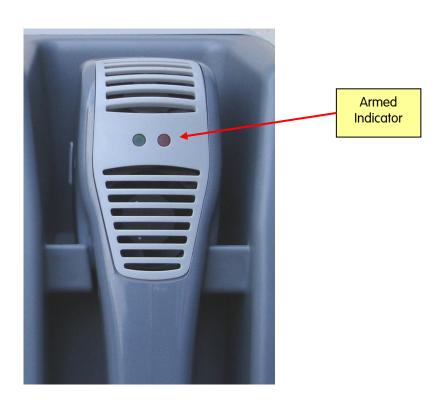


Figure 15: Armed Indicator

The optical pulse is triggered by either pressing the finger. After the pulse has been delivered, the SR (Shots Remaining) indicator will decrement by 1 and an audible tone will sound when the unit is ready to pulse again.

#### Note:

The Energy Level can be adjusted without fully discharging the system. While charged press the MODE button to enter the Energy adjustment screen. Use the UP and DOWN buttons to alter the Energy level. Press the ENTER button to confirm and return to the ARMED screen and continue treatment.

By pressing the ARMED / STANDBY key, the unit will disarm and return to ARMED / STANDBY screen.

Arm / Standby

If the output parameters need to be adjusted, press the MODE key to go to the start of the Mode selection sequence.

If, during usage, the SR (Shots Remaining) indicator reaches zero, the following message will be displayed. Replace disposable unit as described in Section 4.2.

# DISPOSABLE EXPIRED PLEASE REPLACE

**Note:** If the unit remains in ARMED mode for 2 minutes without firing or user intervention, the system will automatically revert to STANDBY mode with the following message displayed.

DISCHARGING CAPACITORS
SYSTEM TIMED-OUT

#### **4.8 Cooling Periods**

To ensure the optimum operational use of the unit is maintained, cooling periods have been incorporated into the design. Once 50 pulses have been delivered to the patient continuously using the same Treatment Program and energy density, e.g. P = 4; E = 10J/cm2, then a Short Cooling Cycle is introduced and the following message displayed for a period of approximately 1 minute.

# SHORT COOLING CYCLE PLEASE WAIT

Once 250 pulses have been delivered to the patient continuously using the same Treatment Program and energy density, e.g. P = 4; E = 10J/cm2, then an Extended Cooling Cycle is introduced and the following message displayed for a period of approximately 5 minutes.

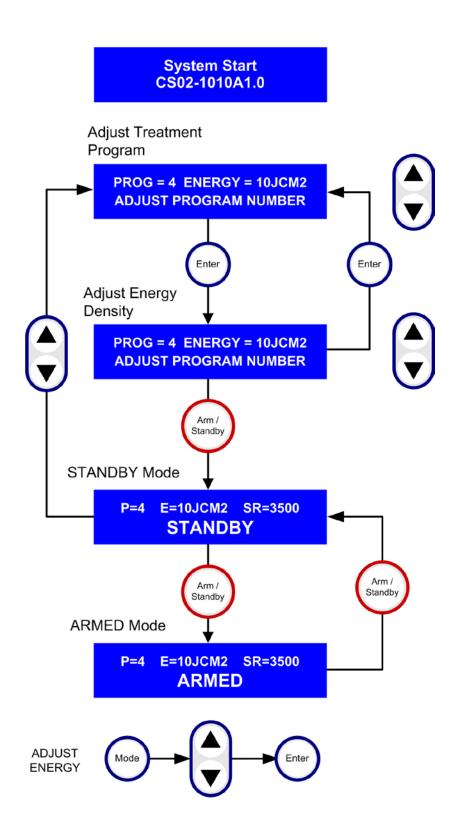
# EXTENDED COOLING CYCLE PLEASE WAIT

#### 4.9 Switch off Procedure

- 1. Ensure unit is Discharged.
- 2. Turn key Counter-clockwise and remove from device to prevent unauthorised use.

### 4.10 QUADRA Q4 Platinum Set-up Quick Guide

The following flowchart shows the Quadra Q4 Platinum set-up procedure.



# **5. Typical Treatment Protocol**

#### 5.1 Indications for Use

The Quadra Q4 Platinum System is indicated for use in cosmetic applications and specifically for long term stable, or permanent, hair reduction.

In addition, the Quadra Q4 Platinum System is indicated for the treatment of superficial benign cutaneous vascular lesions, including rosacea, angiomas and spider angiomas, cherry angiomas and poikiloderma of Civatte, ectatic matting and other superficial venous malformations.

Varicose veins, large lower extremity telangiectasia and larger vascular lesions such as cavernous angiomas, venous lakes, rhynophyma, etc. cannot be treated successfully with pulsed light systems.

The Quadra Q4 Platinum System is also indicated for the treatment of superficial benign pigmented lesions such as age spots, solar lentigenes and other dyschromia.

The Quadra Q4 Platinum System is also FDA cleared for the treatment on mild to inflammatory acne vulgaris.

The Quadra Q4 Platinum system achieves the cosmetic results through the process of selective photothermolysis. Light energy at the appropriate wavelength, pulse duration and energy density is delivered to the target, e.g. the hair shaft or melanin within pigmented blemishes, with minimal interaction with the surrounding healthy skin structures.

#### **5.2 Contraindications**

The contraindications for the Quadra Q4 Platinum procedure are minimal, however the following exclusion from treatment criteria is recommended:

- Tanned skin (active tan)
- Pregnancy;
- A history of keloid scarring;
- Use of medication that may induce photosensitivity to the skin;
- Any inflammatory skin condition at the treatment site;
- A history of skin cancer;
- The client has a history of poor wound healing including Type I Diabetes;
- Vitiligo
- Treatment over certain skin areas such as tattoos, moles, semi-permanent make-up, lip vermillion or mucous membranes.

#### **5.3 Treatment Related Problems**

Potential side effects of treatment with any intense pulsed light system are the following:

- Excessive pain (Action: Stop treatment, cool and moisturize skin, review after 24 hours, re-treat. Likely causes: fluence too high, tanned skin, stress, menstruation and tiredness);
- Excessive persistent heat and redness (Action: cool and moisturize skin, treat as for mild sunburn. Normally resolves in 24 hours. Likely cause: Fluence too high);
- Persistent swelling (Action: cool area thoroughly, consult doctor);
- Itching of treatment area (Action: keep area cool, apply aloe vera gel, consult doctor if condition persists);
- Blistering or crust formation (Action: cool area for pain relief, recommend burn sprays and creams from pharmacy, consult doctor);
- Transient hyper-pigmentation (Action: moisturize, protect from sun exposure and further skin insult i.e. do not rub or scratch, consult operator and doctor if condition persists);
- Transient hypo-pigmentation (Action: moisturize, protect from sun exposure and further skin insult i.e. do not rub or scratch, consult operator and doctor if condition persists).

The use of test patches will minimize the incidences of adverse effects. See also posttreatment care instructions

#### **5.4 Treatment Protocol – General Considerations**

Prior to treatment, the client's general medical history should be obtained, to establish if they have any conditions that would exclude them from treatment. This can be undertaken using a generic consultation form (APPENDIX A).

The client should have the following explained to them:

- The potential for adverse side effects from the treatment, such as transient erythema, blistering and or crust formation, transient hyper-pigmentation, transient hypopigmentation.
- How the treatment works.

- The length of time before a result is noticed.
- Post-treatment care.

Once all this has been carried out the client should then sign a consent form.

The nature of the Quadra Q4 Platinum treatment is non invasive in nature and therefore has the minimum of pre and post treatment procedures. In developing the procedure, emphasis was placed upon the treatment being fast, safe and efficacious to the client.

In general, the only factor that has to be considered prior to treatment, apart from following the standard operating procedure for the safe use of intense pulsed light equipment, is the removal of any cosmetics at the desired treatment location and cooling the skin before and after treatments.

#### **5.5 Post Treatment Care**

Clients should be instructed in post-treatment care and should be given written take-home instructions recommending:

- Don't expose skin to UV (sun exposure or the use of tanning beds) or self tan for at least 2 weeks.
- Don't depilate for 2 weeks (with waxing, plucking, threading or creams) unless advised by the operator to do so,
- 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,
- Avoid very hot baths / showers / steam baths / sauna,
- Avoid swimming in strong chlorinated water,
- 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 and
- Use of sun block SPF 30+.

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

#### **5.6 QUADRA Q4 PLATINUM Treatment Programs**

The Quadra Q4 Platinum is configured with 16 pre-programmed pulse patterns. Each pattern has been developed for a specific treatment that takes into account the clinical condition and clients' skin type.

THE PARAMETERS CONTAINED IN THE FOLLOWING TABLES ARE TO BE CONSIDERED AS GUIDELINES ONLY. THE USE OF TEST PATCHES IS STRONGLY ADVISED AS CLIENT TO CLIENT VARIATION MAY AFFECT THE TREATMENT OUTCOME AND THE POSSIBLE INCIDENCE OF SIDE-EFFECTS.

#### **5.7 HAIR REMOVAL - Typical Treatment Procedure**

For hair removal it is recommended that the treatment site be shaved or trimmed prior to treatment. If the hair is trimmed, care must be taken to ensure that the remaining hair protrudes no more than 1mm above the surface of the skin.

To reduce any possible discomfort during treatment, an ice pack/cool compress should be applied to the skin before and after treatments.

The use of test spots at or near the treatment site prior to the actual treatment is recommended. A sequence of test shots should be used at typical treatment energies at the low end of the described scale allow 20 minutes to elapse before review. Should erythema occur, the energy should be reduced to a lower level and a further test shot should be undertaken. However, slight erythema surrounding the hair follicles after light application is acceptable.

The treatment site should be covered with adjacent pulses of light. Care should be taken to minimize the overlap of adjacent pulses as overlapping may lead to the excessive build-up of heat in the skin. While the principle of selective photothermolysis attempts to ensure that the heat generated by the optical energy is confined to the target structure, e.g. the melanin in the hair shaft, the surrounding epidermal layer of the skin also contains melanin and will therefore undergo a temperature rise. Should concurrent pulses be applied to the same treatment location, the heat generated from the initial pulse may not have time to fully dissipate prior to the application of the subsequent pulse. This accumulation of heat may lead to blistering of the skin and increase the possibility for adverse events.

To ensure continued suppression of hair growth, additional treatments may be required. It is recommended that subsequent treatments are performed at 2-6 week intervals.

Post treatment, cosmetics can be readily applied. No other factors have to be considered.

HAIR REMOVAL						
SKIN TYPE	PULSE	TIME-ON (msec)	TIME-OFF (msec)	ENERGY RANGE (J/cm²)	PROGE	RAM
1	Single	25		12.0 to 16.0 J/cm <sup>2</sup>	4	Α
I	Single	30		13.0 to 17.0 J/cm <sup>2</sup>	5	В
II	Single	30		12.0 to 17.0 J/cm <sup>2</sup>	5	Α
ıı ıı	Single	35		12.0 to 17.0 J/cm <sup>2</sup>	6	В
III	Single	35		12.0 to 16.0 J/cm <sup>2</sup>	6	Α
III	Multiple	15	20	12.0 to 18.0 J/cm <sup>2</sup>	14	В
IV	Multiple	15	20	12.0 to 18.0 J/cm <sup>2</sup>	14	Α
IV	Multiple	20	25	12.0 to 18.0 J/cm <sup>2</sup>	16	В

#### **5.8 SKIN REJUVENATON – Typical Treatment Procedure**

There are two types of skin aging — intrinsic and extrinsic. The rate of intrinsic aging is genetically determined and describes how as we grow older (starting around 30 - 35), our skin naturally becomes thinner and drier. Lower levels of collagen make the skin less elastic. Early signs of sagging and static, deep wrinkles may begin appearing.

Extrinsic aging results from exposure to the environment. Extrinsic aging is the critical element in determining who looks older or younger than their biological age. Exposure to sunlight is a key contributor to extrinsic aging. Photo-aging occur when elastin and collagen breakdown is not replaced, causing fine lines and wrinkles to intensify. Photo-aging also causes pigment changes with development of age spots (sun-induced freckles), uneven skin tone and enlarged pores. Spider veins and broken or dilated capillaries are another sign of photo-aged skin. Lifestyle choices also have an impact on extrinsic aging. Cigarette smoking contributes to the breakdown of elastin and collagen and impairs the body's healing capacity.

The simplest way to see the contrast between intrinsic and extrinsic aging is to compare skin commonly exposed to the sun (face, hands, and neck) and skin not exposed to the sun (usually on the breasts, inner arms or buttocks).

Clients with fine facial wrinkles, slightly loose skin, brown blotchy pigmentation and scattered blood vessels can be improved with facial skin therapy using intense pulsed light technology. Some collagen tightening and remodeling occurs with repeat treatments.

Skin therapy is a purely cosmetic treatment designed to produce younger and healthier looking skin. Skin therapy can treat vascular redness, the appearance of Rosacea, pigmented brown spots, sun damage, skin texture, and collagen structure all at once.

This new technique treats skin damage non-invasively — there is no disruption of the skin's epidermal surface Quadra Q4 Platinum treatments address the effects of photo-aging and sun damage with low risk of complications and virtually no recovery time.

Why choose Quadra Q4 Platinum over other treatment options? The Quadra Q4 Platinum provides a range of treatment programs suitable for skin therapy and allows the operator to select parameters which favor reduction of pigmented blemishes or vascular redness while generally improving skin tone, pore size and fine lines and wrinkles.

#### **5.8.1 Treatment of Benign Pigmented Blemishes**

To treat benign pigmented blemishes, it is recommended that an ice pack/cool compress be applied to the skin before and after treatments. Test patches should be undertaken as described above. The pulses should be applied evenly over the treatment area as described above.

Following treatment it is typical that erythema occurs locally to the pigmented blemishes. This may take 2 to 3 minutes to appear and is typically indicative of localized heating of the selected target. It is common for the treated pigmented blemish to continually darken for 2-3 days following treatment with a resulting mild desquamation. Following desquamation, the skin will appear reddened and should return to normal within 10-14 days.

Additional treatments may be necessary to ensure complete clearance of the blemish. Subsequent treatments should only be performed at the same treatment site at an average of 2 week intervals or when area is completely healed.

PIGMENTED LESIONS						
SKIN TYPE	PULSE	TIME-ON (msec)	TIME-OFF (msec)	ENERGY RANGE (J/cm²)	PROGE	RAM
_	Single	20		13.0 to 15.0 J/cm <sup>2</sup>	3	Α
1	Single	25		13.0 to 17.0 J/cm <sup>2</sup>	4	В
	Single	20		13.0 to 15.0 J/cm <sup>2</sup>	3	Α
II	Single	25		13.0 to 17.0 J/cm <sup>2</sup>	4	В
	Single	30		12.0 to 19.0 J/cm <sup>2</sup>	5	С
	Single	30		11.0 to 16.0 J/cm <sup>2</sup>	5	Α
III	Single	40		12.0 to 15.0 J/cm <sup>2</sup>	7	В
	Multiple	15	20	12.0 to 18.0 J/cm <sup>2</sup>	14	С
IV	Multiple	15	20	12.0 to 18.0 J/cm <sup>2</sup>	14	Α
IV	Multiple	20	25	12.0 to 18.0 J/cm <sup>2</sup>	16	В

#### **5.8.2 Treatment of Vascular Blemishes**

To treat vascular blemishes, such as Telangiectasia, again it is recommended that an ice pack/cool compress be applied to the skin before and after treatment. Test patches should be undertaken as described above.

Immediately following treatment the vessel will blanch or appear purple/grey in color, this is indicative of selective absorption of the incident light within the vessel structure. Over a period of 10-14 days post treatment the vessel will either partially or fully resolve. Additional treatments may be necessary to ensure complete clearance of the blemishes. Subsequent treatments should only be performed at the same treatment site at an average of 2 week intervals or when area is completely healed.

VASCULAR LESIONS						
SKIN TYPE	PULSE	TIME-ON (msec)	TIME-OFF (msec)	ENERGY RANGE (J/cm²)	PROGE	RAM
	Single	20		12.0 to 15.0 J/cm <sup>2</sup>	3	Α
'	Single	25		13.0 to 17.0 J/cm <sup>2</sup>	4	В
П	Single	25		13.0 to 17.0 J/cm <sup>2</sup>	4	Α
II .	Single	30		13.0 to 18.0 J/cm <sup>2</sup>	5	В
III	Single	25		12.0 to 15.0 J/cm <sup>2</sup>	4	Α
"	Multiple	10	20	12.0 to 18.0 J/cm <sup>2</sup>	15	В
IV	Multiple	10	20	11.0 to 14.0 J/cm <sup>2</sup>	15	Α
IV	Multiple	20	25	11.0 to 15.0 J/cm <sup>2</sup>	16	В

### **5.9 INFLAMMATORY ACNE - Typical Treatment**

To treat mild to moderate inflammatory acne it is recommended that an ice pack/cool compress be applied to the skin before and after treatment. Test patches should be undertaken as described above.

The affected area should be uniformly covered with pulses ensuring minimal overlap. Following treatment, the skin may appear reddened with slight swelling around the individual spots. Over a period of 3-5 days the spots should appear less inflamed and may resolve completely. Further treatment can be undertaken at regular intervals to minimize acne flare-ups.

	ACNE LESIONS					
SKIN TYPE	PULSE	TIME-ON (msec)	TIME-OFF (msec)	ENERGY RANGE (J/cm²)	PROGE	RAM
I	Multiple	20	25	8.0 to 12.0 J/cm <sup>2</sup>	16	Α
II	Multiple	20	25	8.0 to 12.0 J/cm <sup>2</sup>	16	Α
III	Multiple	20	25	8.0 to 11.0 J/cm <sup>2</sup>	16	Α
IV	Multiple	20	25	8.0 to 10.0 J/cm <sup>2</sup>	16	Α

			PRO-10C			
SKIN TYPE	PULSE	TIME-ON (msec)	TIME-OFF (msec)	ENERGY RANGE (J/cm²)	PROGR #	RAM
I	Multiple	14	7	8.0 to 20.0 J/cm <sup>2</sup>	10	Α
II	Multiple	14	7	8.0 to 20.0 J/cm <sup>2</sup>	10	Α
III	Multiple	14	7	8.0 to 20.0 J/cm <sup>2</sup>	10	Α
IV	Multiple	14	7	8.0 to 20.0 J/cm <sup>2</sup>	10	Α

#### 6. General Maintenance

#### **6.1 Cleaning the Equipment**

Before cleaning maintenance is carried out, please ensure the unit is disconnected from the mains supply.

The equipment system can be cleaned by wiping with a soft, lint free cloth slightly dampened with 70% Isopropyl alcohol or single use 70% isopropyl alcohol prep wipes. Care should be taken not to spill any cleaning fluids onto the unit.

Additionally, daily checks should be made of the back of the disposable and the connection spring pins. All pins should spring freely, and should be clean and dry. The pins and disposable can be wiped with a <u>DRY</u> soft, lint free cloth.

Please refer to section 4.3 (Cleaning the Handset & Glass Transmission Block) for more cleaning and maintenance instructions.

# **6.2 Visual Inspection**

The mains cable together with the handpiece and system must be inspected for possible wear, cracks or breaks before each use.

# 6.3 Servicing

There are no user repairable parts inside the Quadra Q4 Platinum Equipment. Servicing should only be carried out by factory-qualified personnel.

The potential for electrocution is ever present. Do not operate the equipment without covers and panels or other mounting hardware as supplied and properly installed. Do not touch any part of an open frame unit when AC line voltage is supplied.

The electrical output produced by the power supply is many times the level to be fatal. There is no substitute for caution, prudence and clear thinking when working with high voltages.

### 6.4 Removal and Replacement of the Disposable Lamps.

As described in Section 4.2

### 6.5 Servicing and Maintenance Schedule

Please contact DermaMed Solutions, LLC at 610-358-4447 for information on servicing and maintenance for the Quadra Q4 Platinum.

### **6.6 Safe Disposal**

For safe disposal of the unit or sub-assemblies, please contact DermaMed Solutions, LLC at 610-358-4447.

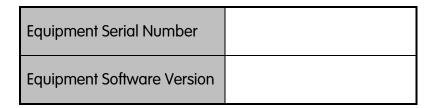
# 7. Fault Diagnostics

This section will help diagnose faults that may be experienced on the equipment from time to time. If a fault is encountered that cannot be easily rectified, please inform the nearest Service Center.

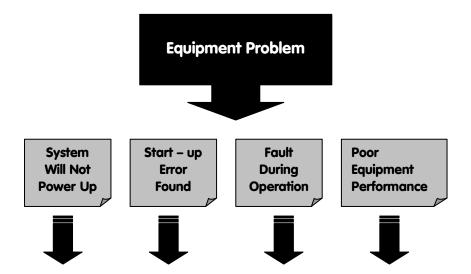
To help the Engineer diagnose the system, it would help if the following information must be available when the service center is called:

- The Equipment Serial Number (found at the rear of the unit).
- The Software Version Number (found at start screen).
- The number of shots fired by the equipment.
- Description of the fault.

To help with diagnosis, please make a note of the system equipment serial number and software version.



If after checking the following points listed in each section, the equipment is still not functioning correctly, please call the nearest Service Center.



### 7.1 Unit Will Not Switch On

- Ensure the mains supply is plugged into the receptacle in the wall and power is available.
- Ensure the switch on the rear of the unit is in the "I" position.
- Ensure the key-switch is in the Horizontal position.
- Ensure Remote Interlock is connected (or Dummy Plug in place).

# 7.2 QUADRA Q4 PLATINUM Error Messages

Error Message	Potential Cause	Remedy / Action	
INTERLOCK OPEN - REPLACE SYSTEM DISCHARGED	Remote Interlock on rear of machine disconnected or dummy plug missing.	Connect remote interlock or replace dummy plug.	
HANDPIECE OPEN - CLOSE SYSTEM DISCHARGED	Front of handpiece open or incorrectly closed.	Ensure disposable unit located correctly and close handpiece.	
LAMP nn FAILURE PRESS ANY KEY TO CLEAR	Flashlamp misfire.	Clear fault and retry. If problem persists, replace disposable unit and retry.	
BAD DISPOSABLE DETECTED SWITCH OFF AND REPLACE	Incorrect or unapproved disposable inserted into handpiece.	Replace disposable unit and retry.	
FAULTY DISPOSABLE SWITCH OFF AND REPLACE	Failure to communicate with disposable.	Remove disposable and refit. If problem persists, replace disposable unit and retry.	
FAILED TO CHARGE SYSTEM SWITCH SYSTEM OFF			
DISCHARGE RELAY CLOSED SWITCH SYSTEM OFF			
INCORRECT CAP VOLTS SWITCH SYSTEM OFF			
HEAD OVER TEMPERATURE SWITCH SYSTEM OFF	Switch off Quadra Q4 Platinum Unit. Wait for 2 minutes. Switch on the Quadro Platinum following standard start-up procedure.  If problem persists, call Service Operator.		
SYSTEM OVER TEMPERATURE SWITCH SYSTEM OFF			
SYSTEM 30V SUPPLY FAILED SWITCH SYSTEM OFF			
HEAD COOLING FANS FAILED SWITCH SYSTEM OFF			
DISCHARGE RELAY OPEN SWITCH SYSTEM OFF			
TOP LAMP MISFIRE	- Flashlamp misfire	- Check Pins.	
BOTTOM LAMP MISFIRE	тазнатр паше	- Replace disposable unit and retry.	

# Appendix A – Typical Client Consultation Form

# **Clinic Name**

Client Name:	Address:
Client Number:	
Therapist's Name:	Dete
Operators Name:	Date:
Please answer the following qu	uestions:
Skin Type	
Other:	
Skin Colour	
☐White ☐Oliv	e Oriental Indian
Afro-Caribbean Sun	-Tanned
Other:	
Skin Conditions	
Pigmented Patches Pror	ne to pigmentation changes
☐Moles ☐Frec	klesAcne
☐Psoriasis ☐Ecze	ema Vitiligo
Other:	
What other methods of Skin the	erapy have you used before?
Cosmeceuticals Che	mical peels Botox Er: YAG / CO <sub>2</sub> Other:
Are you undertaking a course	of treatment that may make your skin photosensitive?
(See attached sheet for informa	ation and a list of common drugs.)
☐Yes ☐No If Yes, what typ	e?
Do you have any kind of allerg	i <u>es?</u>
☐Yes ☐No If Yes, what typ	e?
Do you take medicine for any o	ıllergies?
☐Yes ☐No If Yes, what typ	e?
INDEMNITY:	
I confirm that the information the understood and accept the abo	nat I have supplied is true and correct, and that I have read, ove-mentioned information.
	ent operator, the clinic owners and their staff, the franchiser and their rer of the equipment from any claims whatsoever.
Client Name:	Client Signature:
Date:	
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## Appendix B – Information on Drug-Induced Photosensitivity

#### Information on Drug Induced Photosensitivity

There are many drugs available at the moment that can cause the skin to become very sensitive to light. Whether these drugs are taken by mouth or applied to the skin a reaction can occur. This reaction is called "Drug-Induced Photosensitivity". Therefore, it is very important that you read this information and notify the Doctor/Operator of any drugs that you may be using.

Photosensitivity reactions can be divided into two groups:

**Photo-Toxic Reactions** - these are dose related and can be seen to a slight degree in people who are exposed to sunlight.

**Photo-Allergic Reactions** – these involve the immune system and may be similar to other allergic reactions, swelling, rashes and hives.

The drugs cause this reaction by absorbing the Equipment light (which is in the visible part of the spectrum) that is delivered by our system.

#### **Types of Photosensitivity**

Abnormal and extreme sunburn

Stinging and burning

**Vesicles** 

Hives

**Swelling** 

There is a large variation in the frequency and severity of reactions from client to client. Some clients may blister, have a slight unnoticeable reaction, or will have no reaction at all. For this reason it is advisable that test patches are carried out to determine if any adverse reactions occur.

## **Common Drugs That Can Cause Photosensitive Reactions**

#### **Antibiotics**

Dioxycycline (Vibramycin, Vibratabs)

Demeclocycline (Declomycin) – High incidence.

Tetracycline (Achromycin and others)

Nalidixic Acid (NegGram)

Lomefloxacin (Maxaquin) – Especially noted for severe reactions when they occur.

#### **Blood Pressure and Heart Medications**

Hydrochlorothiazide (Hydrodiuril, Oretic and other names) – Many drugs contain HCTZ as one of the ingredients.

Chlorothiazide (Diuril and other names)

Furosemide (Lasix)

Amiodarone (Cordarone) - High incidence of drug-induced photo-reactions.

#### **Other Drugs**

Chlorpromazine (Thorazine)

Methoxypsoralin

PABA and/or PABA esters – Used in sunscreens, can cause hives and rashes.

## Common Drugs That Cause Photosensitive Reactions Less Often.

Alprazolam (Xanax)	Amitriptyline (Elavil, Endep and other names)
Benzocaine (Sensorcaine and many other numbing products)	Captopril (Capoten)
Chloradiazepoxide (Librium)	Chloroquine
Chlortetracycline	Ciprofloxacin (Cipro)
Co-trimoxazole (Bactrim, Septra)	Dapsone
Diltiazem (Cardizem, and other names)	Diphenhydramine (Benadryl, Benylin and other names)
Enoxacin (Penetrex)	Oestrogens (Birth Control Pills, Premarin and more)
Fluoracil (5-FU)	Glyburide (Diabeta, Micronase, Glynase, and other names)
Griseofulvin (GrisPeg, Fulvicin, and other names)	Haloperidol (Haldol)
Hydralazine (Apresoline)	Ibuprofen (Advil, Motrin, and more)
Isoniazid (INH)	Isotretinoin (Accutane)

Methotrexate	Minoxidil (Loniten, Rogaine)
Naproxen (Naprosen, Alleve, other names)	Nifedipine (Procardia, Adalat)
Norfloxacin (Noroxin)	Nortriptyline (Aventyl, and other names)
Ofloxacin (Floxin)	Oral Contraceptives
Oxytetracycline (Terramycin)	Perfenazine (Trilafon)
Phenylbutazone (Butazolidin)	Phenytoin (Dilantin)
Piroxicam (Feldene)	Prochlorperazine (Compazine)
Promethazine (Phenergan)	Protriptyline (Vivactil)
Quinidine (Quinidex, Quinaglute, Cardioquin, other names)	Quinine (Quinamm)
Sulfonamide antibiotics (Bactrim, Septra, Gantrisin, and others)	Thioridiazine (Mellaril)
Thiothixene (Navane)	Tolbutamide (Tolinase)
Tretinoin (Retin-A)	Trifluroperazine (Stellazine)
Vitamin A	

# **FITZPATRICK SCALE**

Skin Type	Working Classification	Color	
l	Always burns easily, never tans, extremely sensitive to sun	White	
II	Always burns easily, tans minimally, very sensitive to sun	White	
III	Sometimes burns, Tans gradually to light brown, sun sensitive skin	White/ Asian	
IV	Burns minimally, always tans to moderate brown, minimally sun sensitive		
V	Very rarely burns, tans well, sun insensitive skin		
VI	Never burns, deep pigmented, sun insensitive skin	Black	

**Type I**: Primarily red-headed individuals and blonds with light complexions.

**Type II, III**: The largest percentage of Caucasian individuals fall into these categories.

**Type IV**: Individuals of Asian, American Indian, Mediterranean and Latin American descent.

**Type V**: Light complexion African American individuals, those of Indian descent.

**Type VI**: Dark-skinned individuals.

<sup>\*</sup> From Naylor, M.F. & Farmer K.C. Guidelines for Minimizing UV Exposure. In The Electronic Textbook of Dermatology. Drugge, R. and Dunn, HA. (eds) The Internet Dermatology Society, 2000

# **SKIN TYPE WORKSHEET**

Patient's No	ome:		Date:			
Score:		0	1	2	3	4
	What is the Color of your eyes?	LIGHT BLUE, GRAY OR GREEN	BLUE, GRAY OR GREEN	BLUE	DARK BROWN	BROWNISH BLACK
	What is the natural color of your hair?	SANDY RED	BLOND	CHESTNUT, DARK BLOND	DARK BROWN	BLACK
	What is the color of your skin (unexposed areas)	REDDISH	VERY PALE	PALE WITH BEIGE TINT	LIGHT BROWN	DARK BROWN
	Do you have Freckles on SUN exposed areas?	MANY	SEVERAL	FEW	INCIDENTAL	NONE
	What happens when you stay in the sun too long?	PAINFUL REDNESS, BLISTERING	BLISTERING FOLLOWED BY PEELING	BURNS SOMETIMES FOLLOWED BY PEELING	RARELY BURNS	NEVER HAD BURNS
	To what degree do you turn brown?	HARDLY OR NOT AT ALL	LIGHT COLOR TAN	REASON-ABLE TAN	TAN VERY EASILY	TURN DARK BROWN QUICKLY
	Do you turn brown several hours after sun exposure?	NEVER	SELDOM	SOMETIMES	OFTEN	ALWAYS
	How does your face respond to the sun?	VERY SENSITIVE	SENSITIVE	NORMAL	VERY RESISTANT	NEVER HAD A PROBLEM
	When did you last expose yourself to the sun, tanning bed, or tanning creams?	MORE THAN 3 MONTHS AGO	2-3 MONTHS AGO	1-2 MONTHS AGO	LESS THAN 1 MONTH AGO	LESS THAN 2 WEEKS AGO
	Do you expose the area to be treated to the sun?	NEVER	HARDLY EVER	SOMETIMES	OFTEN	ALWAYS
TOTAL SCORE:		SCORE	FITZPATRICK S	KIN TYPE		
		0-7	I			
		8-16	II			
ı			IV			
		OVER 30	V-VI			

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