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INTRODUCTION

Intended Use

The Omega Xp and probes are designed for use in the treatment of a range of conditions from tissue repair and wound care to pain relief. Through research and development Omega have identified the optimal treatment parameters in terms of wavelengths, dosages and pulsing frequencies, which are vital for successful treatment and resolution.

Omega lasers are used every day in medical hospitals and clinics all over the world. The protocols outlined in this Manual are the results of many years of experience and clinical application. The Manual sets down guidelines for use and explains the physiological effects of laser therapy.

Background

Albert Einstein first proposed the theory of laser radiation. However it was many decades before the first working laser was fired and Dr. Theodore Maiman published the first account of laser radiation in 1960. From a virtual revolution in the use of laser for surgical application, benefits began to emerge in the use of lasers for their therapeutic effects when applied at low power intensity.

Dr. Andre Mester, a Professor of Surgery at Semmelweis Hospital, Budapest is often referred to as the grandfather of low level laser therapy. He discovered that irradiation of tissue with low dose levels using a ruby laser (red light) resulted in an increased rate of healing and his subsequent work provided the initial volume of evidence for the efficacy of laser in healing and wound care.

The new science of Low Intensity Laser Therapy (LILT) developed, also known as Low Level Laser Therapy (LLLT), or when related to equipment as Low Power Laser (LPL), Cold Laser, Therapeutic Laser. In this Manual it will be referred to as LILT.

Through research and development Omega have developed lasers for treating an increasing range of conditions from tissue repair and wound care to pain relief. These emphasise the importance of specific wavelength, dosage and pulsing frequencies in treatment.

WHAT IS LASER?

Physics of laser

L light
A amplification by the
S stimulated
E emission of
R radiation

LASER light is:

Coherent
Monochromatic
Collimated

COHERENCE:

All the wavelengths are produced in phase - reinforcing each other and producing the potential power of the laser beam. HOWEVER as coherence is lost in the tissue it is not necessarily relevant for therapy. You will see in the technical section a reference to LASER and SLD (Super Luminous Diode) - LASER is coherent; SLD is not coherent therefore not potentially very powerful. However it is therapeutically effective because it is MONOCHROMATIC:

MONOCHROMATICITY:

Single colour or single wavelength. The purity of wavelength is the most important of laser properties for LILT.

COLLIMATION:

Laser light is often described as highly collimated in comparison with other light sources. This means it is possible to produce a close parallel beam, hence the use of laser for teaching - point a laser pointer at the board and its diameter will alter little with distance as it is moved. The laser diodes Omega specifies for use in their equipment are fairly divergent to reduce any potential risk to the patient. Collimation is not relevant for LILT.

We therefore require monochromatic light diodes to provide:

- **single wavelength**
- **sufficient power**

WHAT DOES LILT DO?

Physiological effects

From the well controlled work on the effects of LILT carried out by Guy's Hospital in London, Ulster University in N. Ireland and centres of excellence in Spain, Italy, Israel, Japan, Switzerland, and Russia there is growing knowledge of the biochemical mechanism of laser therapy. The best researched mechanisms include:

TISSUE REPAIR:

Biomodulation of :

- Cell metabolism and motility
- Collagen (balanced) production
- Mast cell arrival
- Mast cell degranulation (in the case of injury)
- Macrophage arrival and activity
- Fibroblast synthesis
- Protein synthesis
- ADP-ATP synthesis
- Permeability of cell membrane to calcium uptake
- Vasodilation (renewal of blood rich in oxygen)
- Angiogenesis (improved tissue nutrition)
- Systemic response

PAIN RELIEF:

- Endorphin release
- Serotonin - increase in metabolism
- Suppression of nociceptor activity
- Effect on CNS (central nervous system) and PNS (peripheral nervous system)
- Acupuncture point stimulation

LILT RESULTS IN:

- Faster healing of damage
- Considerable increase in tensile strength of repaired tissue
- Balance of collagen production and reduction of scarring
- Stimulation of the immune system
- Pain relief
- Acupuncture point stimulation
- Preventative application

WHAT IS LILT USED FOR?

Clinical Applications

This is a suggestion of a range of common applications

Wound Management:

Ulcers	Venous Ischaemic Neuropathic	Aphthous Diabetic Arterial
Post operative	Skin graft Dupuytrens Tendon repair Caesarean section	Foot and Nail surgery Abdominal surgery Plastic surgery Maxiofacial surgery
General	Pressure sores Acute lacerations Perineal tears	Burns - 2nd & 3rd degree Necrotic tissue Scarring

Pain Management and Rehabilitation:

Soft tissue/sports injuries and joint conditions	Sprains and strains Haematomas Acute backs and necks Osteoarthritis Rheumatoid arthritis Capsulitis	Dupuytrens contracture Carpal Tunnel Bursitis Tendinopathy Mortons Neuroma Sympathetic dystrophy
Chronic Pain	Trigeminal neuralgia Post herpetic neuralgia Brachial neuralgia TMJ	Chronic neck/back pain Metatarsalgia Ankylosis spondylitis Plantar fasciitis
Fractures	Small bone Non union	Green stick Rib pain

Skin Conditions and Viral Infections:

Dermatology Viral infection	Acne Eczema Psoriasis Herpes Simplex	Cold Sores Cuts, grazes, blisters Warts and verrucae Shingles
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Acupuncture:

Acupuncture	Non needle acupuncture Trigger Points Smoking cessation
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CLINICAL GUIDELINES

Understanding LILT

What are you trying to achieve?

- a) **Tissue Repair** - stimulation of the biochemical response of the body to increase vasodilatation, stimulate growth factor response and initiate the body's ability to heal.
- b) **Pain relief** - stimulation of endorphin release, increased rate of metabolising of serotonin and suppression nociceptor activity provide rapid and effective pain relief. Even if pain relief is not the primary objective of the treatment a patient may experience relief of arthritic, rheumatic, back and neuralgic pain as a consequence of the treatment. The clinician will also be providing pain relief in the case of acute injuries and should warn the patient not to over use the injured limb while the anaesthetic effect lasts.
- c) **Acupuncture point stimulation** - used locally and distally.

Wavelength (nm/nanometers)

There is often confusion over the large choice of probes available:

- Each probe contains one or more diodes each with a particular wavelength (nm) and a set power output (mW).
- Cluster probes contain several diodes emitting at the same time.
- Omega lasers use wavelengths between 600nm and 1000nm (see 43-47 for Technical Specification). These wavelengths are not harmful to human tissue but are absorbed by chromophores in the cells, triggering the biochemical modulator effect.

The WAVELENGTH of the light governs the DEPTH OF PENETRATION of the light into the body.

The WAVELENGTH of the light also has specific effects on PHYSIOLOGICAL RESPONSE

- Omega wavelengths have been selected to optimise penetrative effect and cellular response.
- All wavelengths and powers should be clearly labelled on the side of the probe.
- The wavelength you choose depends on the condition and depth you want to treat.

Choice of Probe:

Laminated copies of this chart will be provided with the machine and are available from Omega.

Probe	Penetrative effect	Cellular response	Used for
Visible Red 675nm 30mW Red 660nm 50mW	5% of power penetrates to subcutaneous Very little effective penetration below the dermis	Excellent growth factor response Bactericidal effect	If repair is required to superficial tissue: • Ulcers and wounds • Post surgery • Burns • Dermatology • Skin conditions • Ear and nail point stimulation • Cold sores
IR 820nm 50mW 100mW 200mW 300mW	20% of power penetrates to subcutaneous tissue Much more effective penetration of power Tested to reach up 3 - 4 cm into the tissue	Good growth factor response Endorphin release Higher serotonin levels	If repair is required to tissue below the dermis • Soft tissue/sports injuries • Body acupuncture point stimulation • Trigger points • Pain Relief • Verrucae • Smoking Cessation
IR 915nm 100mW (1W peak)	20% of power penetrates to subcutaneous tissue	Good growth factor response High powers therefore a stronger application of the therapy	• Treatment of pain and injury • Tissue repair • Scar tissue
Cluster: 60 46 31 20	Range of wavelengths combined to produce excellent penetration and volume of irradiation	Excellent growth factor response over a much larger area	• Used for everything, particularly wounds due to the larger area for irradiation • Used after treatment with the single probes to ensure irradiation all around the area of damage • Excellent for softening tissue around points of pain and injury

In most cases at least 1 single probe and 1 cluster probe is used over the same area.

675nm	& cluster	Wound healing/burns/dermatology/post operative
820nm	& cluster	Sports Injuries/pain relief/body point acupuncture

Power (mW = milliwatts) and Energy (J = Joules)

- The clinician must decide how long to treat for. This depends on the power / power density of the probe:

Power Density W/cm ²	=	$\frac{\text{Probe Output (W)}}{\text{Area of irradiation (cm}^2\text{)}}$
Power density (W/cm ²)	=	the 'medicine' i.e. how strong or weak the probe is
Energy density (J/cm ²)	=	the 'dose' i.e. how much of that medicine we give - in the case of laser therapy this dose is TIME

- The minimum Energy Density required to stimulate the required response is understood (see pages 8 and 9) and the Power Density of the Omega probe is known (see page 43-47). It is therefore quite straightforward to calculate the time required to achieve the Energy Density required with any specific Omega probe:

Example:

- You have a 675nm 30mW single probe and you want to give 4 J/cm² per point.

Spot size in contact with the skin	=	0.125 cm ²	
Power of probe	=	30 mW	= 0.030 W
Power Density of probe	=	$\frac{0.030}{0.125}$	= 0.24 W/cm ²

- Consider the Energy Density we need per point is 4 J/ cm²

Energy Density (J/cm ²)	=	Power Density (W/cm ²)	X	Time (seconds)
4	=	0.24	X	Time
$\frac{4}{0.24}$	=	Time		
16.66 (seconds)	=	Time		

- Therefore to achieve 4J/cm² with a 30mW probe (Power Density 0.24W/cm²) you must irradiate for 16.66 seconds.
- Calculated times of exposure are rounded up to the nearest 5 seconds i.e. recommended time is 20 rather than 16.66 seconds.
- To make things easier Omega provide a chart clearly indicating time of exposure for required Energy Density at the depth required allowing flexibility of treatment.
- Be aware of the power of your probe
- Recommended doses are for contact technique. If you treat out of contact treatment times must be increased.
- Treat at 90° to ensure maximum power to the injured tissue.

Laminated copies of these charts will be provided with the machine and are available from Omega.

The following is an example of an Omega dose chart for recommended doses with these specific probes. For other probes please contact Omega Laser Systems. The important parameters to note are the wavelength and power output named on your probe.

OMEGA LASER SYSTEMS TREATMENT GUIDE

Recommended Time/Energy Density Per Point

Treatment on conditions on the surface of the skin Use cluster for large areas, single for small lesions:

	Probe nm + mW	Time Minutes + Seconds	Surface Energy Density (ED) J/cm ²	Pulsing Frequency Hz
Surface of skin/open wounds	675nm 30mW 46 cluster	:35 2:00	6-10 6-10	2.5 - 20 Hz 2.5 - 20 Hz
<i>Verrucae and Warts:</i> Surface of skin	820nm 200mW 46 cluster	Use single first followed by cluster 1:00 96 2:00 6-10		10 KHz 10 KHz
Subcutaneous tissue Below surface of skin - 1 cm	820nm 200mW 46 cluster	:15 2:00	24 6-10	2.5 - 73 Hz 2.5 - 73 Hz
Below surface of skin - 2 cm	820nm 200mW 46 cluster	Use single first followed by cluster :20 32 3:00 10-16		2.5 - 73 Hz 2.5 - 23 Hz
<i>Pain Relief</i> Acute Pain/Neuralgia Chronic Pain/TMJ	820nm 200mW 820nm 200mW	Target the neural pathways 30 48 :45-1:00 72-96		73 - 700 Hz 73 - 700 Hz

The following is a summary combining targeted effect and physiological response, recommended probe and energy density. This is a general guide and can be discussed in more detail with Omega Laser Systems.

Targeted Tissue	Physiological Response	Recommended Probe (nm)	Recommended ED J/cm ²
Surface of skin	Local Growth Factor Response	Single Red (660nm) small areas Cluster Probe large areas	6-10 J/cm ² per point maximum 12 J/cm ²
Soft Tissue Injuries Arthritic conditions	Local Growth Factor Response	Single Infra Red (820nm)	24 J/cm ² per point maximum 48 J/cm ²
Acupuncture/Trigger Points	Point Stimulation	Single Infra Red (820nm)	24 J/cm ² per point maximum 48 J/cm ²
Pain Relief	Change in c fiber transmission	Single Infra Red (820nm/915nm)	48 - 96 J/cm ² per point
Scarring	For cosmetic and pain relief effects	Single Infra Red (820nm/915nm)	24 J/cm ² per point
Verrucae and Warts	For immune system response	Single Infra Red (820nm) AND Cluster probe	96 J/cm ² per point (5) 6-10 J/cm ² per point (1-2)

- The Dosimetry Chart gives set times and does not require clinicians to decide for themselves the energy density they are trying to achieve.
- It is good to use as a back-up checking method but the clinician should be able to decide dose for themselves.
- Recommended Energy Densities can be considered in terms of what the clinician is trying to achieve.

- Take into consideration that fatty areas and black skin absorb more light and require more energy:

Adjust dose of Energy Density to achieve depth of penetration	
Fatty areas	higher
Deep penetration	higher
Black skin	higher
Over 65	higher
Under 10	lower

- You are in control - by changing your times you can supply more or less energy between conditions and between patients.
- A 65 year old with black skin would require higher ED to stimulate a response and could be treated at 8 - 12 J/cm² per point
- A 16 year old, slim with white skin would require lower ED to stimulate a response and could be treated at 6 - 8 J/cm² per point
- 6J/cm² per point is an excellent starting point - enough Energy Density to have an effect on most patients but not taking up more of your time than is required.
- Use higher Energy Densities on stagnant injuries. If there is no resultant inflammatory response within 2 or 3 days increase the Energy Density per point within recommended dose. When the condition has shown an inflammatory response reduce the Energy Density and treat at lower doses until resolution.
- If you are not getting results within 2 or 3 treatments then increase your Energy Density within the recommend doses to provide sufficient Energy Density to the point of damage.
- **Give sufficient dose. If you under expose there will be no response. Providing sufficient Energy Density is the most important factor of your treatment. It is recommended for wounds do not exceed 16 J/cm² per point in case of over-granulation. This caution is NOT relevant to intact skin.**

See Case Histories p14-15 for complete examples of treatment protocols

Pulsing Repetition Rate (Hz/Hertz)

- Pulsing Repetition Rate is measured in Hz (the number of times per second the light is switched on and off) and represents the way the light is delivered - low, medium and high pulses.
- **Consider these as ranges and vary them between and during your treatment with patients as much as you can.**
- General guidelines on pulsing are as follows:

Laminated copies of PRR charts will be provided with the machine and are available from Omega

Pulse Repetition Rate

PRR - Rate at which light is pulsed per second (Hz)

Low (slow and gentle)			Medium (more rapid and intense)			High (very rapid and intense)		
2.5Hz	10Hz	20Hz	73Hz	146Hz	700Hz	1KHz	5KHz	10KHz
TISSUE REPAIR ACUTE INJURY GROWTH FACTOR RESPONSE RESOLVING CONDITIONS Wound and Ulcer Healing Pressure Sores Burns Post Surgical Dermatological Conditions Acupuncture Points			PAIN RELIEF TISSUE REPAIR Neuralgic Pain Maxiofacial Pain Anaesthetic effect COMBINE WITH: Low PRR (healing) High PRR (inflammatory response)			INFECTION CONTROL CHRONIC INJURY VERRUCAE Bactericidal effect Induce inflammatory response Stir up the condition/resolve infection THEN use low pulsing for resolving conditions		

Vary pulsing repetition rate to prevent accommodation

Low	2.5 - 20 Hz	• Slow, stimulatory, gentle treatment for tissue repair ulcer and wound healing. • 20Hz particularly good for cleaning an area of debris. • Use 20Hz for raised/keloid scars. • Acupuncture point stimulation
Medium	73 - 700 Hz	• Slightly more aggressive, good for pain relief • 146Hz particularly good for pain relief • 700Hz excellent for fibroblast cellularity and tensile strength • 700 Hz also used for depressed scars and for building tissue
High	1,000 - 20,000 Hz (1K - 10KHz)	• Very aggressive - used for initially inflaming conditions over the first few treatments. • However once this inflammatory effect has been produced and the condition is sub acute reduce to low pulsing frequency for more gentle stimulatory effect. • Use for bactericidal effect on infected areas. • Verrucae can be treated at any pulsing frequency. 1-10 KHz appear to be the most effective pulsing repetition rates

See Case Histories p14-15 for complete examples of treatment protocols

Pattern of Application

Probe:	Pattern of Application:
Single Red 675nm 660nm	• Use for deep pressure sores, tracking around wounds and small ulcers to target exactly the areas. • For difficult areas and wound sinuses ensure granulation occurs from the base upwards, not simply over the top of the wound • Around ulcers use at regular intervals • For cold sores use at North/South/East/West points around the lesion
Single Infra-red 820nm 915nm	• For repair apply directly onto areas of damage - usually 4 - 8 points per area of injury but could be more if the area of injury is large • For pain relief use comprehensively on nerve roots, musculoskeletal trigger points and other appropriate nerves • Treat local and distal acupuncture points as appropriate • For mosaic verrucae use in a grid pattern across the area.
Cluster Probes: 60 Diode 46 Diode 31 Diode 20 Diode	• Follow after treatment with single probe to ensure the whole area of damage has been treated • Do not use directly over a sinus or deep pressure sore (see single red probe above). However the cluster can be used "behind" the wound to encourage growth factor response under the wound • Use on flat ulcers and wounds where rapid granulation is required. This is more practical than the single probe for large ulcers. • Use in an overlapping pattern, starting at the outside of the wound, overlapping with the last area of treatment and then inside the wound to cover the whole area. • Use a grid pattern if preferred but cover the whole area and some surrounding undamaged tissue.

Frequency of Treatment

Initial treatment could be every day for 2 or 3 days to give the body a boost. However 3 times or even twice per week is sufficient for on-going treatment. Once the body has been stimulated with LILT it will continue to repair itself and does not need treatment every day. Recommended at least once per week to see consistent results.

- use as soon as possible after injury
- give frequent treatments to begin with (first 3 or 4) to ensure you have stimulated the response
- then give treatments less frequently to allow the body to continue with the repair process
- for over active conditions e.g. psoriasis or potential flare up conditions e.g. some RA ensure you leave 2 or 3 days between treatments and keep doses low
- once the condition has resolved the patient should be encouraged to contact you if any symptoms return e.g. a new ulcer, plantar fasciitis, return of neuralgic pain
- laser therapy can be used preventatively if applied at the earliest signs of damage or breakdown

Rate of Response

- How quickly you will see a response differs between patients and between conditions. However you should expect a response within 2 or 3 treatments.
- Be ready to increase your dose if there is no physiological response after 2 or 3 treatments.
- Altering PRR can also stimulate a response.
- In musculoskeletal conditions if you do not see an inflammatory response within 2 or 3 days re-consider your treatment i.e. Energy Density and area of application/damage.

See Case Histories p14-15 for complete examples of treatment protocols

Summary of Key Points

- Adjust dose according to condition and penetration through tissue. (see ED chart and pages 7-9)
- The deeper the condition the more time is needed to achieve the required Energy Density
- Vary pulsing between and within treatments to prevent accommodation. (see PRR chart and page10)
- Treat at 90° to ensure full power is applied to the tissue.
- Treat at least once per week.
- Use barrier technique to prevent cross infection and wipe probes with antiseptic before and after use.
- Warn your patient of the initial anaesthetic effect of the laser to ensure over-use of injured limb does not occur.
- Warn your patient of the potential for an initial inflammatory response. This response is short lived and has an excellent prognosis.

Case studies

Case History 1 (example):

65 year old woman, non infected but painful diabetic ulcer 20cm x 10 cm

Treatment Case History 1:

Wavelength	ED	Time	Pulsing RR	Area of app	Frequency
675nm	6 - 8 J/cm ²	See chart or p8 for treatment times for respective probes	Low	N/S/E/W	2 or 3 x per week
cluster	6 - 8 J/cm ² per point			daisy chain or grid	

After 2 treatments the ulcer is not responding:

**Use higher energy density
Alter Pulse Repetition Rate**

**After 2 treatments the ulcer shows signs of infection: Swab to identify infection
Use antibiotics**

Case History 2 (true case):

45 year old male with persistent paraesthesia and slight muscle weakness in left forearm and hand since an attack several months before. Slight decrease in grip strength, neck clear BUT did find increase in symptoms upon deep pressure over the median nerve at the elbow. His left palm and fingers were also effected.

Treatment Case History 2:

Wavelength	ED	Time	Pulsing RR	Area of app	Frequency
820nm	24 J/cm ²	See chart or p8 for treatment times for respective probes	Medium	6 pts media nerve	2 treatments once weekly
Cluster	per point			3 x elbow 3 x wrist 5 pts radial nerve	

72 hours (improved) - 8 days later disappeared - 1 week later OK

Case History 3 (true case):

28 year old male reported 2 hours after injury to muscles of lower back during a rugby football match - several players collapsed on top of him as he fell to the ground. Severe acute pain in muscles of lower back. Large bruise already apparent over lumbar spine. Tenderness in right buttock apparently unrelated to pain report.

Treatment Case History 3:

Wavelength	ED	Time	Pulsing RR	Area of app	Frequency
Cluster	8 J/cm ²	See chart or p8 for treatment times for respective probes	Low - Medium	4 x buttock	3 treatments once weekly
820nm	24 J/cm ² per point			N/S/E/W around bruise tender point	

After 24 hours experienced remission - full Lumbar movement - Spectacular bruise - 2 more treatments completely disappeared

Case History 4 (true case):

48 year old housewife - intractable neck and shoulder pain following traffic accident 12 months previous. Mild dull ache and stiffness first thing in the morning progressing to severe pain by the end of the day. Pain primarily over C3 - C7 with numerous tender trigger points producing great discomfort on palpation. X-rays showed nothing and anti-inflammatories, codeine and chiropractor had had no result, even a worsening of the condition.

Treatment Case History 4:

Wavelength	ED	Time	Pulsing RR	Area of app	Frequency
820nm	32 J/cm ² per point	See chart or p8 for treatment times for respective probes	Low	Trigger pts Cervical mobilisation TENS Severe aggravation after 12th lasting 36 hours -	1 treatment

Complete resolution - still no problem 6 weeks later

Case History 5 (true case):

36 year old woman reported constant crippling pain in her right wrist (right handed) for 3 week period since carrying heavy objects. Immediate weakness after this activity which had persisted and a 'constant aching pain' had developed which became 'sharp' when the wrist was stressed, especially in extension.

Treatment Case History 5:

Wavelength	ED	Time	Pulsing RR	Area of app	Frequency
820nm	24J/cm ² per point	See chart or p8 for treatment times for respective probes	Low - medium	6 points Hot and pain increased	1 treatment

Reported solitary treatment worked and could carry objects

For clinical guidelines see:

Wavelength	p 5 - 6
Energy Density	p 7 - 9
Pulsing Repetition Rate	p 10
Area/pattern of application	p 11
Frequency of Treatment	p 12
Rate of Response	p 12
Summary of key points	p 13

SAFE USE OF LILT

Clinical Safety

It is recommended the suitability of the patient for laser treatment is assessed and documented before commencing treatment and a Treatment Record Card is provided for that purpose (see page 50). Obtain answers to all the questions on the form to assess suitability for the treatment or any cautions you should employ.

Apart from the requirement to protect the eye from potential ocular hazard, all cautions are designed to protect the clinician as much as the patient and in many cases are based on caution rather than any proven medical concern. Do not hesitate to contact Omega with any queries not mentioned in this Manual.

CONTRAINDICATIONS:

EYE

The laser output of the probes has the potential to permanently damage the eye. Although Omega equipment is designed to be used in contact with skin to minimise the potential for ocular damage it is important that safety goggles* (approved by Omega) are worn by both the patient and clinician during treatment. **At no time during the operation of the laser equipment should the patient or clinician remove their safety goggles.**

PREGNANCY

The laser should never be applied directly over the pregnant uterus and although there is no evidence laser therapy would effect the unborn child we do not recommend treatment during pregnancy in order to protect the clinician from potential involvement. Use of LILT for ear point stimulation would be acceptable, perhaps for smoking cessation in the early stages of pregnancy. The clinic must make a decision regarding this.

CARCINOMA

LILT is used on terminal cancer patients to reduce intractable pain and to aid wound healing. However for the clinic it would be recommended not to use the laser on patients suffering from cancer unless consent is given by the consultant.

IMMUNOSUPPRESSANT DRUGS/PHOTODYNAMIC THERAPY

Any patient undergoing therapy to suppress the immune system or make cells light sensitive for cancer treatment is contraindicated for LILT to avoid any effect on the mechanism of the ID/P therapy.

*** Goggles are required to conform to Standards EN 207 and 208**

CAUTIONS:

EPILEPSY

The eyes of the patients should be completely covered to prevent inadvertent exposure to the visible, pulsed light in case it should stimulate an epileptic fit - then go ahead and treat.

PHOTOSENSITIVITY

It is extremely uncommon for anyone to be photosensitive to the wavelengths used with this equipment; the reaction is more usual to ultraviolet light/sunlight. A reaction would produce redness and tingling which would subside quickly. If anybody is potentially photosensitive, patch test for 2/3 points and leave for 24 hours in case of a reaction. This is also relevant to **DARK SKIN** – treatment over black skin, dark areas of hair and tattoos have occasionally been reported as producing a tingling, needle like sensation. Avoid treating over **DARK HAIR** as this reduces the delivery into the tissue and avoid treating over **TATTOOS**. Sensation is rare but any photosensitive reactions should be reported to the distributor or Omega for assessment.

PREVENTION OF CROSS INFECTION

The laser probe is applied directly onto the skin and must be thoroughly cleaned with an antiseptic wipe before and after use. To prevent contamination of the probe by bacteria or infection of any kind the probe should be covered with a transparent barrier (cling film) before coming into contact with the bacteria/ infection. Please note that good hand washing techniques should also be employed before and after touching the laser as with any other equipment.

Local Cross Infection Protocols must be followed if they differ from the following or if there are special requirements. However these guidelines offer general guidance in the prevention of cross infection between patients when using the Omega Laser equipment.

- Wash hands thoroughly before and after touching the probes or wear gloves.
- Wipe the tip and probe with antiseptic before and after use.
- Use a transparent barrier over the potential infection site to prevent contamination of the probe. Alternatively the chosen barrier can be used to cover the probe but must be replaced after each treatment point to prevent cross-contamination across the treated site
- Cling film is an excellent barrier. However if a sterile barrier is required, transparent sterile drapes manufactured to MDD requirements are available from Omega.
- Tips of Omega single probes, bezel of Omega cluster probes (glass lens), dental and acupuncture tips can be removed to soak or autoclave. Autoclaving of Omega lenses and bezzles are as follows:

Temperature:	134-137 °C
Cycle:	– 3.5 minute
Autoclave:	regulated to HTM 2010

DRUG REGIMES

If a patient is taking prescribed drugs that would interfere with the body's repair process these may reduce the effectiveness of the laser e.g. anti-inflammatories. Higher doses of laser may be required to have an effect with these patients.

STEROID INJECTIONS

Use of laser directly over an area of intramuscular steroidal injections is not recommended for 48 hours after the injection.

THYROID

Do not irradiate directly over the Thyroid - this is a standard precaution with any electrotherapy equipment.

PACEMAKER PATIENTS

Pacemaker Patients **CAN** be treated – however ensure the trigger point locator on the Xp is **NOT** used on a pacemaker patient – use of this application involves the transmission of a current through the body and as a precaution is not used on the patient with a pacemaker.

NOT CONTRAINDICATED:

The following points are often questioned and **ARE NOT** contraindicated or cautioned:

Pins – Metal plates – Plastic Implants – Warfarin – Children

Pacemaker Patients however see caution above with the trigger point locator on the Xp unit

Warnings and Precautions

See pp 51-52 for documented Local Rules

Transport

- The Omega Xp is a portable unit which is supplied with soft padded case which can be used to transport the equipment as hand held luggage.
- If the Omega Xp is to be shipped by third parties either by air, sea or road then the Omega Xp should be packed in a cardboard carton with minimum internal dimensions 350mm x 350mm x 550mm. Suitable packing materials such as flow pack or bubble wrap must be used to pack the Omega Xp.
- On receipt of Omega equipment it is important that the equipment is checked for any damage or defects. Check the outer wrapping carefully for any faults or breakages, however slight. If any damage is found, notify the consignor immediately, reserving the right to check the correct operation of the equipment itself. Inform Omega's offices at the following address, either in writing or by telephone.

Storage and operating conditions

- When the Omega Xp is not being used it should put back in the case provided.
- The equipment is designed to be stored and operated in the following environmental conditions:
 - ambient temperature from +10 to + 40 degrees centigrade
 - relative humidity from 30% TO 75%
 - atmospheric pressure range of 700 hPa to 1060 hPa

Warnings

- The use of Omega equipment in ways other than as specified in this manual could cause hazardous exposure to laser radiation
- The Manufacturer remains liable for apparatus reliability and safety with the exception of the following cases:
 - Modifications and/or repairs carried out by unauthorised personnel
 - Failure of the electrical mains installation to comply with IEC standards
 - Use of apparatus other than as specified in the instructions in this manual.
- When the laser probe is activated the Xp emits a warning bleep before the probe begins to emit and another bleep when treatment time is complete and the probe has stopped emitting.
- In accordance with MDA guidelines there is no target indicating device as the probes are used in contact with the skin.
- The Xp unit and probes should not be used for ophthalmic treatments and the probes should never be used directly in the eyes.
- The device complies with EMC requirements according to IEC 60601-1-2.
- Radio transmitting equipment, cellular phones etc shall not be used in the close proximity of the device since this could influence the performance of the device.

- Particular precaution must be considered during use of strong emission sources such as High Frequency surgical equipment and similar so the e.g. the HF cables are not routed on or near the device. If in doubt consult a qualified technician or your local representative.
- This is a Class 1 Type B continuous operation device. Not for use in the presence of flammable anaesthetic mixtures in accordance with clause 5 and 6.8.1 IEC 60601-1. There is no emission from the unit that could ignite such materials but this is a standard precaution.

Safety Precautions

- The Omega Xp has been designed to comply with current safety regulations for electro-medical equipment. However, the following precautions should be taken:
 - always connect the power supply cable with the key switch in the off position.
 - turn the Xp off before disconnecting the cable
 - never put fingers or metal objects in the laser apertures to avoid damage to the laser diodes.
 - in the event of danger, shut down the apparatus by means of the red button
 - Check the position and meaning of all the labels on the Xp and probes
 - use of the apparatus by unauthorised personnel is strictly prohibited
 - always remove the key from the mains switch and store under restricted access to avoid improper or incorrect use by unauthorised personnel
 - never point the laser beam at the eyes and always wear safety goggles when the equipment is in use

Lifetime/shelf life of spare parts

Spare parts for equipment will be maintained for 5 years after the goods have ceased to be manufactured.

For servicing and support refer to your local distributor or contact Omega.

Maintenance and troubleshooting

Cleaning

- The Omega Xp should only be cleaned once the unit is switched off and the mains lead or battery disconnected. The Omega Xp and probes can be cleaned and dusted using a soft, dry cloth. More stubborn stains or marks can be removed using a cloth dampened with water or a mixture of water and alcohol.
- The coloured tips of Omega single probes and the bezel of Omega cluster diode probes are removable so they can be disinfected using products normally employed for electro-medical equipment (see p 17 for full details)
- No hazard flammability is associated with standard cleaning materials used for this equipment (alcohol or detergents), given the low temperatures reached by laser emissions. The Omega Xp is not suitable for use in the presence of anaesthetic which becomes flammable with air, oxygen, or nitrous oxide.

Routine maintenance

- The Omega Xp and probes do not require any special maintenance. The equipment should be sent annually to be serviced and calibrated by Omega Laser Systems or authorised service engineers.
- The manufacturer declines all liability for apparatus reliability and safety in the event of the following:
 - modifications or repairs carried out by unauthorised personnel
 - failure of the electrical mains installation to comply with IEC standards
 - use of the equipment other than as specified in this manual

Troubleshooting

- In the event of apparatus malfunctions, carry out the following checks:
 - check the plug is connected properly to the mains power socket
 - check the interlock plug is connected properly if a foot switch is being used
 - check all operations have been carried out correctly
 - check all mains fuses and replace if necessary (see section below)

Fuse replacement

- To replace fuses, proceed as follows:
 - disconnect the apparatus from the power mains
 - remove the fuse holder cover located on the mains socket by means of a small screwdriver
 - replace fuses using T500 mA HBC 250V fuses
 - refit fuse holder cover
 - switch on the apparatus

Biocompatibility of applied parts

Material used for parts that come into contact with the patient:

BS1471 HE 30 Aluminium

Toughened plate glass

303 stainless steel

Glass Fibre Optic tip

All these materials have been in common use in medical devices for many years with no reported adverse effects. The temporary nature of the contact with the patient and the fact that contact is non invasive mean that there is no requirement for further testing of the materials in accordance with ISO 10993. However should there ever be any concern related to these materials please contact Omega .

Technical assistance

If technical assistance is required, please contact Omega at the following address

Omega Laser Systems Ltd

2 Deans Hall Business Park
Oak Road, Little Maplestead
Halstead

Essex CO9 2RT

United Kingdom

Tel: +44 (0)1787 477551

Fax: +44 (0)1787 477510

Technical documentation regarding repairable parts may be supplied, subject to company authorisation, and only after the specialised personnel have received adequate instruction regarding the operations.

Warranty

- Omega equipment is provided under warranty for 1 year.
- All equipment is calibrated and checked prior to despatch. One free service is included within the warranty period. Transportation of equipment for this warranty service outside of the UK will be charged.
- Within the warranty period there will be no charge for parts and labour.
- Damage caused by misuse of the equipment will not be covered by the warranty statement.
- Any unauthorised repairs may void the warranty

The company policy of Omega is to constantly update and develop its product ranges with the objective of achieving higher standards of performance and safety. Omega reserve the right to change the design and performance of its product and the content of the Manual without prior notice or liability on its part.

Be aware of the warning of the potential for laser emission and read accompanying documents before use.

Training and Qualifications

- Users of Omega lasers should ensure they abide by any National requirements for legal or registration issues. Contact Omega for more advice.
- Omega will accept no responsibility for users who have not received training with Omega staff or Omega authorised training staff. Contact Omega for details.
- It is the responsibility of the user to appoint a laser supervisor and thoroughly read the manual.
- Additional independent safety and clinical courses are available. Contact Omega for details.

Disposal

When the equipment has reached the end of its useful life there is no particular risk associated with disposal. However please contact Omega if required who are able to dispose of the equipment if applicable.

OPERATING INSTRUCTIONS

Understanding the Keys and Functions:

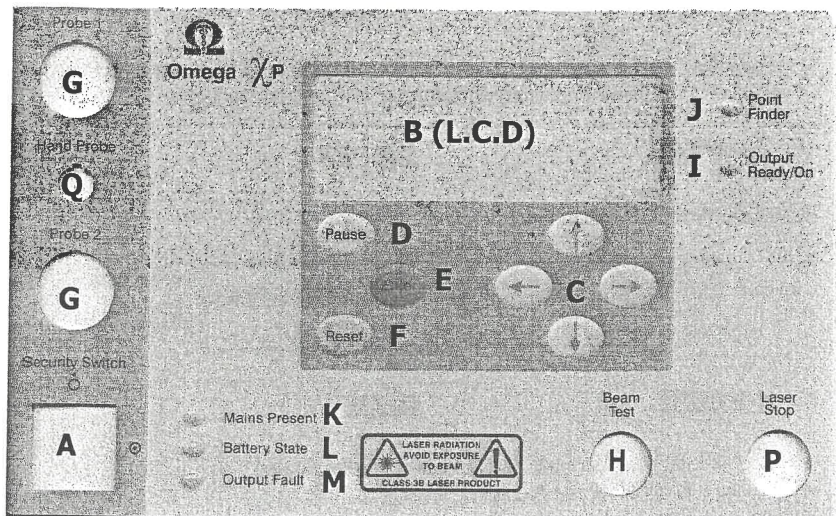
A. KEY SWITCH:

- Used to turn your machine on (clockwise) and off (anticlockwise).
- When the key is removed the machine cannot be activated.
- When the machine is not being used the key should be returned to the area of safe keeping. (See pp 42-49 for documented Local Rules)

B. LIQUID CRYSTAL DISPLAY (LCD)

There are 7 screens:

Welcome	Welcome to Omega Laser Systems Helpline 01787 477551			
Set Treatment	Treatment Standard Treatment A'puncture Treatment Multipulse Beam Power Test			see page 28 see page 32 see page 35
Beam Power Test	Position Probe 1 in Beam Test and Activate Output = mW			see page 35
Select Probe	Select Probe: Probe 1: Not fitted Probe 2: Not fitted			
Set Treatment Time	Treatment Time 00:00		Surface ED J/cm sq 0000.0	
PRR	Pulsing Rate Per Sec LOW: 2.5 10 20 MED: 73 *146 700 HIGH: 1K 5K 10K			
A'puncture Sensitivity Level	1 Low Sensitivity 2 3 4 High Sensitivity			
Run A'puncture	Skin Conduct 00		Treat Time 00:00 Total Time 00:00	
Run Standard Multipulse	Treat Time 00:00	P/Rate	Total Time 00:00	



- Use the $\leftarrow \uparrow \rightarrow \downarrow$ keys to move around the screen
- Use the ENTER (green) button (E) to select the required function and to move to the next screen
- Use the PAUSE (yellow) button (D) to move back through the screens
- Use the RESET (blue) button (F) to return straight back to Select Probe Screen

C. BUTTONS FOR MOVING AROUND THE SCREEN

$\uparrow$ = up

- Move your cursor upwards in any screen
- Increase minutes in the treatment time screen
- Use $\rightarrow$ to locate seconds then $\uparrow$ to increase seconds in the treatment time screen

$\downarrow$ = down

- Move your cursor downwards in any screen
- Decrease minutes in the treatment time screen
- Use $\rightarrow$ to locate seconds then $\downarrow$ to decrease seconds in the treatment time screen

$\leftarrow$ = left

- Move your cursor to the left in any screen

$\rightarrow$ = right

- Move your cursor to the right in any screen

D. PAUSE

YELLOW

- Pause the laser at any time (the button on the probe has the same function)
- Allows the clinician to go back through the screens one by one

E. ENTER

GREEN

Select the function required e.g.:

Set
Treatment
Time

Treatment Standard
Treatment Apuncture
Treatment Multipulse
Beam Power Test

Position cursor

ENTER

F. RESET

BLUE

- Takes the clinician straight back to Select Probe Screen
- Easy way to clear all previous programme
- Does not clear total treatment time
- To clear Total Treatment time turn off the machine

G. PROBE SOCKETS 1 AND 2

- These are where the laser probes are connected to the base unit.
- Numbered Probe 1 and Probe 2
- Any probe fits any socket. For BEAM TEST it is advised:

Beam
Power Test

Position Probe 1 in Beam Test
and Activate
Output = mW

- Note a small screw on the probe connectors
- With this screw pointing towards the operator slide the connector into the hole - it should slide in easily and should not require force.
- The probe connector should be securely screwed into place
- Probes can be left screwed into the connectors when the machine is turned off

H. BEAM TEST

- Allows you to accurately test the power output of the single probes
- The LCD will indicate the power out-put of the probe in mW
- Turn the probe slightly in the BEAM TEST and see the slight variation in power output due to the elliptical nature of the beam
- Test the probes regularly (per day or per week as convenient) to ensure probes are operating within tolerance levels of stated power output

I. OUTPUT READY/ON L.E.D (Yellow)

- When the yellow LASER READY L.E.D is **on** the laser probe is capable of being activated
- When the yellow LASER READY L.E.D is **flashing** the probe is emitting. This is a safety feature and the clinician should always be aware that the LED is red or flashing

J. POINT FINDER ON L.E.D (Blue)

- When the acupuncture point finder is being used the blue POINT FINDER L.E.D is a visual indicator of the proximity of the probe to an acupuncture point, allowing the clinician to be aware of how close to a point the probe is:
 - ji. Slow flashing – the lowest indication of proximity – there is a point close but not close enough
 - jii. Rapid flashing – very close to the point but not quite enough.
 - ji. When the blue POINT FINDER L.E.D is **on** the sensitivity measurement is above 20, indicate an acupuncture point, and the probe will begin emitting. The Output Ready/On L.E.D. (I) should be flashing indicating emission.

K. MAINS PRESENT L.E.D (Green)

When Xp unit is connected to the mains the MAINS PRESENT L.E.D. will be illuminated in green. When the battery is being recharged from the mains this L.E.D. will be illuminated.

L. BATTERY STATE L.E.D (HIGH Green) (MEDIUM Yellow) (LOW Flashing Yellow)

- The batteries are charged when the unit is plugged into the mains supply, irrespective of the position of the key switch
- There are 2 rates of charge: Fast(1.2 amps) and Trickle (0.16 amps)
- Upon connecting the unit to the mains supply (key switch off) batteries are charged at fast charge until fully charged – this will be achieved within **3 – 4 hours** from full discharge.
- Once the batteries are fully charged the unit reverts to trickle charge, allowing the unit to be continually left connected to the mains to ensure fresh batteries for the next use. The automatic change from fast to trickle charge once the battery is fully charged prevents any possibility of damage to the cell batteries.
- Application of mains power with the **key switch off** will always start **fast charge**, even with fully charged batteries, however it will revert to trickle charge after 15minutes.
- Application of mains power with the **key switch on** will always start **trickle charge**.
- A fully charged battery will provide **3 hours** continuous operation with the **cluster probe** and **5 hours** of continuous operation with the **single probes**.

- The battery/charge status L.E.D. indicates as follows:

Mains	Keyswitch	Battery/charge status L.E.D.	Mains Power LED
Off	Off	Off	Off
Off	On	High Green Medium Yellow Low Flashing Yellow 30 mins remaining	Off
On	Off	Fast Charge Flashing Green Trickle/Full Green	Green
On	On	Off	Green

M. OUTPUT FAULT L.E.D (LOW POWER Flashing Red) (HIGH POWER Red)

- During treatment the output of the laser probe is constantly monitored to make sure that power output remains within tolerance.
- If the **power output (mW)** of the probe is more than **20% below** the output stated on the label the OUTPUT FAULT L.E.D. will **flash red**. The probe will continue to emit.
- If the **power output (mW)** of the probe **exceeds more than 20%** of the output stated on the label the OUTPUT FAULT L.E.D. will be continuous **red** and the probe will stop immediately.
- The clinician should contact Omega or authorised representative for service/repair whenever the OUTPUT FAULT L.E.D. is illuminated.

N. POWER/MAINS INLET SOCKET

O. INTERLOCK

To allow the use of a footswitch or door switch to turn off the laser equipment if someone comes into treatment room while the laser is being operated. If the user has a requirement for the Interlock facility please contact the Distributor and/or Manufacturer. They will be able to provide the procedure for installing the Interlock as well as providing all the relevant parts and expertise.

P. LASER STOP

Pressing this button immediately stop the laser from emitting. To deactivate this switch once it has been activated, pressed the button again.

Q. HAND PROBE SOCKET

To allow the use of the acupuncture/trigger point finder, the hand probe must be plugged in to this socket.

Operating the Xp Laser Base Unit

Introduction

Before using the Omega Xp ensure you have received training from an Omega member of staff or their authorised training staff and that you have read thoroughly all the accompanying documents.

The Omega Xp is maintained in a padded case for protection against accidental damage. Once it has been removed from the case it is important that the unit is initially given a visual inspection to make sure that has been no obvious damage caused in transit.

In the case there will also be:

- 2 mains key switches
- 1 mains lead
- 2 pairs of safety goggles
- Laser warning sign that can be put outside the room being used for treatment
- A copy of this manual
- A selection of probes to be used in treatment

The Xp unit can be operated from Mains supply or from Battery.

MAINS: Connect the mains lead to the socket marked N on the Xp diagram and plug the other end into the mains supply. Switch on the unit using the security key switch A. The Mains Present L.E.D. (K) will be green.

BATTERY: Switch on the unit using the mains power key switch A. The Battery State L.E.D. (L) will indicate the current state of charge. See (L) for instructions.

In the case will also be a variety of probes to be used in treatment. These are plugged into the sockets on the side of the unit marked G on the Xp diagram. To plug in a probe the plug must be lined up with the pins of the socket and pushed home. There is a locking screw thread which should always be used to prevent the probe accidentally becoming loose and coming out of the socket.

The probes can be used in either socket.

It should always be remembered that safety goggles should be always be worn by the user and the patient while the Xp is being used.

Power Output (mW) and Pulse Repetition Rate (Hz) check:

Regularly check the power output of the single probes using the Beam Test (see 3 below for instructions). If the beam power output is more than 20% lower than the label indicates, please contact Omega.

To check the PRR, select standard treatment, single or cluster probe, time 30 seconds and PRR 2.5Hz. Activate the probe and check the 'probe on' LED is flashing and not continuous. If the 'probe on' LED is not flashing at 2.5 Hz but is emitting a continuous output, the probe is not pulsing correctly, please contact Omega.

Use of Omega Probes

Omega Probes are ergonomically designed for ease of use. The handle has two flat sides and a rubber top to prevent probes from slipping on smooth surfaces.

The Omega Xp has two probe sockets so two probes can be attached. Only one probe can be used at any one time

After training you will be confident to begin treatment.

Single Diode Probes

- select the probe checking the label carefully
- visible laser single probes have red diode covers and invisible laser single probes have blue diode covers for ease of recognition (Always check the label in case diode covers have been incorrectly fixed)
- there is a laser aperture label on the side of the probe indicating where the laser aperture is
- to connect the probe to the Omega Xp push the cable connector
- into either probe 1 or probe 2 socket and tighten the screw lock.
- using the instructions given in later sections on this manual you will be able to programme the treatment
- when in the select probe menu the Omega Xp will recognise the probes in the sockets and will ask for confirmation of your choice of probe
- once programmed for treatment the probe is capable of being activated
- to activate the probe press the raised rubber circular section to the front end of the probe and release
- **remember to wear safety goggles at all times during treatment**
- once activated the L.E.D. in front of the switch will light
- to stop the probe press the circular raised rubber circular section to the front end of the probe and release
- to remove a probe simply unscrew the screw lock and pull the probe out holding the plug and the Omega Xp

Multiple Diode Probes

- operating the cluster multiple diode probes is the same as for the single diode probes because the handle is common to both probes
- For ease of use the cluster probes have an adjustable head that rotates 90 degrees in one plane

Cleaning Omega probes

Single diode and multiple diode probes can be cleaned in the same way as the Omega Xp (see p17). Furthermore the coloured diode covers of the single probes can be removed to allow thorough disinfection to prevent cross infection. Once the tip is removed for cleaning replace it with a blank plastic diode cover to prevent unintentional damage to the diode.

The probes have been designed to be used with the blue or red tips screwed on. Never use the probes without these coloured diode covers.

1.0 To Set Treatment Standard

This programme is used when you wish to use a single pulsing repetition rate for treatment, for example only 20Hz or only 146Hz.

1.1 Turning on the Xp Laser Base Unit

Plug the mains lead into the machine if mains is required and turn the Mains Key Switch clockwise. The **welcome screen** will appear:

Welcome to Omega Laser Systems Helpline 01787 477551

followed by the **treatment selection screen**.

1.2 Treatment Selection

To select Treatment Standard use the $\uparrow\downarrow$ buttons to move the cursor to highlight Treatment Standard and press ENTER (the green button).

Treatment Standard	Position cursor
Treatment A/puncture	
Treatment Multipulse	
Beam Power Test	ENTER

1.3 Probe Selection

Having selected Treatment Standard the **select probe screen** will appear. Probes to be used in treatment should be placed in the sockets marked Probe 1 and Probe 2 and the screw lock tightened to secure the probes.

See p 5 - 6 for
clinical
guidelines

Select Probe:	Position cursor
Probe 1: 820nm 50mW	
Probe 2: 46 cluster	ENTER

Any probe can be connected to any socket. However for Beam Test the single probe should be connected in Probe Connector 1. Use the $\uparrow\downarrow$ buttons to move the cursor to highlight the probe to be used and press ENTER (the green button) to confirm the selection.

1.4 Dose/Treatment Time/Energy density

Having selected the probe to use for treatment the **treatment time screen** will appear and the cursor will be flashing on the minute indicator.

See pp 7-9 for
clinical
guidelines

Treatment Time	Surface ED J/cm sq	Select Treat Time
00:00	0000.0	ENTER

To select the treatment time use the $\uparrow\downarrow$ buttons to increase and decrease the number of minutes. Pressing the $\rightarrow$ button will move the cursor to allow the number of seconds to be set in multiples of five seconds using the $\uparrow\downarrow$ buttons. If the $\uparrow\downarrow$ buttons remain depressed this allows rapid, continuous scrolling through time. Press ENTER (the green button) to confirm selection. The energy density calculation on the right side of the display will change with

time. The Xp automatically recognizes each Omega probe and output power and will calculate the surface energy density for any particular Omega probe for a given time. If you know the dosage per point you wish to treat with it is possible to scroll through minutes/seconds until the required dosage is reached. It should be remembered that the Energy Density calculation is for the skin's surface only.

Example: 820nm 50mW.	Treatment		Surface ED	Select Treat Time ENTER
	Time		J/cm sq	
	01:00		0024.0	

1.5 Pulsing Repetition Rate (PRR)

Having selected the treatment time the **Pulsing Rate per second (PRR) screen** appears.

See p 10 for clinical guidelines	Pulsing Rate Per Sec				Select PRR ENTER
	LOW:	2.5	10	20	
	MED:	73	*146	700	
	HIGH:	1K	5K	10K	

Selection is made using ←↑→↓ buttons to move the cursor to highlight the required PRR. Selection is made by pressing ENTER (the green button). If the ENTER button is pressed accidentally on the wrong PRR then press the PAUSE (the yellow button) and the **PRR screen** will reappear. To change the PRR move the cursor over the correct PRR and press ENTER (the green button)

1.6 Activating the Laser

Having selected the type of treatment, the probe, the treatment time and the pulsing repetition rate, the **run screen** is showing and ready to commence treatment.

Treat Time 01:00	P/Rate 146	Total Time 00:00	Press the button on the side of the probe to activate

The yellow LASER READY/ON L.E.D. should be lit indicating the laser is capable of being activated. To begin treatment press the button on the side of the probe. The laser will start emitting and the LASER READY/ON L.E.D. will start flashing to give a visual warning that the laser is in use. The L.E.D on the probe will also be lit during emission.

1.6.1 BEAM ATTENUATION

At any point during treatment the equipment can be stopped. This can be done in five different ways.

- 1.6.1.1 **Pressing the button on the probe.** The treatment is paused with the current point treatment time held. This might be done for example if someone walks into the room without safety goggles.
- 1.6.1.2 **Pressing the PAUSE (the yellow button) on the machine** to scroll back through the screens one by one. The treatment is paused and the **PRR screen** appears. This may be done if it is decided a different PPR is more appropriate but you still want to hold the time per point so far treated. Simply move the cursor over the new PPR and press ENTER (the green button). The **run screen** will appear with the new PPR displayed but point treatment time unaltered. The probe can then be reactivated.

- 1.6.1.3 **Pressing the RESET (the blue button).** The treatment is stopped with the point treatment time cancelled and a new probe selection required. The treatment type will still be Treatment Standard
- 1.6.1.4 **Pressing the Laser Stop (Red circular button).** This will immediately stop the laser output from the probe. To enable laser output the red button must be pressed again.
- 1.6.1.5 **Switching off the machine using the key switch.** This will stop the treatment turning off the machine and cancelling the treatment programme as well as the total treatment time.

1.7 Monitoring Treatment

While treating the patient the Treatment Time will count down on the display and the Total Treatment time will increase. When the point treatment time is completed the laser will automatically switch off and default back to the point treatment time that was previously programmed - this is an advantage when you are using the same point treatment regime several times. Total treatment time indicates the time the laser has been emitting since the Xp was switched on. For example, if you have treated at 1 minute per point for 4 points the total treatment time will be 4 minutes. To repeat the treatment for another point simply press the button on the side of the probe.

Treat Time	P/Rate	Total Time
01:00	146	04:00

Press the button on the side of the probe to activate

1.8 Stopping the Treatment

At any point during treatment the equipment can be stopped. This can be done in five different ways.

- 1.8.1 Pressing the button on the probe. The treatment is paused with the current point treatment time held. This might be done for example if someone walks into the room without safety goggles.
- 1.8.2 Pressing the PAUSE (the yellow button) on the machine to scroll back through the screens one by one. The treatment is paused and the **PRR screen** appears. This may be done if it is decided a different PPR is more appropriate but you still want to hold the time per point so far treated. Simply move the cursor over the new PRR and press ENTER (the green button). The **run screen** will appear with the new PRR displayed but point treatment time unaltered. The probe can then be reactivated.
- 1.8.3 Pressing the RESET (the blue button). The treatment is stopped with the point treatment time cancelled and a new probe selection required. The treatment type will still be Treatment Standard
- 1.8.4 Pressing the Laser Stop (Red circular button). This will immediately stop the laser output from the probe. To enable laser output the red button must be pressed again.
- 1.8.5 Switching off the machine using the key switch. This will stop the treatment turning off the machine and cancelling the treatment programme as well as the total treatment time.

1.9 Amending treatment programmes (from run screen)

1.9.1 Changing Dose/Treatment Time/Energy Density

If it is decided to change the treatment time once the treatment programme has been fully set this can be done without changing the PRR. Press PAUSE (the yellow button) until you reach the **set treatment time screen**.

See pp 7 – 9
for clinical
guidelines

Treatment Time 01:00	Surface ED J/cm sq 0024.0
----------------------------	---------------------------------

Select Treat Time
ENTER

Use the ↑↓ buttons to increase or decrease the treatment time and press ENTER (the green button) to confirm the selection. The **run screen** will appear immediately and the probe can be activated.

1.9.2 Changing the probe

This can be done in 2 ways:

1.9.2.1 Pressing the PAUSE (the yellow button) 3 times will take the clinician back to the **select probe screen**. Use the ↑↓ buttons to move the cursor to the preferred probe and press ENTER (the green button). The treatment time previously set will have been cancelled but the total treatment time will be unaffected.

1.9.2.2 Pressing the RESET (the blue button) will default back to the **select probe screen**. Use the ↑↓ buttons to move the cursor to the preferred probe and press ENTER (the green button). The treatment time previously set will have been cancelled but the total treatment time will be unaffected. The treatment type will still be Treatment Standard. If Treatment Multipulse or Beam Power Test are required press PAUSE (the yellow button) and the **treatment selection screen** will appear. Treatment Multipulse or Beam Power Test can then be selected by moving the cursor over the required option and pressing ENTER (the green button).

1.9.3 Changing the Pulsing Repetition Rate (PRR)

Press the PAUSE (the yellow button) and **PRR screen** will appear. Use the ↑↓ buttons to move the cursor to the preferred PRR and press ENTER (the green button). The **run screen** will reappear at exactly the same point the treatment was paused. Press the button on the side of the probe to continue treating.

1.9.4 Changing the Treatment Standard/Treatment Multipulse

Pressing the STOP (the blue button) will default back to the **select probe screen**. Press PAUSE (the yellow button) and the **treatment selection screen** will appear. Treatment Standard or Multipulse can then be selected by moving the cursor over the required option and pressing ENTER (the green button).

2.0 To Set Treatment Multipulse

This treatment programme is used when the clinician wishes to use 3 automatically rotating PRR's without having to reprogramme the treatment details for the new PPR. Once the treatment programme is set the PRR's will change every 5 seconds between the 3 selected PRR's

2.1 Turning on the Xp Laser Base Unit

Plug the mains lead into the machine if mains is required and turn the Mains Key Switch clockwise. The **welcome screen** will appear:

Welcome

Welcome to Omega Laser Systems Helpline 01787 477551

followed by the **treatment selection screen**.

2.2 Treatment Selection

To select Treatment Multipulse use the $\uparrow\downarrow$ buttons to move the cursor to highlight Treatment Multipulse and press ENTER (the green button).

Treatment Selection

Treatment Standard
Treatment A puncture
Treatment Multipulse
Beam Power Test

 Position cursor
ENTER

2.3 Probe Selection

Select probe as described in section 3.

2.4 Dose/Treatment Time/Energy density

Select the treatment time/Energy Density as described in section 1.4.

2.5 Pulse Repetition Rate (PRR)

Treatment Multipulse allow 3 PRR's to be selected. Using the $\leftarrow\rightarrow\downarrow$ buttons move the cursor to each chosen PRR and press ENTER (the green button).

Only once the 3 PRR's have been selected will the **run screen** appear and the Probe be capable of being activated.

See p 10 for clinical guidelines

Pulsing Rate Per Sec			
LOW:	2.5	10	20
MED:	*73	*146	*700
HIGH:	1K	5K	10K

 Select
3 x PRR
ENTER

To change a selected PRR before all 3 PRR's have been selected move the cursor over the PRR to be changed and press ENTER (the green button). This will cancel the selection and allow you to move the cursor to the correct PRR.

To change any of the PRR's once all 3 PRR's have been selected and the **run screen** is showing press PAUSE (the yellow button) to return to the **PRR screen**. Again, as above, cancel current PRR by positioning cursor and pressing ENTER (the green button) to clear, then position the cursor over a new PRR and ENTER to select.

2.6 Activating the Laser

You have now chosen the type of treatment, the probe, the treatment time and the pulsing repetition rate and are in the **run screen** ready to commence treatment. The yellow OUTPUT READY/ON L.E.D. will be lit indicating the laser is capable of being activated. To begin treatment, press the button on the side of the probe. The laser will start emitting and the OUTPUT READY/ON L.E.D. will start flashing to give a visual warning that the laser is in use. The yellow L.E.D on the probe will also be lit during emission.

Treat Time	P/Rate	Total Time
01:00	73 146 700	00:00

Press the button on the side of the probe to activate

2.7 Monitoring Treatment

While treating the patient the Treatment Time will count down on the display and the Total Treatment Time will increase. When the point treatment time is completed the laser will automatically switch off and default back to the point treatment time that was previously programmed - this is an advantage when you are using the same point treatment regime several times. Total treatment time indicates the time the laser has been emitting since the Xp was switched on. For example, if you have treated at 1 minute per point for 4 points the total treatment time will be 4 minutes. To repeat the treatment for another point simply press the button on the side of the probe.

Treat Time	P/Rate	Total Time
01:00	72 146 700	04:00

Press the button on the side of the probe to activate

2.8 Stopping the treatment

At any point during the treatment you can stop or pause the equipment. This can be done in five different ways. For detailed description see section 1.8:

- 2.8.1 Using the button on the side of the probe
- 2.8.2 Using the PAUSE (the yellow button).
- 2.8.3 Using the RESET (the blue button).
- 2.8.4 Using the Laser Stop (red circular button)
- 2.8.5 Using the Switch.

2.9 Amending treatment programmes (from run screen)

At any point during the treatment you can amend the programmed treatments.

2.9.1 Changing Dose/Treatment Time/Energy Density treatment time

See section 1.9.1

2.9.2 Changing the probe

See section 1.9.2

2.9.3 Changing the Pulsing Repetition Rate (PRR)

Press the PAUSE (the yellow button) and **PRR screen** will appear. Use the ↑↓ buttons to move the cursor to the PRR to be cancelled and press ENTER (the green button). The * indicating the PRR will have disappeared showing the PRR has been cancelled. Use the ↑↓ buttons to move the cursor to the preferred PRR and press ENTER (the green button). The * will now indicate the newly selected PRR. When 3 PRR have been selected and entered the **run screen** will reappear at exactly the same point the treatment was paused. Press the button on the side of the probe to continue treating.

2.9.4 Changing the Treatment Standard/Treatment Multipulse

Pressing the RESET (the blue button) will default back to the **select probe screen**. Press PAUSE (the yellow button) and the **treatment selection screen** will appear. Treatment Standard or Multipulse can then be selected by moving the cursor over the required option and pressing ENTER (the green button).

3.0 To Set Beam Test

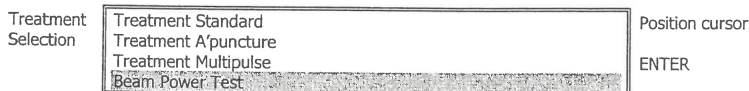
This is used when the clinician wishes to test the beam power output of the single probes. The beam test routine bypasses the output monitor system and will allow output from the probes outside the 20% allowed tolerance. If the probe has been stopped from emitting because the output monitor system has detected output above tolerance do not then check the output of the probe using the beam test. Contact Omega or your nearest authorised service centre to have the equipment inspected.

3.1 Connect Probe

Connect the single probe to Probe Connector 1.

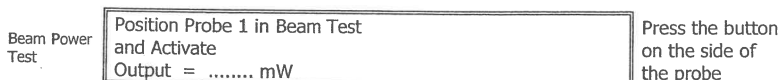
3.2 Treatment Selection

Select Beam Power Test in the Treatment Selection Screen using the ↑↓ buttons to move the cursor to highlight Beam Power Test and press ENTER (the green button).



3.3 Beam Power Test

Position the tip of the Probe in the Beam Test Aperture and activate the probe by pressing the button on the side. The Beam Power Test Screen will indicate the power output of the probe in mW. The power output is tested at PRR 10KHz.



3.4 Returning to treatment

When the power output has been tested, press the button on the side of the probe to stop the probe and return to Treatment Selection Screen.

3.5 Low Power Output

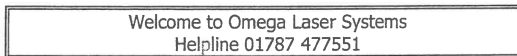
If the power output reading is more than 20% below the stated output on the probe label then the Xp's output monitor system will activate the red Output Monitor LED. Output will continue but the user is advised to contact Omega or your authorised Service Engineer to discuss appropriate repair.

4.0 To Set Treatment Acupuncture

This programme is used when you wish to use the acupuncture point finder to identify acupuncture or pain trigger points and then treat. The patient holds a conductive hand probe and using the acupuncture tip on the single probe the resistance is measured. Acupuncture/trigger points or damaged tissue are indicated by a lower resistance than other parts of the body.

4.1 Turning on the Xp Laser Base Unit

Plug the mains lead into the machine if mains is required and turn the Mains Key Switch clockwise. The **welcome screen** will appear:



followed by the **treatment selection screen**.

4.2 Treatment Selection

To select Treatment Acupuncture use the ↑↓ buttons to move the cursor to highlight Treatment Standard and press ENTER (the green button).



4.3 Probe Selection

Select probe as described in section 3.

4.4 Dose/Treatment Time/Energy density

Select the treatment time/Energy Density as described in section 1.4.

4.5 Pulsing Repetition Rate (PRR)

Select the PRR as described in section 1.5.

4.6 Sensitivity Level

Ensure the Hand Probe is plugged into the Hand Probe aperture (Q) and the patient is holding the hand probe.

Select the level of sensitivity required. The higher the sensitivity level the greater the sensitivity to resistance. The Lowest sensitivity setting is the least sensitive to skin resistance.

Start with low sensitivity – position the cursor and ENTER.

1	2	3	4
---	---	---	---

Position cursor
ENTER

4.7 Skin Conduction Measurement

APS 1	Acu-find 00
POINT	TOTAL
00:15	00:00

Press the button on the side of the probe to activate

The screen example above indicates sensitivity level 1 has been selected and a treatment time of 15 seconds per point has been entered. Total treatment time is 00:00 – the unit has not yet been activated.

The yellow Output/Ready L.E.D. will be illuminated indicating the probe is ready to be fired. However this will not be possible unless an acupuncture point has been detected.

Place the metal acupuncture tip of the probe on the skin of the patient. Note the Skin Conduct level. If the probe is in proximity to an acupuncture point/pain trigger point the Skin Conduct level will show a numerical increase. When the Skin Conduct reaches between 7 and 15 the blue Point Finder L.E.D. will flash slowly.

APS 1	Acu-find 05
POINT	TOTAL
00:15	00:00

When the Skin Conduct reaches between 15 and 19 the blue Point Finder L.E.D. will flash more quickly.

APS 1	Acu-find 11
POINT	TOTAL
00:15	00:00

When the Skin Conduct reaches 20 and above the blue Point Finder L.E.D. will remain constantly illuminated and the probe will automatically begin to emit.

APS 1	Acu-find 20
POINT	TOTAL
00:15	00:00

Acu point indicated.
Treat time will begin to count down

To stop the probe remove the tip from the skin and the probe will automatically stop emitting.

4.8 Changing the Sensitivity Level

If the clinician is finding it difficult to locate the acupuncture point on the Low Sensitivity Level it is necessary to select Sensitivity Level 2. Press the Yellow Pause button to move back to the Sensitivity screen (see below). Move the cursor to highlight Level 2 and Enter.

1 Low	2	3	4 High
----------	---	---	-----------

Position cursor
ENTER

Now you are again in the Acupuncture run menu with the only difference being the Sensitivity Level is now 2 and therefore it will be easier to locate the acupuncture points.

APS 2	Acu-find 20
POINT 00:15	TIME TOTAL 00:00

Follow the steps in 1.7 above.

If the clinician is still experiencing difficulty in identifying the points check the following:

- The hand probe is plugged into the Xp unit
- The patient is holding the hand probe
- The correct Sensitivity Level has been selected for that patient
- The proximity of the point is indicated by the numerical skin conduction reading and the blue L.E.D.

4.9 Monitoring Treatment

While treating the patient the Treatment Time will count down on the display and the Total Treatment time will increase. When the point treatment time is completed the laser will automatically switch off and default back to the point treatment time that was previously programmed - this is an advantage when you are using the same point treatment regime several times. Total treatment time indicates the time the laser has been emitting since the Xp was switched on. For example, if you have treated at 1 minute per point for 4 points the total treatment time will be 4 minutes. To repeat the treatment for another point simply move the probe to another acupuncture point and when it has been successfully located the probe will automatically start to emit.

APS 1	Acu-find 20
POINT 00:15	TIME TOTAL 00:00

4.10 Stopping the treatment

At any point during the treatment you can stop or pause the equipment. This can be done in five different ways. For detailed description see section 1.8:

- 4.10.1 Using the button on the side of the probe
- 4.10.2 Using the PAUSE (the yellow button).
- 4.10.3 Using the RESET (the blue button).
- 4.10.4 Using the Laser Stop (red circular button)
- 4.10.5 Using the KEY Switch.

4.11 Amending treatment programmes (from run screen)

At any point during the treatment you can amend the programmed treatments.

4.11.1 Changing Dose/Treatment Time/Energy Density treatment time

See section 1.9.1

4.11.2 Changing the probe

See section 1.9.2

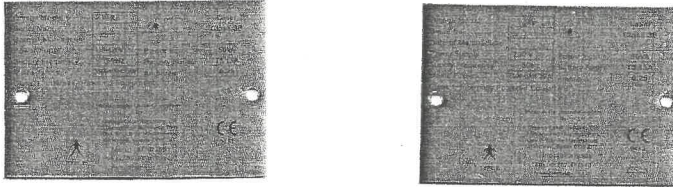
4.11.3 Changing the Pulsing Repetition Rate (PRR)

See section 1.9.3

APPENDIX A

Technical Specification of Omega Xp and Probes

Figure 1: Xp Base Unit: Manufacturers Identification Plate



Which includes:

- | | |
|---|----------------------------|
| (1) Model | Xp |
| (2) Power Supply | 110/230 Volts |
| (3) Power Input | 50 VA |
| (4) Serial Number | |
| (5) Date of Manufacture | |
| (6) Type B applied part. | |
| (7) Laser radiation symbol | |
| (8) Fuses | Fuse type T500 mA HBC 250V |
| (9) Amperes | Mains current usage 0.25A |
| (10) Symbol warning user to read accompanying documents | |

Technical Specifications

Laser Type	Laser Diode
Wavelength and output power; depends on the laser probe	675nm 30mW, 660nm 50mW 820nm 50mW, 100mW, 200mW, 915nm 100mW (1W peak)
Exposure Mode:	Selectable pulsed (quasi-continuous)
Beam divergence:	Typically 9 x 30°
Frequency modulation:	2.5, 10, 20, 73, 146, 700, 1K, 5K, 10K Hz
Duty Cycle	90°
Method of Optical Output:	Lens-coupled, acupuncture tip and dental tips (optional)
Laser trigger:	Fingerswitch
Electrical:	Class 1, in accordance with EN 60601-1
Mains power supply:	110/230 V; 50/60 Hz
Mains fuses:	T500 mA HBC 250V
Intended Duration	Continuous
Classification: Therapy Laser	Class IIb In accordance with EN 60825-1
Device Classification:	Class IIb, non-invasive, active device in accordance with MDD/93/42/EEC, Annex II, Rule 9/12.7.23
Display of Xp Unit:	LCD
Weight:	3.02 Kilos
Dimensions:	140mm Height x 125mm Depth x 220 mm Wide
Safety Standards:	The Xp laser conforms with the product requirements of compatibility by application of BSEN 60601-2-22:1996, BSEN 60601-1 1990, BSEN 46001:1997 according to directive number MDD 93/42/EEC

Single Probes:

Output tolerance of Laser Diodes

<±15% Stated Probe Label Output Power

Measurement of uncertainty

5%

Increase in measured quantities

0%. Diodes are the main source for potential increases in measured quantities over time. Laser diodes suffer negligible obvious degradation until they fail.

675nm 30mW Visible Laser Probe

Wavelength	675nm ±15 nm
Power Output	30mW
NOHD	120mm
Beam Divergence	9 x 38 degrees Typ
Laser Class	3B
Lasing Medium	GaAlAs

660nm 50mW Visible Laser Probe

Wavelength	660nm ±15 nm
Power Output	50mW
NOHD	120mm
Beam Divergence	9 x 38 degrees Typ
Laser Class	3B
Lasing Medium	GaAlAs

820nm 50mW Infrared Laser Probe

Wavelength	820nm ±15 nm
Power Output	50mW
NOHD	155mm
Beam Divergence	25 x 10 degrees Typ
Laser Class	3B
Lasing Medium	GaAlAs

820nm 100mW Infrared Laser Probe

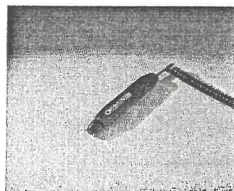
Wavelength	820nm ±15 nm
Power Output	100mW
NOHD	430mm
Beam Divergence	7 x 35 degrees Typ
Laser Class	3B
Lasing Medium	GaAlAs

820nm 200mW Infrared Laser Probe

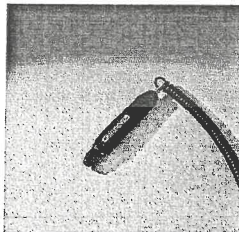
Wavelength	820nm ±15 nm
Power Output	200mW
NOHD	605mm
Beam Divergence	7 x 35 degrees Typ
Laser Class	3B
Lasing Medium	GaAlAs

915nm 1W (100mW average) Infrared Laser Probe

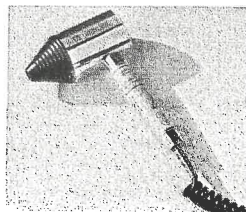
Wavelength	915nm ±15 nm
Power Output	100mW
NOHD	430mm
Beam Divergence	7 x 35 Degrees Typ
Lasing Medium	GaAlAs



675nm 30mW / 660nm 50mW Probe



820nm 50/100/200mW Probe



915nm 1W Probe

Cluster Probes:

Output tolerance of Laser Diodes

<±15% Stated Probe Label Output Power

Measurement of uncertainty

5%

Increase in measured quantities

0%. Diodes are the main source for potential increases in measured quantities over time. Laser diodes suffer negligible obvious degradation until they fail. 2% allowance for LED annual degradation.

31 Diode Cluster Probe:

Laser Diode

Wavelength 820nm ±15 nm
Power Output 15mW
NOHD 215mm
Laser Class 3B
Lasing Medium GaAlAs
Beam Divergence 18x17.5 degrees Typ

Non Laser Diodes

10 x 660nm 15mW L.E.D.'s
10 x 950nm 25mW L.E.D.'s
10 x 880nm 25mW L.E.D.'s

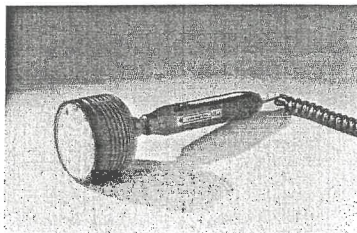
46 Diode Cluster Probe:

Laser Diode

Wavelength 820nm ±15 nm
Power Output 15mW
NOHD 215mm
Laser Class 3B
Lasing Medium GaAlAs
Beam Divergence 18x17.5 degrees Typ

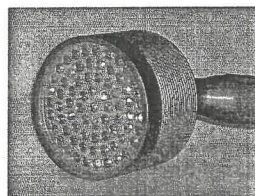
Non Laser Diodes

10 x 660nm 15mW L.E.D.'s
10 x 950nm 15mW L.E.D.'s
10 x 870nm 25mW L.E.D.'s
10 x 880nm 25mW L.E.D.'s
5 x 940nm 25mW L.E.D.'s



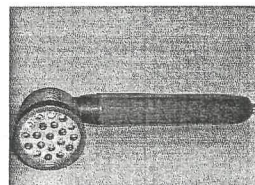
60 Diode Cluster Probe Non Laser Diodes

24 x 660nm 10mW L.E.D.'s
12 x 810nm 20mW L.E.D.'s
12 x 940nm 20mW L.E.D.'s
6 x 880nm 20mW L.E.D.'s
6 x 850nm 20mW L.E.D.'s



20 Diode Cluster Probe Non Laser Diodes

8 x 660nm 10mW L.E.D.'s
4 x 810nm 20mW L.E.D.'s
4 x 940nm 20mW L.E.D.'s
2 x 880nm 20mW L.E.D.'s
2 x 850nm 20mW L.E.D.'s



5 x Laser Diode Cluster Probes:

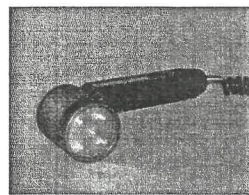
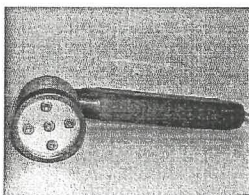
Laser Diode

Wavelength 5 x 660nm ±15 nm
Power Output 50mW

Wavelength 5 x 820nm ±15 nm
Power Output 100mW

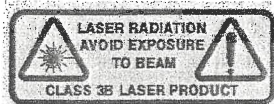
Wavelength 5 x 820nm ±15 nm
Power Output 200mW

NOHD 215mm
Laser Class 3B
Lasing Medium GaAlAs
Beam Divergence 18x17.5 degrees Typ



Reproductions of labels used on Omega Equipment

Figure 1. Warning Label on front of Xp and Excel Unit



Warning of the potential for laser emission and need to read accompanying documents before use.

Figure 2. Laser Aperture label



Figure 3. 675nm 30mW Probe Label



Figure 4. 660nm 50mW Probe Label



Figure 5. 820nm 50mW Probe Label



Figure 6. 820nm 100mW Probe Label



Figure 7. 820nm 200mW Probe Label



Figure 8. 915nm 1W (100mW average) Probe Label

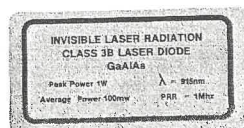


Figure 9. 31 Diode Cluster Probe Label



Figure 10. 46 Diode Cluster Probe Label



Figure 11. 20 Diode Cluster Probe



Figure 12. 60 Diode Cluster Probe Label



Figure 13. 5 x 660nm 50mW Cluster Label



Figure 14. 5 x 820nm 100mW Cluster Label

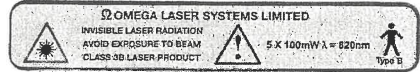


Figure 15. 5 x 820nm 200mW Cluster Label



Figure 16. Battery Label

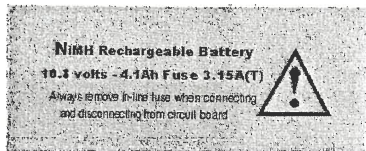


Figure 17. USA Compliance Label

Complies with 21 CFR 1040.10 and 1040.11 except as modified pursuant to FDA Laser Notice No. 50 dated July 26, 2001 and with any other applicable FDA Notices, Amendments and or Exemptions

Accreditation:



Approved Goggles:

Approved for supply, conforming to requirements of EN 207

Noir – LM-50
CTL - 2109

APPENDIX B

OPERATORS WHO MAY BE AUTHORISED

Authorised operators of the laser are:

- i) Members of staff suitably trained in the use of the Omega laser
- ii) Staff being trained under the direct supervision of a trained member of staff.
- iii) Engineers and technicians of Omega and authorised technical staff.

APPENDIX C

AUTHORISED PERSONNEL

- a) Authorised Operators are:

APPENDIX D

THE LASER PROTECTION SUPERVISOR

The Laser Protection Supervisor for this equipment at is:

The duties of the LPS are listed in Appendix D. In the event of the above named member of staff leaving a replacement will be agreed between the LPA and the appropriate manager and the Health Authority (if appropriate) informed of the change.

APPENDIX E

DUTIES OF THE LASER PROTECTION SUPERVISOR

The duties of the Laser Protection Supervisor are:

1. To have a good working knowledge of current DOH guidelines and the hazards posed by the laser.
2. To ensure that staff engaged in laser work are adequately trained and conform to the local rules.
3. All operators and assistants must read the local rules and sign that they have understood these rules.
4. To ensure that the laser is serviced on a regular contractual basis.
5. To ensure that service engineers conform to local rules.
6. To participate in the annual inspection of the laser unit by LPA.
7. To freely liaise with the LPA. In particular inform the LPA of:
 - a) Any incident involving the use of the laser
 - b) Any changes to the laser or the room which is likely to have safety implications
 - c) Any changes in the performance of the laser or servicing problems.
8. To ensure that safety signs, local rules, safety spectacles/goggles etc. are kept in good condition and up to date.
9. To keep a note book of servicing and faults of the laser.

APPENDIX F

I have read, understood and will abide by the Local Rules for the Omega Laser:

Signature

Name

Date _____

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

LILT Treatment Record Card:

Name: Tel. No:

Address: NH No:

Clinic Ref:

Date of Birth: Laser Ref:

Condition	Details	Caution Yes/No	Treat Yes/No
Pregnancy			
Cancer			
Photodynamic Therapy			
Photosensitivity			
Epilepsy			
Infection in wound			
Current Medical Treatment/Drug Regime			

REQUIRED TREATMENT:

PATIENT SIGNATURE:

CLINICIAN SIGNATURE:

DATE:

LILT PROTOCOL RECORD CARD:

Page

Name:

Tel. No:

Address:

NH No:

Clinic Ref:

Date of Birth:

Laser Ref:

Date	Clinician	Condition	Protocol	Progress
			Probe: Time: ED: PRR: Total time:	
			Probe: Time: ED: PRR: Total time:	
			Probe: Time: ED: PRR: Total time:	
			Probe: Time: ED: PRR: Total time:	
			Probe: Time: ED: PRR: Total time:	
			Probe: Time: ED: PRR: Total time:	
			Probe: Time: ED: PRR: Total time:	
			Probe: Time: ED: PRR: Total time:	
			Probe: Time: ED: PRR: Total time:	

APPENDIX G- EXAMPLE OF LOCAL RULES

The following is an example of rules as defined by the most rigorous Laser Protection Officers. While they appear a little complicated they are actually quite simple, based on common sense and guidelines in the manual already incorporate them.

This is included in the manual as a documentary template should any Clinic or Department wish to ensure all paperwork is up-to-date and operating within today's standards. Too often Departments are delayed in using a Low Intensity Laser as Local Rules have to be written from scratch. These should help.

THE RULES:

Safe use of the laser depends on strict adherence to the following rules:

1. A register should be kept of:
 - a) Personnel authorised to operate the equipment, See Appendix B
 - b) Personnel authorised to assist in the use of the equipment See Appendix B

The register of names is in Appendix C. This should be held by the LPS. As this changes and is updated details should be sent to LPA and Registering Authority.
2. One authorised operator shall be nominated as the Laser Protection Supervisor (LPS) see Appendix D and will abide by the rules see Appendix E.
3. The key required to operate the instrument shall be:
 - a) Clearly and permanently labelled
 - b) Kept locked away when not in use
 - c) Only available to authorised personnel
4. These rules apply as soon as the cubicle/room becomes a laser controlled area i.e. when the electrical supply is switched on.
5. It is the responsibility of the authorized staff present during the use of the laser to be aware of the hazards involved, to be familiar with the manufacturer's instructions and these local rules. The operating manual is to be kept with the laser.
6. The operator is responsible for ensuring that persons assisting in the performance are fully aware of safety procedures and he/she is responsible for any visitors.
7. The laser is only to be used in a designated room with an appropriate sign on the door to indicate laser is in use. Correct use of the sign on the door is essential i.e. the sign should NOT be shown if the laser is NOT in operation and MUST be shown when the laser IS in operation.
8. Care should be taken with any reflective surfaces i.e. do not shine the laser directly at reflective surfaces and windows should have blinds or curtains drawn.
9. All personnel (operator and patient) are to wear appropriate safety goggles at all times during operation. Goggles are kept with the machine.

10. Personnel should never look directly into the laser beam even when wearing goggles.
11. The laser should not be switched on unless it is directed at a clinical target or a power measuring instrument (direct to tissues - not on a reflective surface or air).
12. The operator selects the appropriate probe, selects an appropriate time and pulsing frequency treatment mode. They then press the ON switch on the probe.
13. At the end of each total treatment session, remove the key and return to holder.
14. All users must have received training on the safe use and clinical application of the laser including prevention of cross infection, contraindications and cautions, indications for use, understanding of wavelength, power density, energy density and pulsing frequency.
15. Servicing - this is only to be carried out by authorized agents (Omega Laser Systems) and should be carried out at least annually.
16. All engineering faults must be recorded by the operator in the Fault Log Book and brought to the immediate attention of the LPS and the LPA.
17. Any clinical concerns must be recorded by the operator in the Fault Log Book and brought to the immediate attention of the LPS and the LPA.
18. Before initial treatment with any patient they must be screened for suitability for the treatment, address and any other relevant details recorded - (See Treatment Record Card page 49).
19. All treatment protocols must be recorded after each treatment for each patient (see Protocol Record Card page 50). This MUST be completed, both for accurate recording for repeated clinical efficacy and for records in the case of litigation. Protocol recording must be completed for ANY treatment, not just laser. These protocols to be kept together with patient details.
20. Operators must sign statements that they have read and understood these local rules (see Appendix F). These statements will be held by the LPS.

