Ellipse Plus Range - Operator's Manual

Manual to accompany demo version of system

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Notice on Intellectual Property Rights

Ellipse A/S has been granted the following patents:

US 8.226.696: Main claim is directed to IPL combining water as a filter with a UV filter. Patent issued July 2012. (European patent pending – ref 98304722.6/ EP0885629)

EP2027827: Main claim is skin cooling by directional flow of cold air. Patent issued February 2012. (US patent pending - ref US12/193.845)

Software Version:

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Chapter 1: YOUR ELLIPSE SYSTEM

1.1 System Type

This manual covers three separate Ellipse systems: Ellipse Light SPT$^+$, Ellipse I^{2}PL$^+$ and Ellipse MultiFlex$^+$. For simplicity, and since they have a similar software platform, these will be referred to as "your Ellipse system".

These devices are intended to be used only by persons who have a thorough knowledge and understanding of skin conditions and of light-skin interaction.
It is the obligation of the user of these devices to follow all national, state and local regulations regarding treatments performed with these devices.

Your Ellipse system is a cabinet containing a computer, touch sensitive screen, an on-screen keyboard and the electronics that provide energy and control of the power. Applicators enabling treatment of specific conditions are connected to your Ellipse system by means of a flexible cable, which provides power and circulating (demineralized) water supply to the applicators. To press a button, simply press the screen where the button is located.

The actual configuration of your Ellipse system will be decided by you at the time of purchase, but the list of possibilities is tabled below. Throughout this manual:

Items that are relevant for all systems will be shown without highlighting.

Items relevant for SPT$^+$ only are highlighted in green

Items relevant for I2PL$^+$ and MultiFlex$^+$ are highlighted in blue.

Items relevant for MultiFlex$^+$ only are highlighted in orange.

Many of the features are common to all systems, but Ellipse Light SPT$^+$ can be seen as a "light" version of the Ellipse I^{2}PL$^+$, while Ellipse MultiFlex$^+$ is a multi-platform system with additional treatment possibilities.

Feature	SPT$^+$	I^{2}PL$^+$	MultiFlex$^+$
On-screen keyboard	✓	✓	✓
"Traditional" Keyboard (optional)			✓
Choice of colour scheme.	✓	✓	✓
Expert Mode		✓	✓
Pulse Definition Mode			✓

Intense Pulsed Light Treatments			
Hair Removal	✓	✓	✓
Diffuse Redness and Pigment (VL^+ applicator only)	✓		
Diffuse Redness and Pigment (VL^+ or PR^+ applicator)		✓	✓
Telangiectasias Face (VL^+ applicator only)	✓		
Telangiectasias Face (VL-2 or PR^+ applicator)		✓	✓
Port Wine Stains		✓	✓
Pigmented Lesions		✓	✓
Acne Vulgaris		✓	✓
Poikiloderma of Civatte (as a subset of Diffuse Redness and Pigment)		✓	✓
Nd:YAG Laser Treatments			
Leg Vessels			✓

1.2 System Documentation

The system documentation is designed to provide you with the information needed to use your Ellipse system safely and effectively.

Throughout the documentation, cross-references to other chapters of the same document will be shown in the form "See Chapter X: Heading". Cross-references to other sections of the same document will be shown in the form "See Section X.Y.Z: Heading". Cross-references to Figures will be shown as "See Fig. Y". References to other documentation produced by Ellipse A/S for your Ellipse system will be shown as in the example "see 1MAN8438-**Ellipse Plus Range - Essential Information**." The instruction to press a specific button will be given as in the example "press <**Exit**>".

The documentation is divided into four parts:

1) **1MAN8438-Ellipse Plus Range - Essential Information** covers the safety instructions for your Ellipse system; its cleaning and maintenance; safety labeling; CE and UL / CSA conformity; IEC symbols and technical specifications.
2) This **User Manual** (**1MAN8439**) deals with the daily use of your Ellipse system.
    a. Specifically Chapter 1 introduces the system and documentation; explains the intended use of your Ellipse system; gives background information, outlining treatment indications and contraindications.
    b. Chapter 2 explains the day-to-day operation of your Ellipse system including Treatment Scenarios.
    c. Chapter 3 covers Expert Mode, and applies to I^2PL^+ and MultiFlex$^+$. It also covers Pulse Definition Mode, which applies only to Ellipse MultiFlex$^+$
    d. Chapter 4 covers changing applicators.

3) **1MAN8329 –Ellipse Applicators – Instructions for Use** covers the safe use of the various intense pulsed light applicators (hand-pieces) that work with your Ellipse system.
4) **1MAN7953 – Ellipse Nd:YAG Applicator – Instructions for Use** covers the safe use of the Nd:YAG laser available on the Ellipse MultiFlex+.

Note that subsequent / supplementary information will be in the form of Application Notes, supplied with the System and Applicators. Contact your Ellipse representative if you have any questions.

1.3 Intended Use

Use (using Intense Pulsed Light)			
Your Ellipse system is intended to be used for medical treatment of changes in the anatomy or of a physiological process in the skin, as tabled below:			
	SPT+	I²PL+	MultiFlex+
Hair Removal (permanent hair reduction)	✓	✓	✓
Treatment of Vascular Lesions (Telangiectasias - Face)	✓		
Treatment of Vascular Lesions (Telangiectasias - Face)		✓	✓
Treatment of Vascular Lesions (Port Wine Stains)		✓	✓
Treatment of sun-damaged skin to reduce diffuse redness and pigment.	✓	✓	✓
Treatment of Mild or Moderate (non-cystic) Inflammatory Acne Vulgaris		✓	✓
Treatment of Epidermal Pigmented Lesions		✓	✓
Poikiloderma of Civatte (as a subset of diffuse redness and pigment)		✓	✓
Use (using Nd:YAG laser)			
Your Ellipse system is intended to be used for medical treatment of changes in the anatomy or of a physiological process in adult skin, as tabled below:			
Leg vessels			✓

Indications for Use

Subject to a treatment being allowed on your Ellipse system, its use is restricted to certain combinations of Skin Types and Degrees of Suntan.

Note: Fitzpatrick Standard Skin Type Definitions.

The table below gives a general description of the six Skin Types categorized by dermatologist Thomas B Fitzpatrick. Other combinations of hair, eye and skin colours can occur in each Skin Type.

Skin Type	Typical Skin Type Definition	Skin Reaction on over exposure to UV light	Comments on Skin Type
1	Red-blond hair Blue-green eyes Very light skin	Always burns Does not tan	Pale, sometimes mixed with freckles. Usually admit that they burn.
2	Light to medium hair Light to medium eyes Light to medium skin	Usually burns Seldom tans	Normally the first consideration for average light skin (aside from obvious Skin Type 1). Often deny that they burn but admit to turning pink and needing to take care in sun.
3	Medium hair Medium to dark eyes Medium to olive skin	Moderate burns Usually tans	Usually does not recognize that they burn moderately if exposure is moderate. Will comment that they "Can get a good tan with care".
4	Dark hair Dark eyes Dark olive to light brown skin	Burns mildly Moderate browning	Consider they tan easily. Will rarely burn from moderate exposure in northern climates. Often surprised when they get a "little" sunburn while visiting higher intensity locations.
5	Dark hair Dark eyes Dark skin	Seldom burns. Deep browning	Seldom burn. This usually requires no previous exposure for months, then exposure to very high intensity levels (100+ on the SUNSOR scale – a sunny summer day in Florida).
6	Dark hair Dark eyes Very dark skin	Does not burn No change in colour	Individuals have very good pigmentation that affords exceptional protection in ultraviolet light.

Note: Selecting Degree of Suntan

Degree of Suntan is defined as a colour change in the skin because of exposure to sunlight.

NONE	Would be the fairest possible colour of the chosen Skin Type.
LIGHT	Would be slightly tanned colour of skin.
MEDIUM	Would be a tanned colour of skin
MED.HEAVY	Would be a darker tanned colour of skin
HEAVY	Would be the darkest possible colour of the chosen skin type.

The table below shows the approved Indications for Use

Application	Treatment Variable	Fitzpatrick Skin Type					
		1	2	3	4	5	6
Hair Removal HR+, HR-L+ , HR-S Applicators	Hair Thickness (Thin, Normal, Thick)	✓	✓	✓	✓	✓	⊘
Hair Removal HR-D+ Applicator	Hair Thickness (Thin, Normal, Thick)	✓	✓	✓	✓	✓	✓
Telangiectasias - Face VL+ Applicator	Vessel Size (Thin Medium Thick)	S	S	S	⊘	⊘	⊘
Telangiectasias – Face VL+ , PR+ Applicators	Vessel Size (Thin Medium Thick)	I	I	I	I	⊘	⊘
Port Wine Stains VL+ , PR+ Applicators	Colour (Red, Blue)	I	I	I	I	⊘	⊘
Diffuse Redness and Pigmentation VL+ Applicator	Skin	S	S	S	S	⊘	⊘
Diffuse Redness and Pigmentation VL+ , PR+ Applicators	Skin	I	I	I	I	⊘	⊘
Poikiloderma of Civatte (as subset of Diffuse Redness and Pigmentation) VL+ , PR+ Applicators	Skin	I	I	I	I	⊘	⊘
Mild or moderate (non-cystic) inflammatory acne vulgaris PR+ Applicator	Skin	I	I	I	I	⊘	⊘
Pigmented Lesions PL , PL-W, PL+ Applicators	Lesion Colour - (Light, Medium, Dark)	I	I	I	I	I	⊘
Leg veins and leg telangiectasias Nd:YAG Applicator	Vessel Size (Ø 0.1-3.0mm) and colour	L	L	L	L	L	L

Key: ✓ Allowed on all systems; S Allowed on SPT+ only; ⊘ Not Allowed

I Allowed on I²PL+ and MultiFlex+ only L Laser treatment on MultiFlex+ only

Note: Patients with darker Fitzpatrick Skin Types (4 or above) or who are suntanned should **always** be treated with extra care and attention.

The correct applicator for your Ellipse system

The introduction of a new series of "Plus" applicators, allows a greater variety of applicators to be connected to your Ellipse System. Full details of applicator part numbers (reference numbers) and applicator/system compatibility can be found in **1MAN8329 –Ellipse Applicators – Instructions for Use.**

1.4 Successful Treatments using your Ellipse system

Initial Interview

Prior to the first treatment session, ascertain the client's skin type, sun tan and medical history to ensure (s)he falls within the range of suitable clients. Take particular note of tattoos or pigmented lesions that occur on the treatment area, and note any contraindications to treatment (see Section 1.12 Contraindications).

General Pre-treatment Preparation

Always ensure you are aware of the potential hazards and general safety precautions associated with light-based treatments. See 1MAN8438-Ellipse Plus Range - Essential Information**.** Also refer to this manual: Sections 1.19 Contraindications and 1.20 Adverse Effects

Before treatment, always:

- Remove patient's make-up (to avoid skin burns).
- Ensure there are no tattoos or permanent make-up in the treatment area. These must not be treated as the pigment absorbs part of the light energy and this can lead to a skin burn.
- Shave the treatment area if required, and remove the shaved hairs from the skin.
- Avoid use of flammable liquids to clean the skin or prepare it for treatment. Use soap and water for skin cleaning, wash the skin afterwards with pure water and dry it before applying the coupling gel.
- Apply optical coupling gel.
- Use appropriate eye protection (for operator, bystanders and client).

General Treatment Guide

- Identify the treatment type and enter this onto your Ellipse system. Some treatments enable you to treat a range of target colours or sizes – identify your target accurately and enter this also.
- Identify the Skin Type according to the Fitzpatrick Skin Type scale. Accurately enter this onto your Ellipse system.
- Identify the Degree of Suntan. If necessary compare Degree of Suntan of the treatment site with an area not exposed to the sun.
- Your Ellipse system adjusts the default energy according to the Skin Type and degree of suntan selected, and the pulse length according to the target size or colour.
- Ensure that the client's combination of Skin Type and Degree of Suntan is permitted in the indications for use. See 1.3 Intended Use. Default settings are placed in the lower end of the therapeutic window. This is the energy setting for a given treatment that gives a notable beneficial effect with low risk of side effects. To optimize the results, the energy setting (J/cm²) can be increased to the upper part of the therapeutic window. This is found based on the practitioner's clinical knowledge, and by judging both the skin reaction and the patient's tolerance of pain. Using clinical endpoints to determine the therapeutic window ensures continued effectiveness without compromising safety.
- Use an appropriate amount of gel on the treatment area. The amount for each treatment is described in sections 1.5 to1.11**.**
- Place the I²PL Applicator Light Guide (or for laser treatments, the Nd:YAG applicator cooling tip) perpendicular to the skin surface to ensure maximum light penetration.

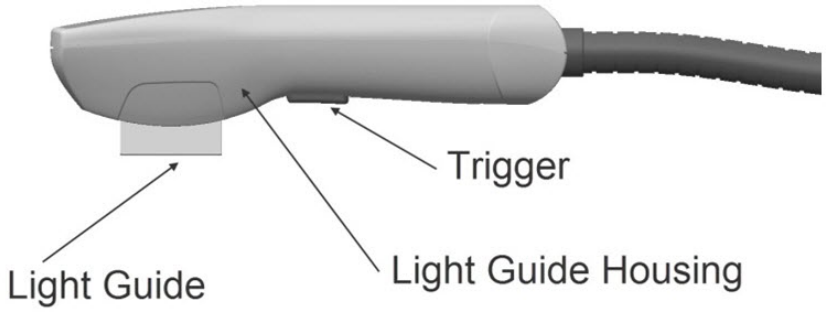


Fig 1. Position of I²PL Applicator Light Guide

1 Working light.	2 Aiming beam / laser beam
3 Cooling tip.	4 Trigger button.

Fig 2. Position of Nd:YAG cooling tip

- Always perform test shots, based on the recommended settings. Observe both patient discomfort and skin reaction - erythema (redness) or edema (swelling). The test shot should be relevant to the treatment site, but should not be prominent.
- The treatment protocol for an individual patient must be based on each patient's clinical examination, skin type, history and tissue response. The final judgment lies in in the hands of the user of this device.

- Do not slide the applicator across the treatment site; lift it and place it down again. This avoids a build-up of optical coupling gel on the side of the applicator, and reduces the risk of side effects.
- If you need to shoot the same area again (maybe using a higher energy), allow the skin to cool for at least 1 minute between shots.
- Do not use Expert mode to adjust treatment parameters until you understand the theory and have gained significant experience. The treatment parameters shown under the Normal Settings are those that have been clinically proven to be safe and effective.
- Do not use Pulse Definition mode to create treatment parameters until you understand the theory and have gained significant experience.

General Post-Treatment Care

After the final shot, remove the gel and dry the skin surface with a soft cloth.

Soothing gel or a cold compress placed against the skin may be comforting for the patient. Instruct the client to not expose the treated area to sunlight or solaria for 1 month after treatment. Use a sun block – minimum SPF 30 when exposure to sunlight is inevitable.

1.5 Hair Removal – Intense Pulsed Light

Target Chromophore: Melanin

The target is melanin in the hair and hair bulb. These are heated to ensure conduction of heat to the hair follicle. Only hairs in the growing phase can be treated, therefore multiple treatments are necessary.

Good results can always be achieved if treating dark hair on a fair skin. Treatment of blond, light-red or grey hairs is not effective because of lower melanin content.

Wavelength

The HR, HR-3 and HR$^+$ applicators emit light with wavelength 600 nm – 950 nm. This gives high absorption in melanin. The penetration depth of these wavelengths is enough to reach even the deeper hair follicles.

Small areas of hair can be treated with the HR-S applicator. This uses the same wavelengths but has a diameter of 8mm. Because of the size, the maximum possible energy is capped at 16.5J/cm^2.

Large areas of hair can be treated with the HR-L$^+$ applicator. This uses the same wavelengths as above but has a spot size of 48mm X 18mm to allow faster treatments with less overlapping.

For dark skinned patients, the HR-D and HR-D$^+$ applicators emit light with wavelength 645 nm – 950 nm. This enables safe treatments in patients with a higher skin concentration of melanin. The penetration depth of these wavelengths is again enough to reach the deeper hair follicles.

Pulse Duration

The pulse duration is dependent on the hair thickness. Your Ellipse system automatically selects the appropriate pulse duration when the operator

states the thickness of the hair. Thin hair needs less energy to heat up, and relatively low energy is used. Thick hair needs more energy to heat up, and a higher energy is used. In general the highest energies should only be used in connection with longer pulse durations.

Identifying Hair Thickness

Examine the hair thickness at each treatment session. Hairs that remain following initial treatment tend to be thinner than the original. If a treatment area has hair of mixed thickness, target the thicker hair first. Target the remaining thinner hairs during later treatments.

Thin Hair - typically, fine moustache hair. The thin hair setting may be appropriate for subsequent treatment of hairs from body sites that originally had normal thickness hairs.

Normal Hair - typically, body hairs, as found on legs, arms, and back. After a couple of treatments in areas with normal hairs, the remaining hairs tend to be thinner, so check and treat for the thickest remaining hairs.

Thick hair - typically, beard, armpit, or pubic area. After a couple of treatments in areas with thick hair, the remaining hairs tend to be thinner, so check and treat for the thickest remaining hair. Thick hairs are more typically found in persons with skin type 3 - 6.

Hair Pre-Treatment Care

In the 30 days before treatment, do not:

- Pull out the hair with tweezers, wax or use depilatory creams.
- Bleach the hair.
- Sunbathe, nor use solaria nor use fake tan that dyes the epidermis.

Hair Treatment

Mark the treatment borders with a RED pen or WHITE pencil. Do not use other colours, as they will absorb the light and cause skin burns.

Because this treatment involves pressing the applicator against the skin, only a thin layer of gel is needed. Ensure that the gel does not dry out during treatment.

Press the applicator firmly against the skin surface. This increases the efficacy due to:

- Reduction of the distance between skin surface and hair.
- Squeezing blood out of the superficial blood vessels. This will reduce the absorption of light by the hemoglobins (hemoglobin and oxyhemoglobin).

The energy can be increased until follicular or general erythema (redness) is observed or until the level of patient discomfort is reached.

Note: in darker Skin Types (4, 5 or 6), erythema may take from a few minutes to a few hours to develop. Therefore you should always make a test shot well in advance of starting treatment.

Synchronization of the Hair Growth Cycle

The effect of a low energy setting can be to synchronize all hairs in the resting phases to an early anagen (growth) phase. This means more hairs are seen after the treatment, which might be a disappointment for a patient who is not informed of the possibility. The next treatment however, will be even more efficient, as more hairs are in the early growth phase.

Intervals between Hair Treatments

The interval depends on the anatomic site treated as well as the individual patient. It is recommended to perform the next treatment when re-growth can be observed in the treated area.

Special for Hair Treatment

The desired treatment effect is perifollicular erythema (redness around the hairs) / perifollicular edema (swelling around the hairs), although this is not always seen.

1.6 Vascular Treatments (Telangiectasias - Face Telangiectasias - Face, Port Wine Stains) - Intense Pulsed Light

Special Notes:

Ellipse SPT$^+$ users have access only to the Ellipse VL-2 and VL$^+$ applicators.

I2PL$^+$ and MultiFlex$^+$ users have access to both the Ellipse VL-2 and VL$^+$ applicators and the Ellipse PR and PR$^+$ applicators and can treat both Telangiectasias – Face and Port Wine Stains.

MultiFlex$^+$ owners who wish to use an Nd:YAG to vessels on the legs should additionally read Section 1.11 Telangiectasias and Reticular Vessels (Nd:YAG Treatment),

Because vascular treatments do not involve pressing the applicator against the skin, a *slightly* thicker layer of gel is helpful. Ensure that the gel does not dry out during treatment.

Target Chromophore: Hemoglobin

The target chromophores are hemoglobin and oxyhemoglobin in the blood inside the vessels. The light absorbed by the blood is transformed into heat, and then conducted to the vessel wall. The protein in the vessel wall will be destroyed if it reaches 70°C for more than 1ms. As a result the blood will coagulate and the destroyed vessel wall will gradually disappear.

Wavelength

The wavelengths used have high absorption in hemoglobin and oxyhemoglobin and no absorption by the competing chromophore water. Since these wavelengths are also absorbed by melanin, patients with darker skin and particularly those with suntan should not be treated.

I2PL$^+$ and MultiFlex$^+$ users have access to both the Ellipse VL-2 and VL$^+$ applicators and the Ellipse PR and PR$^+$ applicators which emit light with wavelengths in the range 555 nm – 950 nm, 530 –750 nm, respectively.

When using the PR/PR$^+$ applicator is possible, absorption in blood vessels is significantly higher than with the VL-2/VL$^+$ applicator, meaning reduced energy is required.

Initially use the PR/PR$^+$ applicators only for treating red vessels above the heart and proceed with caution.

Pulse Duration

Pulse duration is dependent on vessel thickness.

The thermal relaxation time of the vessel depends on its diameter. Thicker vessels have a longer thermal relaxation time than thinner vessels. The pulse duration must be close to the relaxation time of the treated vessel. Your Ellipse system automatically selects appropriate pulse duration, when the operator enters the thickness of the vessels. Thin vessels need less energy to heat up, and a relatively low level of energy is used. Thicker vessels need more energy to heat up, and a higher energy is used. Do not combine high energy setting and short pulse duration, since the vessel might heat up so rapidly that purpura (bruising) results. To avoid this, decrease the energy setting or increase the pulse duration.

Guide to Vessel Size – (Telangiectasias-Face)

Consider use of Diffuse Redness and Pigmentation procedure for removal of areas of pigment (and vessels with a diameter less than 0.1mm, which appear on the skin as diffuse redness). These may otherwise act as a mask over individual vessels requiring treatment.

Thick Telangiectasias: Is used for individual vessels larger than 0.5 mm diameter.

Medium Telangiectasias: Is used for individual vessels between 0.1 to 0.5 mm in diameter.

Thin Telangiectasias: Is used for groups of vessels less than 0.1 mm in diameter, where there is no pigment "mask".

Treatment Area - Telangiectasias

Areas above the heart are in general easy to treat, due to relatively low hydrostatic blood pressures in these areas.

Leg vessels should not be treated using Intense Pulsed Light.

Thick vessels are in general more difficult to treat than thinner vessels.

Guide to Vessel Size – Port Wine Stains (I^{2}PL$^+$ users only).

Vessel size in Port Wine Stains is indicated by the colour of the overall lesion. Larger and deeper vessels (typically found in older patients) are blue in colour. More superficial vessels are red. Your Ellipse system describes the vessels in terms of these colours.

Vascular Pre-Treatment Care

Ensure a low Degree of Suntan for the skin; this requires no sun tanning, fake-tan nor solarium for 30-60 days before treatment. If necessary postpone the treatment.

The patient should not smoke in the 4 hours prior to treatment, as this can cause restriction in the blood vessels.

Special for Vascular Treatment

Do not press the applicator against the skin, but let it lightly touch the skin surface.

After each of the first few shots, it is recommended to examine the skin and the vessel closely for reactions and if necessary to gradually adjust the chosen treatment parameters (energy). Observe the treated area within 1 second after each shot. You should see a temporary darkening (bluish colour) of the brightest red vessels. If the skin turns a greyish colour, then the energy setting is too high and should be reduced.

Be careful not to select an energy setting that is too high. A skin burn may first show up several hours after a treatment.

Vascular Post-Treatment Care

For medical users, if the chosen energy setting is near to the upper limit, consider using a strong (group IV) topical glucocorticosteroid, e.g. clobetasol dipropionate ointment immediately after the treatment.

The intervals between the treatments depend on the time it takes for the treated area to clear up, which means the time it takes for the body to re-absorb the coagulated blood (typically 1 month).

1.7 Diffuse Redness and Pigmentation - Intense Pulsed Light

Special Note:

Ellipse SPT$^+$ users have access only to the Ellipse VL-2 and VL$^+$ applicators.

Ellipse I^{2}PL$^+$ and MultiFlex$^+$ users have access to both the Ellipse VL-2 and VL$^+$ applicators and the Ellipse PR and PR$^+$ applicators.

Target Chromophores – Hemoglobin and Melanin

Melanin is produced in epidermal cells called melanocytes, and transported to structures called keratinocytes. Keratinocytes are destroyed if heated to 70°C for more than 1 ms.

Hemoglobin and oxyhemoglobin are found in the blood inside the vessels. The light absorbed by the blood is transformed into heat, and then conducted to the vessel wall. The protein in the vessel wall will be destroyed if it reaches 70°C for more than 1 ms. As a result the blood will coagulate and the destroyed vessel wall will gradually disappear, removing the unwanted small visible vessels and diffuse redness.

Wavelength

The Ellipse VL-2/VL$^+$ applicators and the Ellipse PR/PR$^+$ applicators emit light with wavelength in the range 555 nm – 950 nm, 530 –750 nm, respectively.

These wavelengths have high absorption in hemoglobin, oxyhemoglobin and melanin - and no absorption by the competing chromophore water.

Patients with skin types 1, 2 or 3 are good candidates for treatment of diffuse redness and pigmentation. Best results are obtained if the patient has a low Degree of Suntan.

I²PL⁺ and MultiFlex⁺ users: The recommended Applicator usage for diffuse redness and pigmentation is tabled below. Usage is recommended on the basis that the patient has a nil or light Degree of Suntan.

Skin Type	Primary Condition		
	Diffuse Redness	Equal Mix	Pigmentation
1	PR/PR⁺	PR/PR⁺	VL-2/VL⁺
2	PR/PR⁺	PR/PR⁺	VL-2/VL⁺
3	VL-2/VL⁺ (PR/PR⁺ with caution)	VL-2/VL⁺	VL-2/VL⁺
4	VL-2/VL⁺	VL-2/VL⁺	VL-2/VL⁺
5	DO NOT TREAT		
6			

Pulse Duration

Diffuse redness and pigment is treated using a double 2.5 ms pulse, with a delay of 10 ms to treat the entire area, since the pigment acts as a mask over the larger vessels.

Individually visible telangiectasias are treated subsequently (see note on following page) using the Telangiectasias Face treatment described in Section 1.6.

Note: If treating relatively few medium vessels, this treatment can immediately follow treatment of pigment and diffuse redness. Any thick vessels (diameter greater than 0.5mm) or large areas of medium vessels (diameter greater than 0.1mm) should be treated four weeks after pigment or diffuse redness treatment.

Energy Settings

Treatment of diffuse redness and pigment is carried out with short pulse duration and 7-12 J/cm^2.

Diffuse Redness and Pigmentation Pre-Treatment Care

Note: Closely examine the pigmented lesions and vessels ensuring that all are benign. If in doubt, the patient should be referred to a specialist for further examination including the possibility of a biopsy.

Special for Diffuse Redness and Pigmentation Treatment

The applicator should not be pressed against the skin. Normal blood-flow is required to gain the optimal treatment.

Because Diffuse Redness and Pigmentation treatments do not involve pressing the applicator against the skin, a *slightly* thicker layer of gel is helpful. Ensure that the gel does not dry out during treatment.

A normal skin reaction is that solar lentigines and other pigmentation will turn darker in colour and appear to lift from the epidermis. Treatment of diffuse redness will be successful if general erythema is seen over the treatment area.

Diffuse Redness and Pigmentation Post-Treatment Care

For medical users, if the energy setting has been chosen near to the upper limit, consider using a strong (group IV) topical glucocorticosteroid, e.g. clobetasol dipropionate ointment immediately after the treatment.

Patients should expect 1-3 treatment sessions before clearance of all pigment and diffuse redness. The final result and the number of treatments depend on a number of factors e.g., Degree of Suntan, position (dermal or epidermal) and colour of the lesion, previous treatments, pre-treatment care.

1.8 Pigment Treatments (Epidermal) - Intense Pulsed Light

Target Chromophore: Melanin

Melanin is produced in epidermal cells called melanocytes, and transported to structures called keratinocytes. Keratinocytes are destroyed if heated to 70°C for more than 1 ms.

Wavelength

The Ellipse PL, PL-W and PL$^+$ applicators emit wavelengths from 400 nm to 720 nm, which have a good absorption by melanin, and no absorption by the competing chromophore water. Hemoglobins are removed from the target area by pressing the applicator down on the skin surface. Larger pigmented lesions can be treated with the PL-W /PL$^+$ applicator which produces the same waveband.

Pulse Duration

Treatment of pigmented lesions defaults to using the settings: 7ms light pulse – 25ms delay – 7ms light pulse.

Energy Settings

It is necessary to ensure sufficient energy is used to heat the target to 70°C for at least 1ms.

Pigment Pre-Treatment Care

Identification of Lesion Colour Parameter

Lesion Colour Light  : is used for area with very light pigmented spots.

Lesion Colour Medium  : is used for medium pigmented spots.

Lesion Colour Dark  : Is used for dark pigmented spots.

Be aware that the pigment applicator is developed for treatments of epidermal pigmented lesions, such as solar lentigines, seborrheic keratosis etc. Do not attempt to treat dermal pigmented lesions.

Special for Pigment Treatment

Treat only the pigmented area, if the pigmented area is smaller than the Light Guide, then punch a hole in a piece of white paper or white gauze and cover the surrounding area, treating through the hole. (Never use any type of metal foil as this will heat up and may lead to epidermal damage.)

Use only a thin layer of gel.

Press the applicator firmly against the skin surface. By doing so, you will squeeze blood out of the superficial blood vessels. This will reduce the absorption of light by the hemoglobins.

Observe the skin reaction. A sign of successful treatment is that the lesion turns darker or black a few minutes after shooting and lifts from the epidermis. If it is possible to remove the lesion from the skin surface by wiping with a piece of gauze, then the energy setting used is too high. Reduce energy by 1-2 J/cm^2 before proceeding.

Pigment Post-Treatment Care

If the energy setting has been chosen near to the upper limit, consider using a strong (group IV) topical glucocorticosteroid, e.g. clobetasol dipropionate ointment immediately after the treatment.

Redness / erythema and crusting can be found and will disappear 1-2 weeks without additional treatment.

The intervals between the treatments depend on the time it takes for the treated area to heal up (typically 1 month).

1.9 Acne Vulgaris Treatment - Intense Pulsed Light

The expression "Acne Vulgaris" when used in connection with Intense Pulsed Light treatment is an abbreviated use of the approved Intended Use Mild or moderate (non-cystic) inflammatory acne vulgaris.

Target Chromophores – Hemoglobins in blood vessels supplying the sebaceous glands

The primary effect of Ellipse Acne Vulgaris Treatment is selective photothermolysis in hemoglobins. This reduces the number of blood capillaries that supply the sebaceous glands. However, treatment combines selective photothermolysis with the photodynamic pathway: selected light is absorbed in porphyrins produced by the bacteria. Free oxygen radicals are produced and a bactericidal effect is induced.

Acne Vulgaris Treatment is carried out as a combination treatment using adapalene cream or gel 0.1% in addition to treatment with Intense Pulsed Light. Adapalene is marketed as Redap® and as Differin®. Adapalene works by reducing the inflammation caused by acne vulgaris, and by reducing (normalizing) the thickness of the skin in the treated area. This reduces the numbers of comedones (the hair follicles containing a mixture of sebum and keratin).

The effect of combining the therapies is to speed up this reduction in the number of blackheads/whiteheads.

Notes: Adapalene is prescription medication, and its use should always be in accordance with the manufacturer's specifications. P. acnes are highly resistant bacteria, and no treatments (including use of light) can offer a permanent "cure". Intense Pulsed Light and adapalene offer an effective method or reducing the visible effects of the bacteria.

Wavelength

The PR and PR^{+} applicators emit yellow light in the range of 530 – 750 nm. This waveband covers the absorption peaks for hemoglobin and oxyhemoglobin.

Pulse Duration and Energy Settings

Acne vulgaris treatment is carried out with the very short pulse duration, a double 2.5 ms pulse, with a delay of 10ms, used in connection with a relative low energy of 7-9 J/cm2.

Acne Vulgaris Pre-Treatment Care

Select the patient carefully: Patients with skin types 1 2 or 3 are good candidates for Acne Vulgaris treatment. Best results are obtained if the patient has a low Degree of Suntan from sunbathing or solarium. We do not recommend treatment of skin type 4 patients with medium, medium heavy or heavy pigmentation nor any patient with skin type 5 or 6 until further studies have been conducted.

Adapalene is often prescribed to commence 1 month before the beginning of Intense Pulsed Light treatment. Daily application of adapalene should continue throughout the course of treatment.

Special for Acne Vulgaris Treatment

Closely examine any pigmented lesions ensuring that all are benign. If in doubt, the patient should be referred to a specialist for further examination including the possibility of a biopsy. Check for and treat actinic keratoses and seborrhea warts before embarking on any Intense Pulsed Light treatment.

Because acne vulgaris treatments do not involve pressing the applicator against the skin, a *slightly* thicker layer of gel is helpful. Ensure that the gel does not dry out during treatment.

Do not apply any pressure when using the applicator. The target for acne vulgaris treatment is hemoglobin. Hemoglobin (blood) will be "pushed away" from the treatment area if any mechanical pressure is applied. Ideally, the applicator should lightly touch the surface of the skin.

Carefully observe the skin reaction throughout the treatment and adjust the settings accordingly.

End point: Treat acne vulgaris with sufficient energy so that a slight erythema is observed after a couple of minutes

Acne Vulgaris Post-Treatment Care

Patients who have been treated in the upper part of the therapeutic window may benefit from a Cold Pac (3M). Alternatively use a plastic bag containing crushed ice to hold against the skin immediately after the treatment.

Make an appointment for follow-up treatment 3 - 4 weeks later.

Immediately after treatment a stinging sensation and erythema are common. On day 2 and 3 edema may be present. Also during the first day a "dirty look" of mottled superficial brownish pigmentation may appear. This peels off spontaneously after around 14 days depending on how severe the melanin pigmentation was before commencement of the treatment. This pigmentation consists mainly of photo oxidised melanin and may be covered with make-up. (Histology reveals a phototoxic reaction in the vesicles that contain melanin.) Show pictures of this pigmentation effect to prepare patients, otherwise they may come back worried after a few hours. Patients should expect 4 treatments separated by 3 - 4 week intervals.

Medium term continuation of treatment with adapalene alone is normal, to prevent the formation of new comedones. Repeat the treatment sessions after 3 – 4 months if necessary.

Additional Contraindication for Acne Vulgaris Treatment

Be aware of and follow the manufacturers' advice regarding contraindications to the medication (hypersensitivity to the medication or any ingredient of the medication).

1.10 Poikiloderma of Civatte / Diffuse Redness and Pigmentation Subset) - Intense Pulsed Light

Special Note:

Ellipse I^{2}PL$^+$ and MultiFlex$^+$ users have access to both the Ellipse VL-2 and VL$^+$ applicators and the Ellipse PR and PR$^+$ applicators.

Since Poikiloderma of Civatte is a combination of diffuse redness **and** dyspigmentation, the Photorejuvenation parameters settings contained in Section 1.7 are used. By definition, the primary condition will be an equal mix.

Skin Type	Applicator
1	PR/PR$^+$
2	PR/PR$^+$
3	VL-2/VL$^+$ (PR/PR$^+$ with caution)
4	VL-2/VL$^+$
5	DO NOT TREAT
6	

Pre-Treatment care, Treatment notes and post-treatment care are identical to those for Diffuse Redness and Pigmentation contained in Section 1.7

1.11 Telangiectasias and Reticular Vessels (Nd:YAG Treatment)

Initial Notes:

Ellipse MultiFlex+ users with an Nd:YAG applicator are able to treat leg telangiectasias and reticular vessels with a diameter between 0.1mm and 3mm. Treatment of vessels with a larger diameter is not allowed.

An *extremely* thin layer of optical coupling gel is required; this must not be allowed to dry out during treatment, so apply gel only to a small area at a time.

On legs: treatments using intense pulsed light are not recommended – the preferred treatment is use of Nd:YAG.

Caution! the operator should test the air flow before shooting and allow sufficient time for the air to cool the skin.

Target Chromophore: Hemoglobins

The target chromophores are hemoglobin and oxyhemoglobin in the blood inside the vessels. The light absorbed by the blood is transformed into heat, and then conducted to the vessel wall. The protein in the vessel wall will be destroyed if it reaches 70°C for more than 1ms. As a result the blood will coagulate and the destroyed vessel wall will gradually disappear.

Wavelength

The Nd:YAG applicator produces light with a wavelength of 1064nm.

Pulse Duration

Pulse duration is dependent on vessel size.

The thermal relaxation time of the vessel depends on its diameter. Thicker vessels have a longer thermal relaxation time than thinner vessels. The pulse duration must be close to the relaxation time of the treated vessel. Your Ellipse system automatically selects appropriate pulse duration, when the operator enters the thickness of the vessels.

Guide to Vessel Size

A vein gauge is supplied with the Nd:YAG applicator. This shows how vessels of different diameters appear at the skin surface. Placing the gauge next to the vessel allows the user to make a direct measurement of the vessel size, and this information should be entered as a treatment parameter onto the Ellipse system.

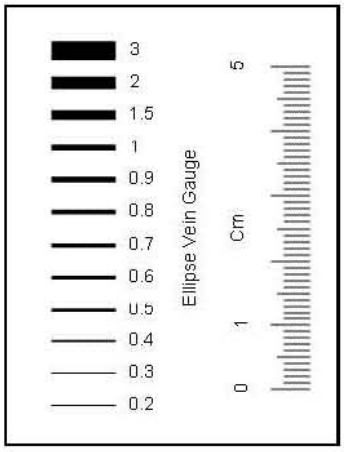


Fig 3. Ellipse Vein Gauge

Generally, larger vessels are placed a little more deeply in the skin. Accurately selecting the vessel size will allow the system to provide the correct spot size, pulse length and default energy.

Spot Size, Treatment Area and Direction

Unlike intense pulsed light treatments, Nd:YAG treatment of telangiectasias and reticular vessels uses high energy, in a very localized spot. Treatment of a vessel is similar to spot welding. The entire length of the vessel is not treated; instead the laser beam is fired at set intervals along the vessel.

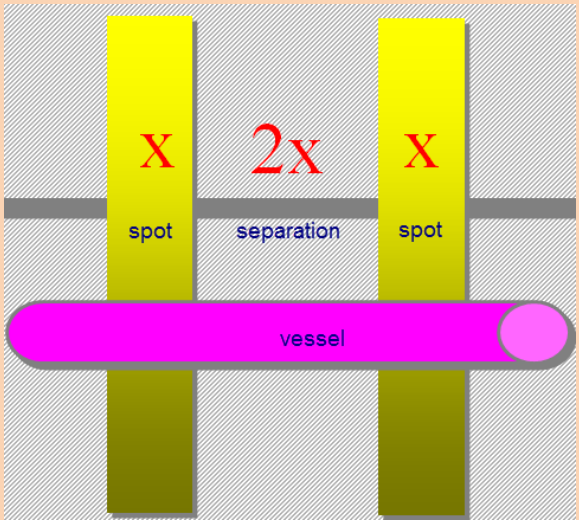


Fig 4. Shot separation

Note that the spot size is always larger than the vessel size, and that a gap of 2X spot size should always be left between individual shots.

Vessel size mm	Blue Vessels			Red Vessels		
	Pulse duration ms	Spot size mm	Fluence J/cm2	Pulse duration ms	Spot size mm	Fluence J/cm2
0.1-0.2	16	1.5	190	8	1.5	190
0.2-0.3	25	1.5	210	12	1.5	210
0.3-0.5	32	3.0	250	16	3.0	250
0.5-1.0	45	3.0	285	25	3.0	285
1.0-3.0	64	5.0	200			

Note also that not more than two shots should be fired in the same location in the same treatment, even if there is no apparent reaction.

To determine the optimum sequence of shots, find the feeder vessel for the telangiectasias, and follow the direction of flow from the direction of the feeder towards the edge of the vessel.

Pre-Treatment Care

Ensure a low Degree of Suntan for the skin; this requires no sun tanning, fake-tan nor solarium for 30-60 days before treatment. If necessary postpone the treatment.

The patient should not smoke in the 4 hours prior to treatment, as this can cause restriction in the blood vessels.

Special for Nd:YAG Treatment of Telangiectasias and Reticular Vessels

Do not press the applicator against the skin, but let it lightly touch the skin surface, so that the cooled air flow is uninterrupted. Allow the cooled air to pre-cool the area before the shot, and to subsequently cool the same area for two seconds after the shot.

After each of the first few shots, it is recommended to examine the skin and the vessel closely for reactions and if necessary to gradually adjust the chosen treatment parameters (energy). Dependent on vessel size, the vessel may disappear completely, or may darken. Erythema and edema after the shot also indicate coagulation of blood in the vessel, and you should expect a reduced blood flow past the treatment site if you press and then release pressure on the vessel.

Post-Treatment Care

If the chosen energy setting is near to the upper limit, consider using a strong (group IV) topical glucocorticosteroid, e.g. clobetasol dipropionate ointment immediately after the treatment.

The intervals between the treatments should typically be minimum 2 months.

Cooling the skin with a moist cloth may comfort the patient whenever a burning sensation occurs but excessive cooling may lead to hypo pigmentation.

Erythema and edema are normal post-treatment reactions and will disappear after a couple of days without additional treatment.

After treatment the skin area should not be exposed to sunlight during the healing period of 1-2 months or as long as visible post treatment reaction (erythema, edema or minor bruising) can be seen.

Use a sunscreen min. SPF 30 that protects against UVA and UVB rays to avoid post inflammatory hyper pigmentation.

The intervals between treatments depend on the time it takes for the treated area to clear up i.e. for the body to re-absorb the coagulated blood. Normal treatment intervals will be 8 weeks but in some cases destruction and clearing of blood vessels can take 3 months.

Note: the Ellipse Nd:YAG applicator has three interchangeable treatment feet.

- Standard full circular foot – is the normal attachment, used to treat most vessels.
- A semi-circular foot is chosen for treatment of vessels where a full circle would make positioning the Nd:YAG difficult)
- A full circular foot with crystal is chosen where a feeder vessel is obscured by surrounding diffuse redness. Light pressure can be applied to squeeze blood out of the smaller vessels, leaving the feeder vessel more visible and therefore more easily targeted.

Do not use the Nd:YAG unless one of the three feet is attached.

1.12 Contraindications

It is not possible for this document to give a future-proof set of contraindications. The rate of production of new drugs (medications) means that new information on drugs (and combinations of drugs) appears daily. Most countries have an up-to-date register of drugs and their side effects, including photosensitivity. If in doubt, the user should seek expert medical opinion from those with the ability to research the effects of disease and genetic conditions, and further to research the side effects of medication. Such information can also be obtained by emailing clinical@ellipse.org. Currently known contraindications are:

- Patients with any **disease or genetic condition causing photosensitivity; or patients exposed to photosensitizing substances**.
- Patients undergoing treatment with **anticoagulants (anti-clotting drugs)** or any **medication causing sensitivity to light.**
- Patients suffering from **long term diabetes** or **hemophilia**.
- Patients tending to produce **keloids (raised red scars)** or **hypertrophic (abnormal amounts of) scarring**.
- Patients with **suntanned skin** or **fever**.

- Patients taking **topical or systemic steroids**, or taking **non-steroidal anti-inflammatory drugs,** as these actively work against the treatment.
- Patients who have **smoked tobacco within 4 hours** prior to treatment where the target chromophore is hemoglobin.
- A treatment should never be carried out over a **tattoo**. Patients who have a tattoo *near* the area they wish treated should be treated with care as the ink will absorb light and cause a burn. The term tattoo also includes permanent makeup.
- Patients who have received gold injections where there has been some leakage or spillage into the epidermis in the target area. This presents as an area of dark (grey) tissue which will absorb the light energy.
- Acne vulgaris treatment: Be aware of and follow the manufacturer's advice regarding contraindications to the prescription medication, for example Adapalene (hypersensitivity to the medication or any ingredient of the medication).

Contraindications for Vascular Treatments

All general contraindications above are valid for all treatment types, but when performing Vascular Conditions**, be especially aware of the following subgroup of contraindications and notes:**

- **Clients undergoing treatment with anticoagulants (anti-clotting drugs) or any medication causing sensitivity to light.**
- **Clients tending to produce keloids (abnormal amounts of scarring) or hypertrophic scarring (raised red scars).**
- **Clients with sun-tanned skin.**
- **Clients with fever.**

Vascular Treatment Notes:

- To obtain maximum results advice the patient to avoid smoking in the 4 hours before treatment, where the target is hemoglobin.
- Areas containing fillers or fat injections may be affected by heat from the light exposure.

Amended Contraindications for Nd:YAG treatments.

- Patients taking topical or systemic steroids, or taking non-steroidal anti-inflammatory drugs, as these actively work against the treatment.
- A treatment should never be carried out over a tattoo. Patients who have a tattoo in or near the area they wish treated should be treated with care as this can cause a burn.
- Patients with any disease or genetic condition causing photosensitivity to infra-red light.
- Patients undergoing treatment with anticoagulants (anti-clotting drugs) or any medication causing photosensitivity to infra-red light.
- Patients suffering from long-term diabetes, as diabetes may affect the skin healing process.
- Patients suffering from hemophilia or other excessive bleeding and lack of clotting blood problems (coagulopathies).
- Patients tending to produce keloids (abnormal amounts of scarring) or hypertrophic (raised red scars) scarring.
- Patients with fever.
- Patients who have received gold injections where there has been some leakage or spillage into the epidermis at the treatment site. This presents as an area of dark (grey) tissue which will absorb the light energy.

Contraindication notes

Treat with Care:

- Although not specifically contraindicated, patients who are pregnant or who have a heart pacemaker fitted are normally not treated.
- Clients with any sort of implants in the treatment area should be treated with care. Modern silicone implants produce little risk, but metal implants, such as plates or screws used on broken bones can heat and expand, causing significant discomfort.

Note (Since women normally experience a natural synchronization of hair growth after giving birth, hair removal treatments should wait until then. There is no contraindication of nursing (breast-feeding) mothers, but the doctor should ensure that any proposed medical or cosmetic treatment enhancers (such as topical retinoids) will not be excreted in human milk.

- Areas containing fillers or fat injections may be affected by heat from the light exposure.
- Pregnant patients should not be treated with Nd:YAG, although there is no specific risk associated with Nd:YAG Laser treatment.

1.13 Adverse Effects

The risk of adverse effects (side effects) following Ellipse treatment is low. The risk can be minimized by following the procedure below:

- The patient should avoid sun exposure during and within one month of the end of the course of treatment. – This minimizes the risk of hypopigmentation or hyperpigmentation.
- Keep the applicator light guide free of dirt and hair (this reduces the risk of burn marks on the skin).
- Treat darker skinned patients (Skin Type 3 and especially Types 4, 5 or 6) with caution, allowing extra time to see the results of a test shot, and only increase from the default energy slowly and with care. (This reduces the risk of blistering, hypopigmentation and hyperpigmentation). These patients must be extra careful to avoid sun exposure.
- **Caution:** Lower energy should be applied over bony areas as these are at higher risk of adverse effects, since the light is reflected back from the bone. **Note:** Bony areas include (but are not limited to such as breastbone, shin or forehead). Attention should also be paid to areas with thinner skin. At all times, the operator must monitor skin reaction and get feedback from client on comfort.
- Do not use excess gel, and wipe any build-up of gel from the sides of the crystal light guide. This reduces the risk of undirected light escaping from the sides of the applicator.

Known possible temporary side effects accepted in connection with vascular IPL treatments

In general relatively frequent but temporary side effects can be seen in connection with vascular IPL treatments as detailed in "Vascular Lasers and IPL's: Guidelines for Care" from the European Society for Laser Dermatology (ESLD):

- Edema, lasting from few hours to 3-5 days.
- Erythema, lasting from few hours to 1-3 days
- Crusting and hyperpigmentation subsided within 1 week

Treatment Specific Adverse Effects:

Telangiectasias

Caution: Vascular IPL treatment of radiodermatitis might lead to longer lasting hypo-pigmentation.

Side Effects of Nd:YAG Lasers

Nd:YAG lasers have been used for many years for treatment of leg veins. The following side effects which are harmless acute reactions which resolve within a week following treatment are reported:

- The most common acute reactions were reported to be blanching, erythema, edema, darkening of the vessel, bruising, and swelling. More rare reactions were purpura, edematous papules, superficial erosions, and crusting.
- Mild pain may occur during treatment, but active skin cooling reduces the risk.
- Post inflammatory hyperpigmentation is likely to appear. Although the data found in the listed references do not permit a true statistical analysis, a trend is seen towards lower likelihood if skin cooling is employed.
- Case reports of telangiectatic matting exist. At follow up such occurrence is efficiently treated with the Ellipse VL-2 applicator.
- Case reports on persistent superficial thrombus formation exist.

The physician will not be able to inform the patient properly prior to treatment, or do a proper follow-up, if information about these side effects has not been communicated.

Chapter 2: TREATMENT SCENARIOS

2.1 General

This chapter provides step-by-step instructions for each of the treatments available on your Ellipse system. Remember that buttons are pressed by touching the screen where the button is located.

Your Ellipse system user interface is divided into a number of tab-cards – these are seen across the top of the screen. To make system operation easy, each tab card displays a number of screen buttons and text fields. These are organized to address specific steps in the patient treatment or set up procedure.

2.2 Before You Start

Installation of your Ellipse system is detailed in **Installation Note 1MAN8283**.

On power-up, the System will automatically perform a self-test to check that all components are safely installed. If the test reveals any irregularity, an error message will appear. You will not be able to treat a patient until the self-test is passed.

2.3 Logging On

The power supply to your Ellipse system is located at the rear of the cabinet. Press the "on" switch (symbol|) to power up and the "off" switch (symbol O) to turn off the power supply. (Refer to Section 2.18 Shut Down) For normal use, an ATX power button on the front of your Ellipse system allows the system to be switched on while the power supply is connected. If electrical power is supplied to your Ellipse system, the button is green when your Ellipse system is switched on and orange when switched off (standby mode).

One or two applicators must be connected to your Ellipse system on power-up. (If you need to change applicators, follow the procedure shown in Chapter 4 Changing applicators.) Your Ellipse system will automatically go through a Microsoft Windows startup screen and then show a self-test interface. This will normally be blank (while the system runs automatically), but errors will show if an applicator is not connected or if a problem exists.

Fig 5. Initial Self Test

After the self-test has completed, you must log onto the system. The factory default settings are to have one administrator and one operator. However your distributor will often personalize these settings for your clinic. The system remembers the last person to have logged in. **NOTE: only Operators can perform treatments.** Administrators can alter settings and set up operators, but cannot treat patients. The onscreen keyboard will automatically open to allow you to enter your password. **Hint**: If you wish to minimize the onscreen keyboard at any time, press the keyboard button shown.

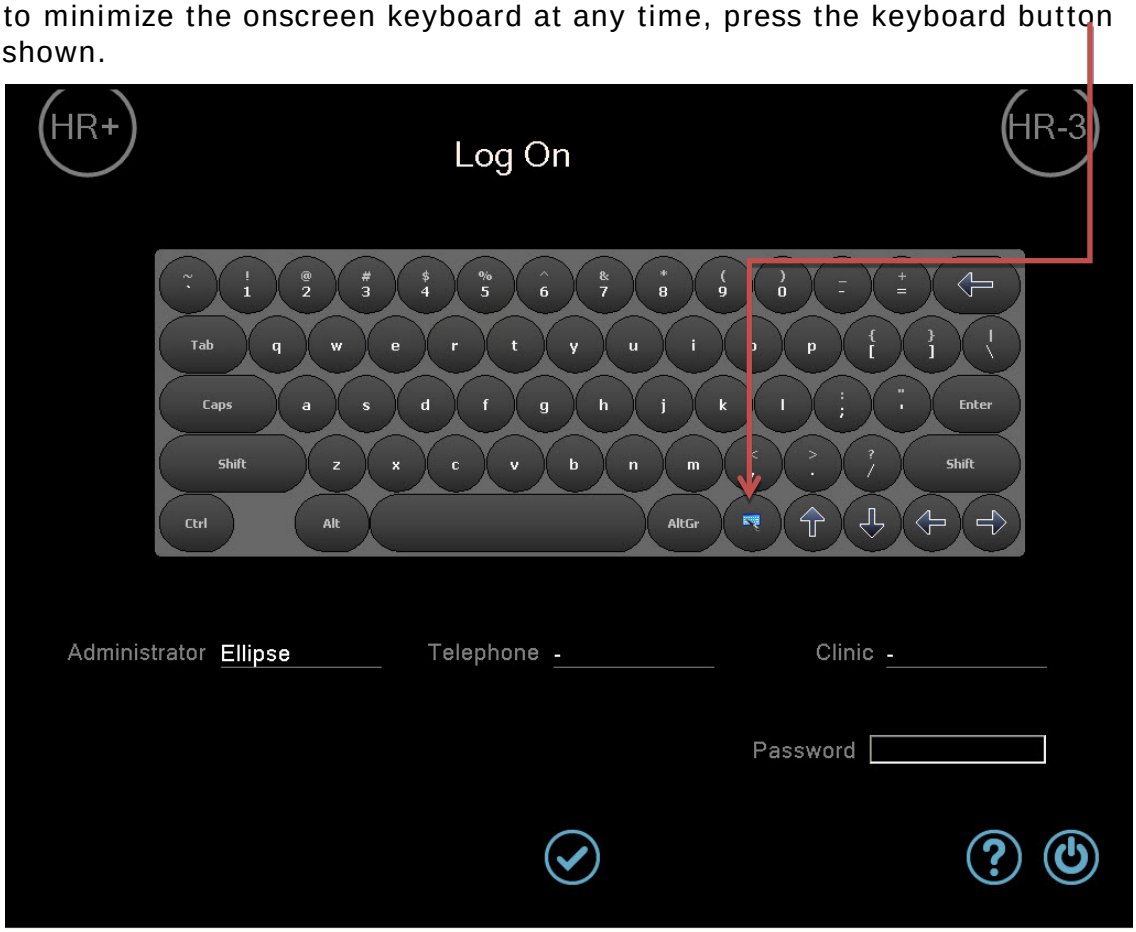


Fig 6. Default Log On Screen

The standard keyboard (inset) will be replaced by the icon: 

Pressing the icon will cause the keyboard to revert to the original size.

MultiFlex+ owners using the optional keyboard will see a slightly different Log On Screen:

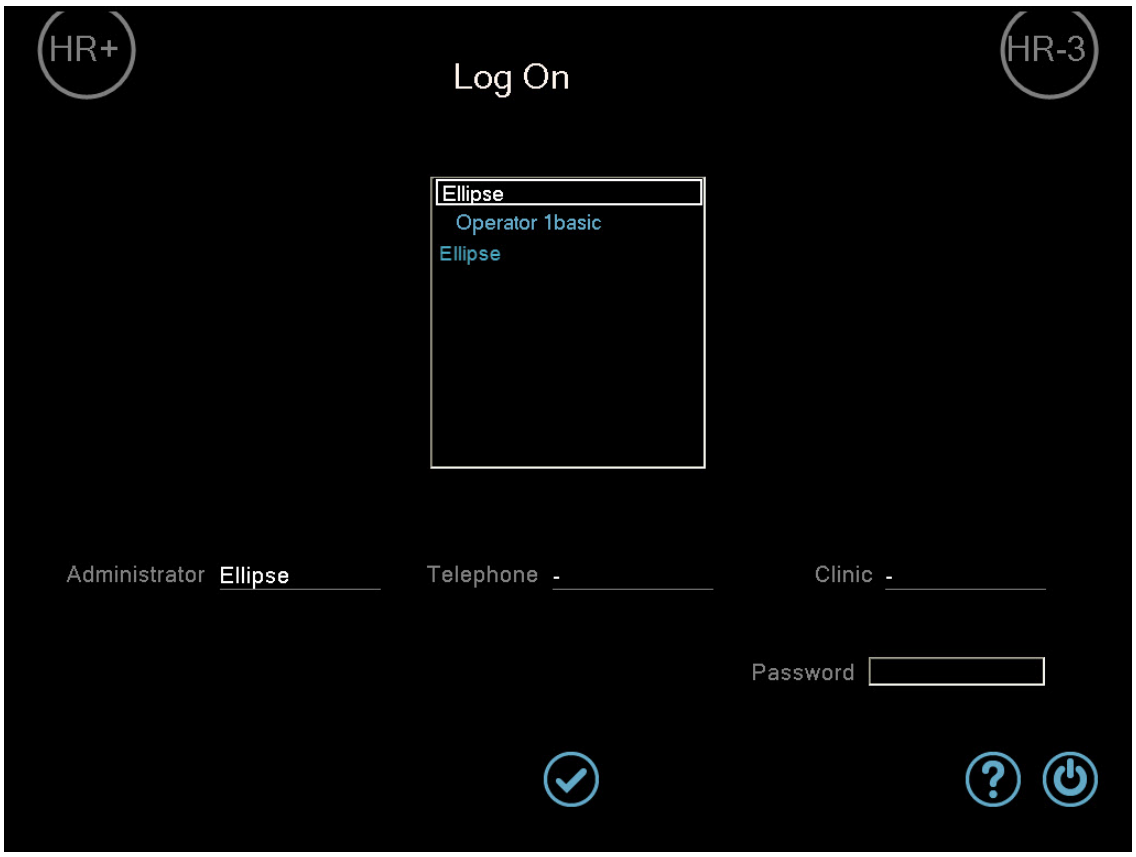


Fig 7. Default Log On Screen (MultiFlex⁺ with keyboard)

The supplied default password is "**1234**". This can be changed (either during the initial setup, or at any time of your choosing).

If the password is changed, remember to make a note of it. When the correct password is entered, press the confirm  icon.

If you make an error when entering your password, you can correct it using normal keyboard keys. If the password entered is incorrect you will be notified.

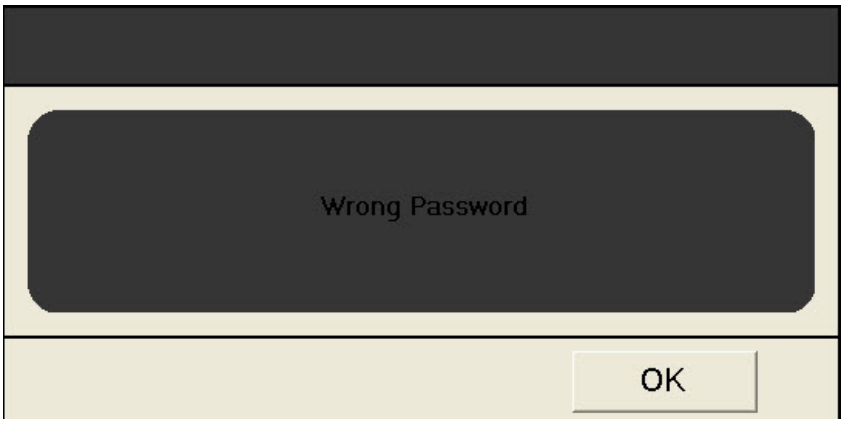


Fig 8. Incorrect Password Warning

If this happens, then press <**OK**> and re-enter the password, then press the confirm icon.

If you press the power off icon, the system will shut down.

If you have logged on as an Administrator, you will be taken to the Settings screen.

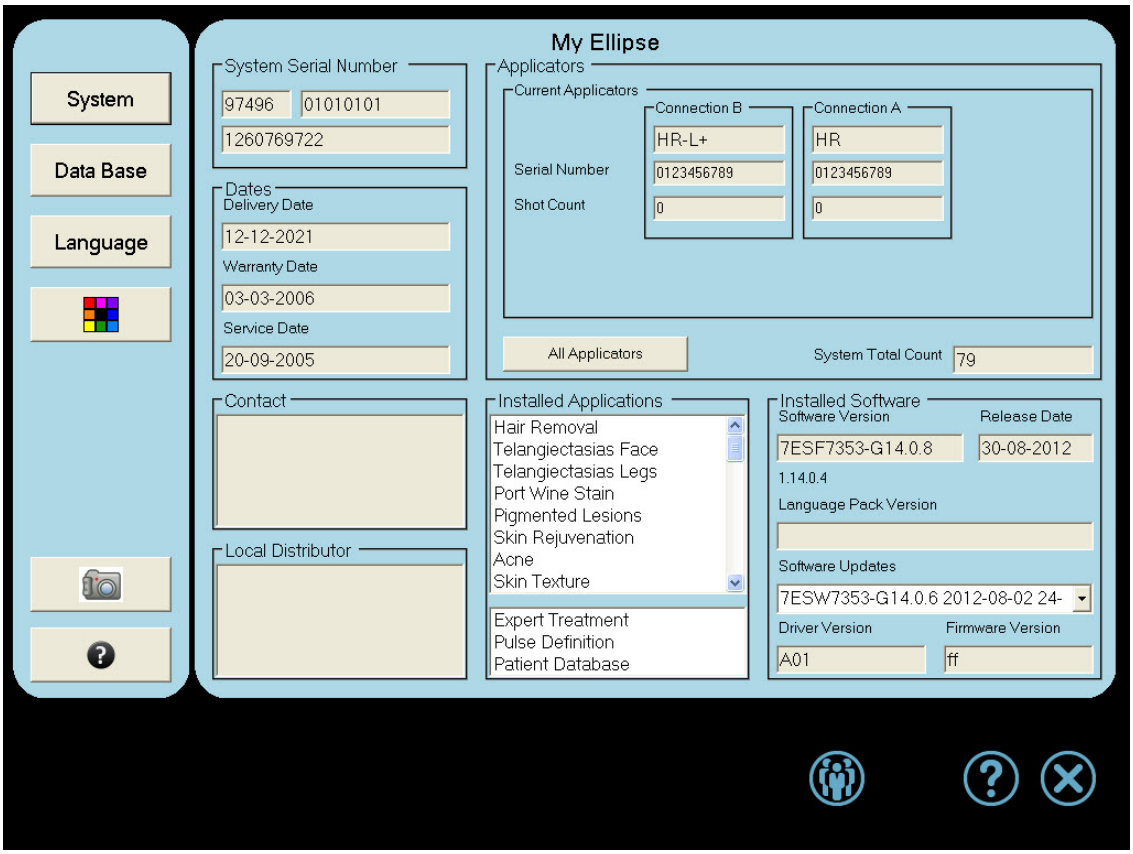


Fig 9. Initial Settings Screen

The Settings Screen details how your Ellipse system is configured. This initial view will be different from that shown in Fig 9, depending on how your system is set up. The Settings Screen is covered in more detail in Section 2.17 Settings.

This section of the manual will continue with guidance on operating the system. To continue, you will need to log in as an operator. If you are logged in as an Administrator, you will need to Log off – press the exit icon shown in the bottom right corner of the screen. This will result in the Log Off / Shutdown box being displayed:

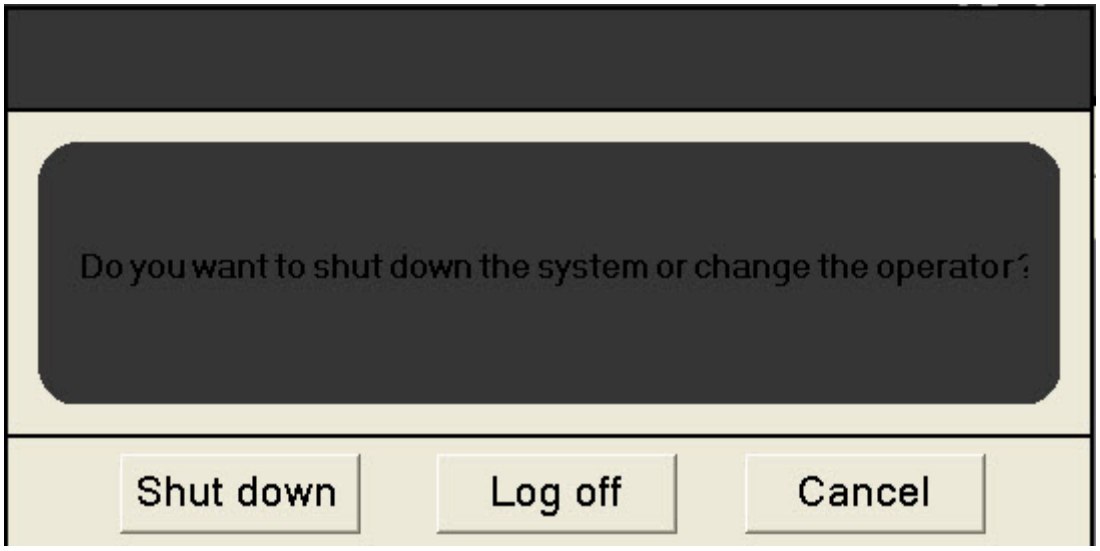


Fig 10. Log Off / Shutdown box

If you press **<Shut down>**, the system will shut down. If you press **<Log off>** you will be taken to the Log on Screen shown in Fig 6 or Fig 7. Simply select the operator name to log on – note the name turns from blue to white when selected.

Then enter the password and press  . You will be taken to the Patients Screen  (Section 2.5).

2.4 Help and Error Messages

Help

At any time, you can get access to the on-screen manual by pressing the help  icon. This is located in the bottom right corner of the Patients Screen  , Patient Parameter Screen, and all Treatment and Expert Treatment screens. It is located at the bottom left of the Settings Screen  .

Pressing the Help button will open the on-screen User Manual or Clinical Workbook as an Adobe Acrobat File.

Adobe Acrobat Icons	
Icon	Function
	Print Help File (requires a printer to be connected)
	Save Help file – choose a USB external drive
	Send Help File as Email – DO NOT PRESS
	Start Acrobat Connect Meeting - DO NOT PRESS
	Go to Previous Page of Help File
	Go to Next Page of Help File
	Current / Total Help File Page
	Select Text and Images Tool – DO NOT PRESS
	Page through the contents
	Enlarge tool (magnify selected area)
	Decrease magnification of page
	Increase magnification of page
	Sign – DO NOT PRESS

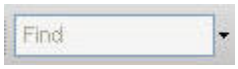
Adobe Acrobat Icons	
Icon	Function
	Adjust size to fit page width
	Adjust size to fit full page
	Find Text
	Display page Thumbnails (you have the option to enlarge or reduce image size)
	Display Bookmarks (you have the option to hide the bookmark after pressing it)
	Search for Text
	Adobe Help
	View File Attachments - DO NOT PRESS
	View Comments - DO NOT PRESS
	Close the Help Screen and return to Ellipse page

Fig 11. Adobe Acrobat Icons on the help screen

The on-screen User Manual contains full information on your Ellipse system (comprising this document and Essential Information). The Clinical Workbook is a marketing document providing background information.

Error Messages

Error messages can be seen during Self Test, and occasionally your Ellipse system may display an on-screen error or warning message. These fall into 3 categories.

Fig 12. A simple instruction to take action

Fig 13. Notification that you have made an error.

Fig 14. Notification of a System Error.

If you are unclear as to the meaning, contact your Ellipse representative.

If you see a System Error Message, do not attempt to repeat the shot with the applicator in contact with the patient, until you are sure it is safe to do so. Therefore if you repeat the shot, the applicator should be held away from the patient's skin.

When an error message appears during self test, you will most often get sufficient help from the error message. However if the message is not clear, you should contact your Ellipse distributor. Errors are logged by your Ellipse system, so a Service Technician will be able to see all errors that have occurred.

2.5 Patients Screen

The Patient screen is used to display patients who already exist in the database (initially none) and to enter data for new patients into the database. A patient treatment session will always start on the Patient Screen.

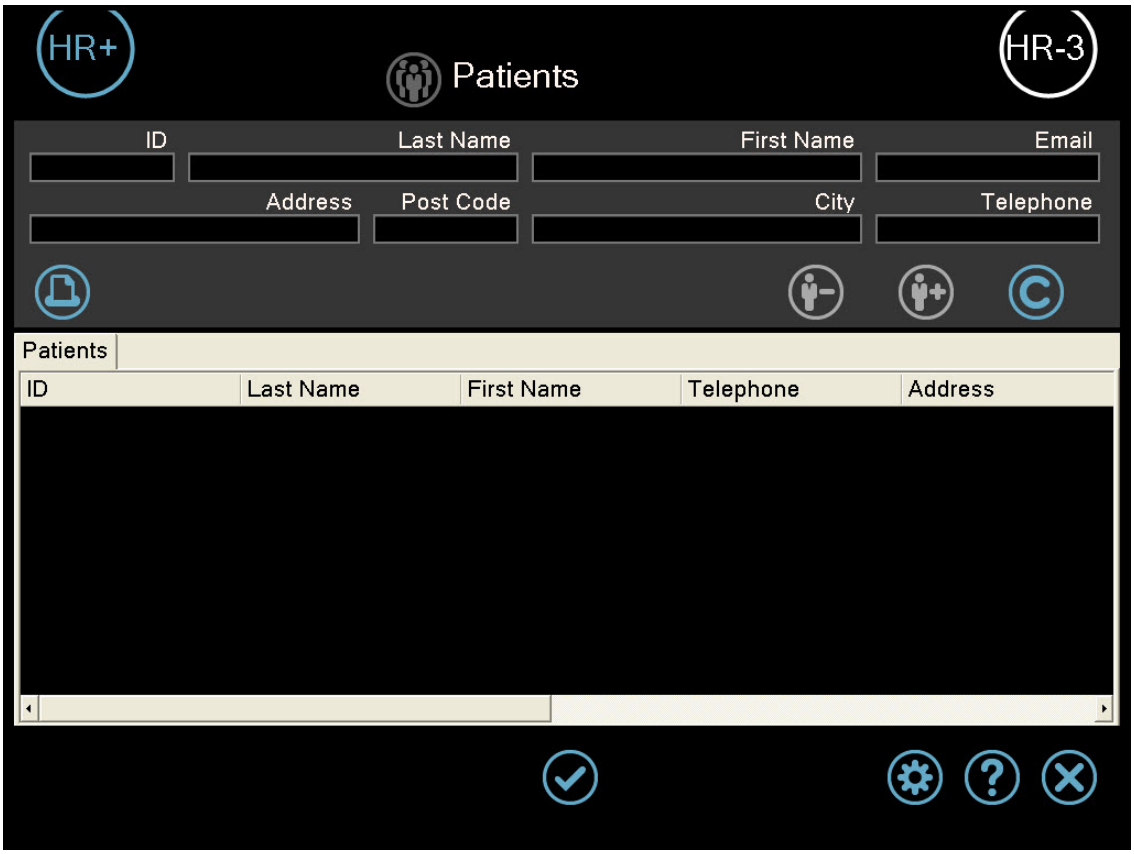


Fig 15. Patients Screen

Adding a New Patient

When you first select the Patients Screen, you will see a screen showing all existing clients as in Fig 15 (initially there will be none).

You will notice a flashing cursor in the ID field. This is the only field that must be entered. If you use a standard ID (e.g. social security number, billing number) for all your patients, then you can enter this now in the ID field. Alternatively, your Ellipse system will autogenerate an ID for you later. As soon as you enter text in any field, the **Create Patient** icon changes colour.

It is recommended to add the extra information to be able to identify patients accurately. Press the Tab key on the keyboard – or press the last name field on the screen - to move to the next field (Last Name) and type the name. You can press Tab to move forward from field to field, or Shift followed by Tab to move backwards. Use the backspace button on the keyboard to clear data from the field you are working in. To clear all the information you have entered for a patient, press the clear data icon.

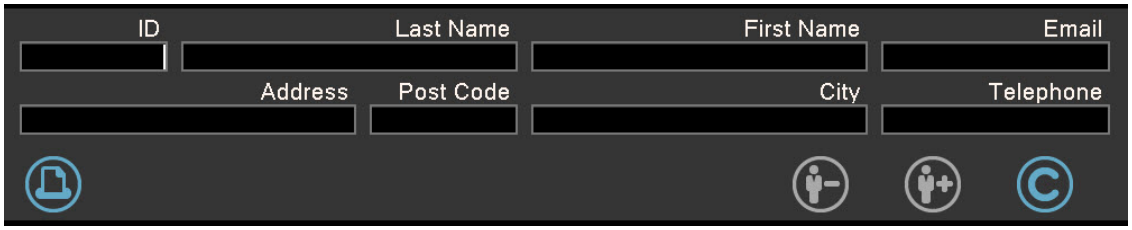


Fig 16. Patient Information

When you have entered the information, press to add the information to the database.

If you have not entered an ID, you will be prompted to do so.

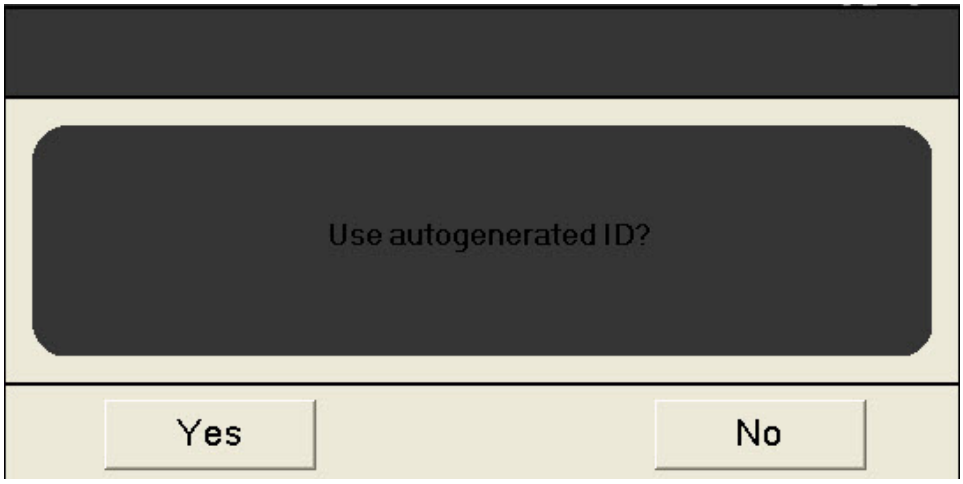


Fig 17. ID Reminder

If you don't wish to use the system-generated ID, then press <**No**> and add your own chosen ID. Or press <**Yes**> to use the system generated one.

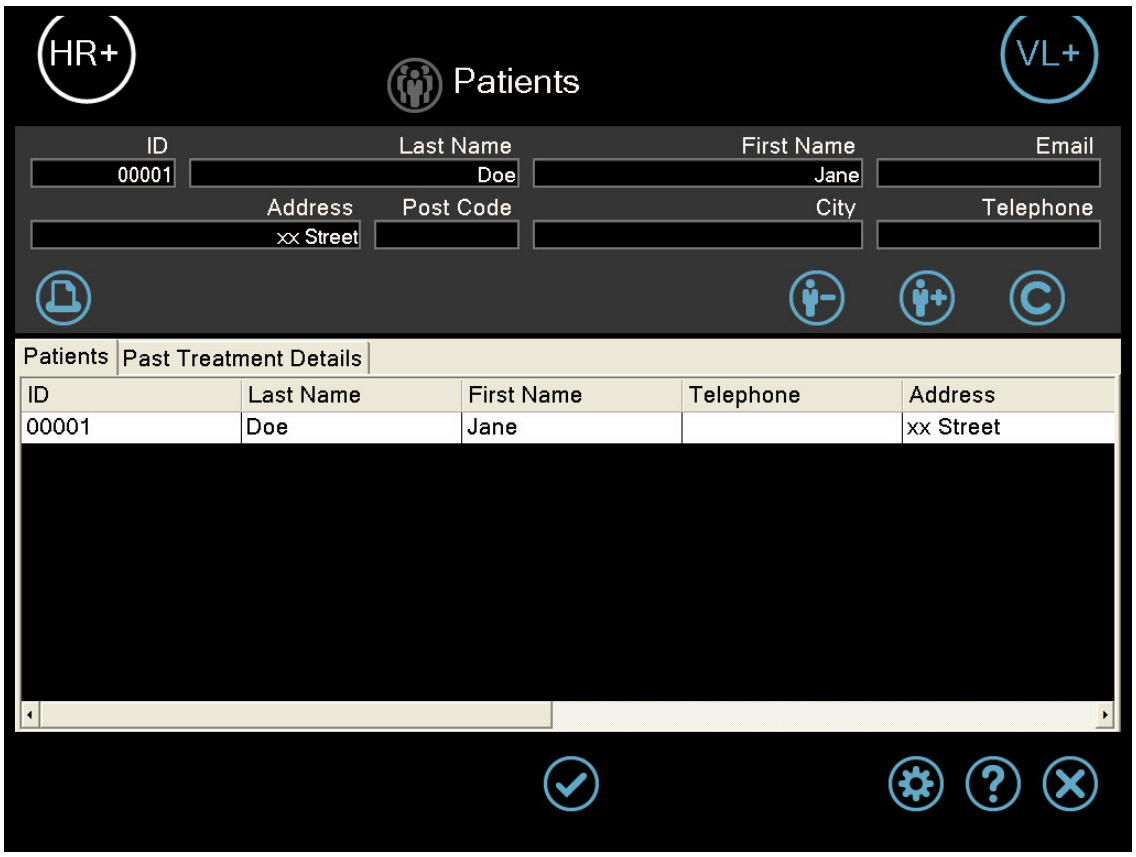


Fig 18. Patient Added

If you wish to add another patient, then press the clear data icon to clear data for the previous entry and then the actions detailed above.

To continue to the Patient Parameters (List of Treatments) Screen, press . go to Section 2.6 Treatment Selection.

Note that you can delete a patient by selecting the patients name and pressing the **Delete Patient** icon. You can also print out the patient details – if you have a printer attached – by pressing the Print icon.

Treating an Existing Patient

The Patients Screen opens by showing a list of all existing patients. If the patient to be treated already exists in the database, they can be found easily. You can sort the patients by ID, name or address by pressing the appropriate column heading. Pressing the heading for a second time will reverse the order of the patients.

Treating an existing patient is done by simply pressing on his or her name. The selected patient will be highlighted in white and his or her data displayed in the text field.

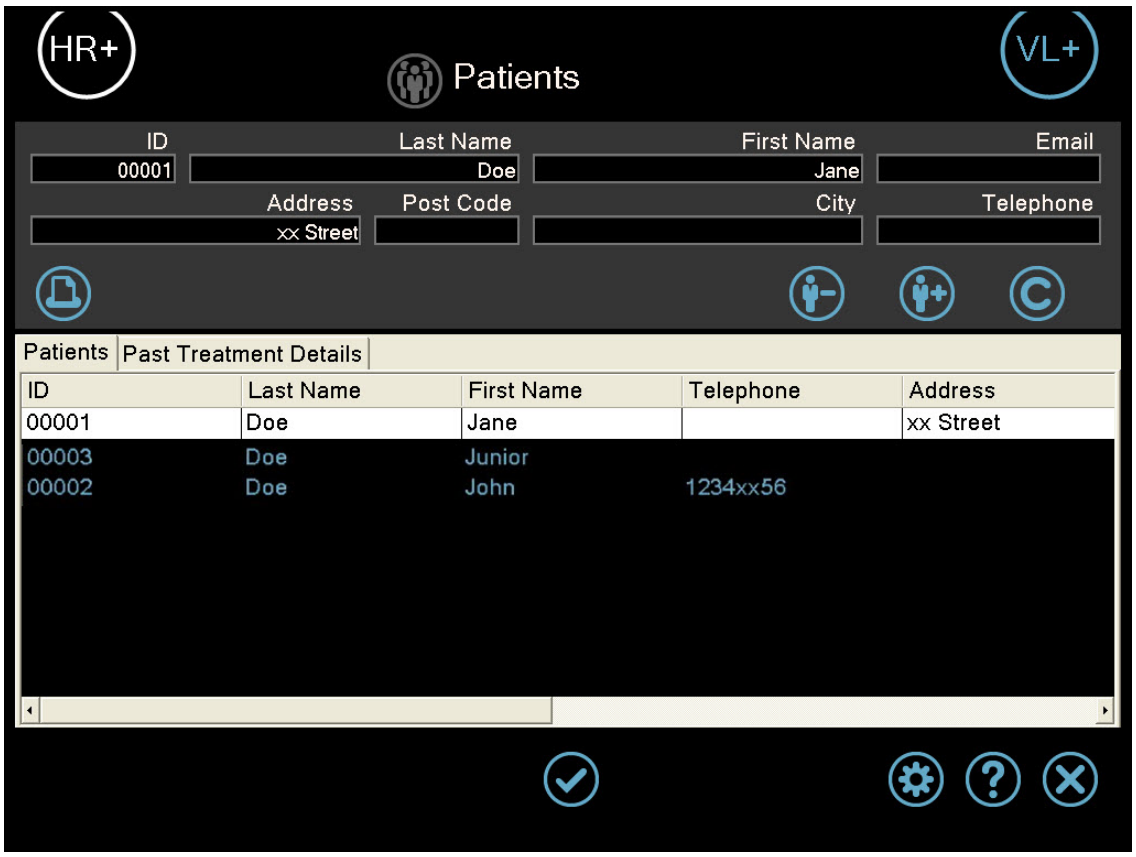


Fig 19. Patient Selected

If you have so many patients that it becomes difficult to find a specific one simply by pressing on her name, it is possible to enter partial data in any field. The example below shows a patient highlighted by matching part of the telephone number.

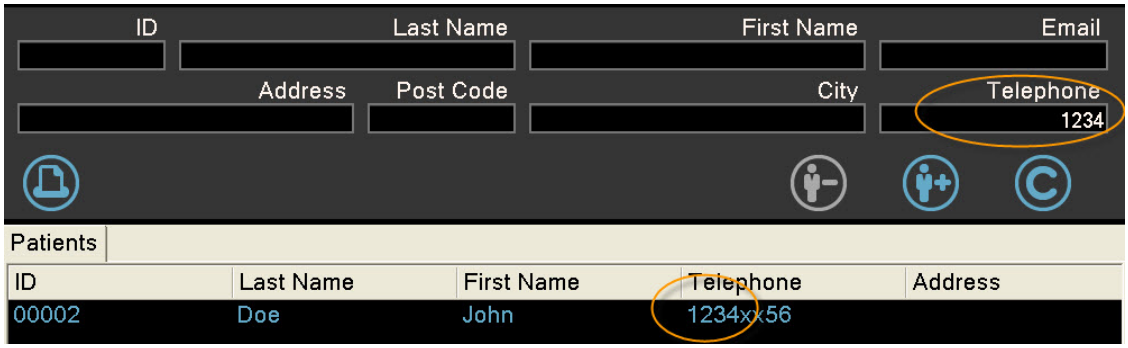


Fig 20. Patient Data Matched

As soon as the number of patients matching the selection criteria is manageable, you can select the patient you wish to treat by pressing the name.

Once an existing client is selected, it is possible to edit the data for that client. Simply type over the data you wish to change. (Note that it is not possible to edit the ID field.) When finished, press the  icon.

You are then clear to start the treatment. Ensure you have selected the correct patient and then press the confirm  icon. Go to Section 2.6 Treatment Selection.

When a patient from the list of patients is selected (by pressing the screen over her name) a new tab card opens

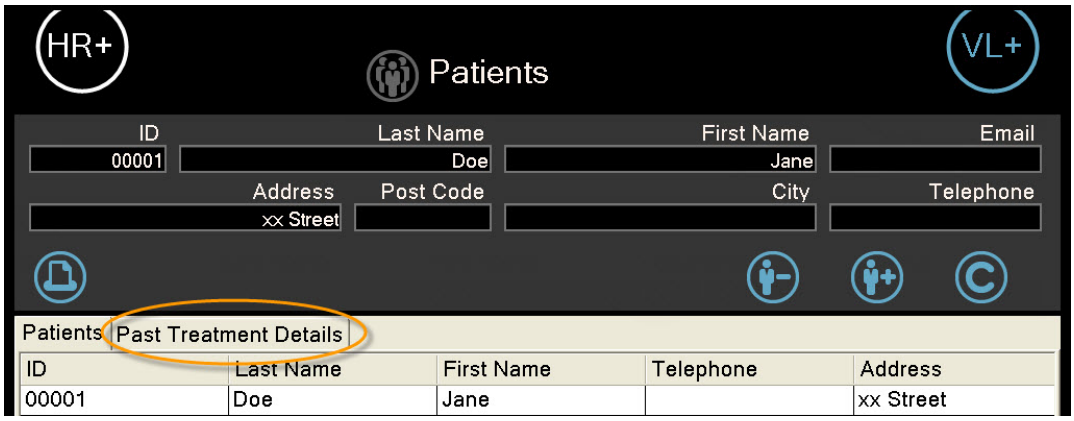


Fig 21. Patient Screen

Pressing <**Past Treatment Details**> will open a screen showing the previous treatments:

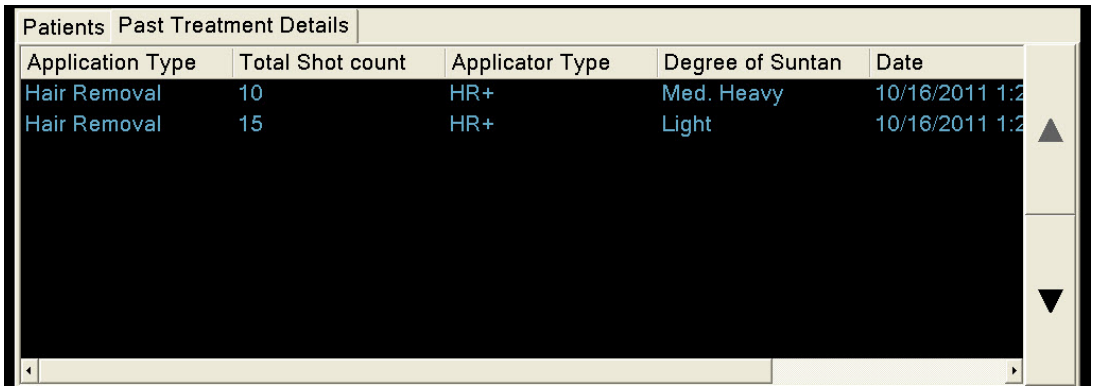


Fig 22. Past Treatment Screen

You can look at the details of a previous treatment by selecting it. For example highlighting the second treatment shown in the figure above will result in the following screen:

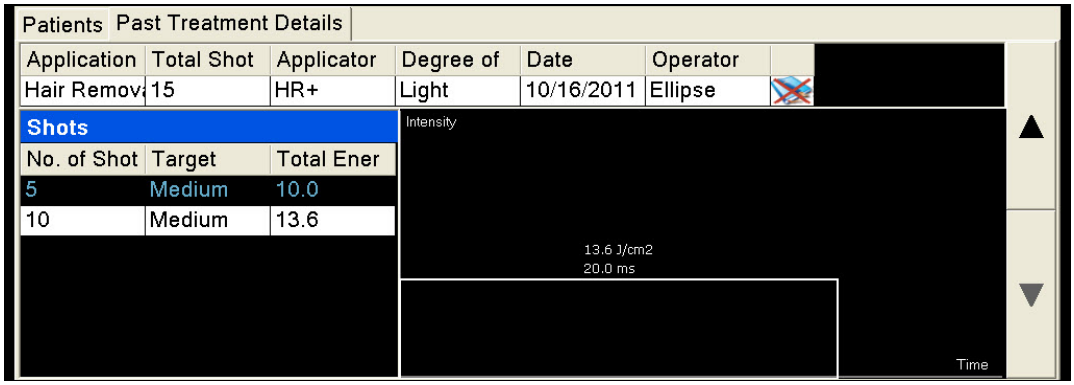


Fig 23. Past Treatment Detail Screen

You can repeat a previous treatment by pressing the confirm icon. If you press , you will be asked to confirm the Degree of Suntan before you are taken to the treatment screen. You can make adjustments to the treatment energy directly from the treatment screen.

Note

Patient parameters may have changed. The system prompts the operator to confirm the degree of suntan (as this is the parameter that can change most). However, always bear in mind that the target size may have changed from a previous treatment. Is the vessel size or hair thickness identical? The skin type will be unchanged, but all other parameters may change from body site to body site and between treatments.

Changes may have occurred in applicator output. The applicator used to carry out the new treatment may be a different one than was used to carry out the previous treatment. Slight differences in applicator output do exist, and even if the same applicator is used to carry out the treatment, a large number of shots may result in a slight reduction in power.

Human error. It is possible to select the wrong line from a list of previous treatments. At the initial treatment several different energy settings may have been used to determine a successful treatment.

Recommendation
Always double check the parameters used before commencing the treatment.

By pressing the Print icon, you will be given the option of printing the latest treatment or all treatments for the chosen patient.

By clicking the arrow up button in the right side of the screen, you return to the "Past Treatment Details" overview as shown in Fig 22.

2.6 Treatment Selection

Patient Parameters (List of Treatments) Screen0000022222222 can be reached from any screen where you see the treatments icon. However it is normally reached from the Patients Screen by pressing the confirm icon. Before you press , ensure you have selected the patient you wish to treat. If you have not selected a patient, you will be prompted to select one. Ellipse strongly recommends you do **not** perform anonymous treatments.

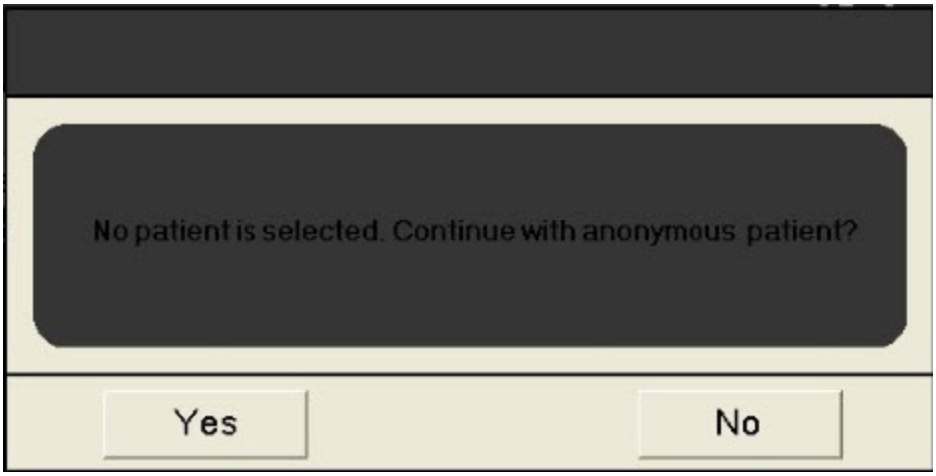


Fig 24. Reminder to Select Patient

If you press <**No**> you will be given the opportunity to select the patient for treatment.

After you press  , you will be asked to enter treatment parameters. This happens in 3 or 4 stages, depending on the treatment being carried out.

- Stage 1 is the selection of the treatment from those available on your system.
- Stage 2 is the Fitzpatrick Skin Type.
- Stage 3 is the Degree of Suntan of the **area** where treatment will be performed.
- Stage 4 is the treatment parameter (basically the colour or size of the target). Note there is no treatment parameter for diffuse redness and pigmentation or acne vulgaris.

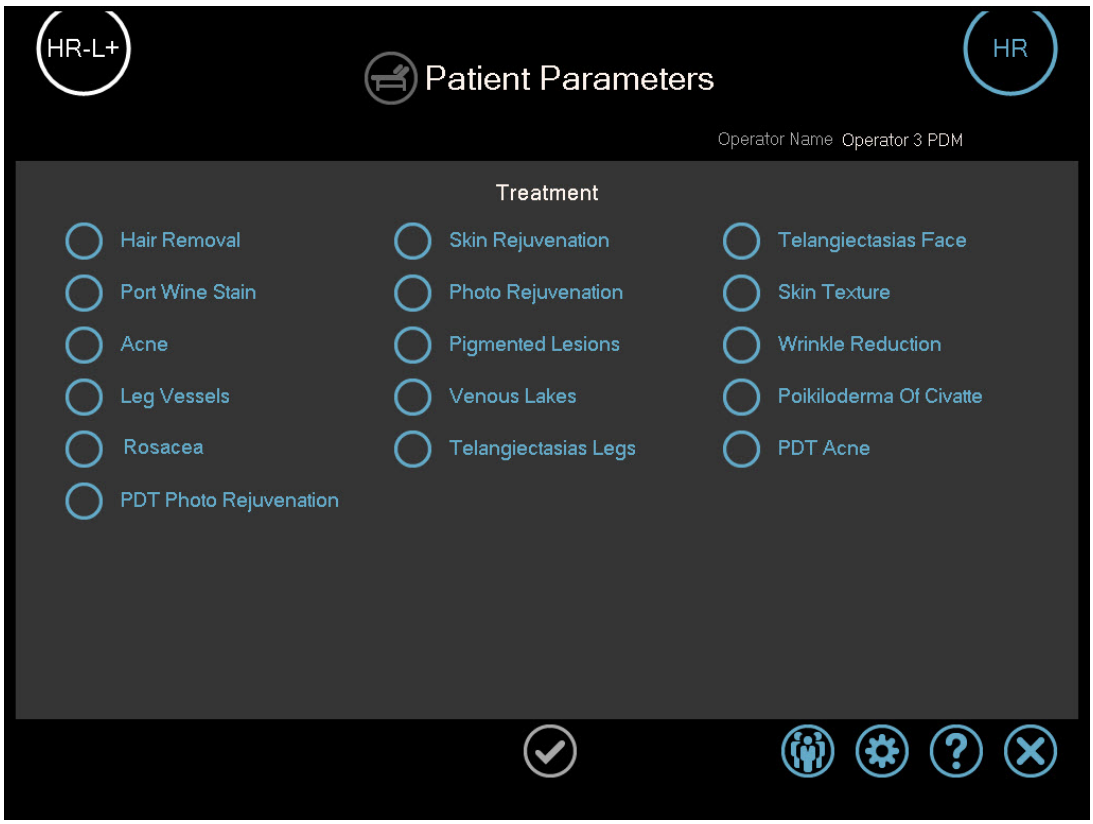


Fig 25. Patient Parameters Screen – Treatments (International to be replaced with US Version)

When you have selected the treatment (by pressing the circle or treatment name next to it) the treatment will be highlighted. The list of treatments will shrink, to allow the next parameter to appear.

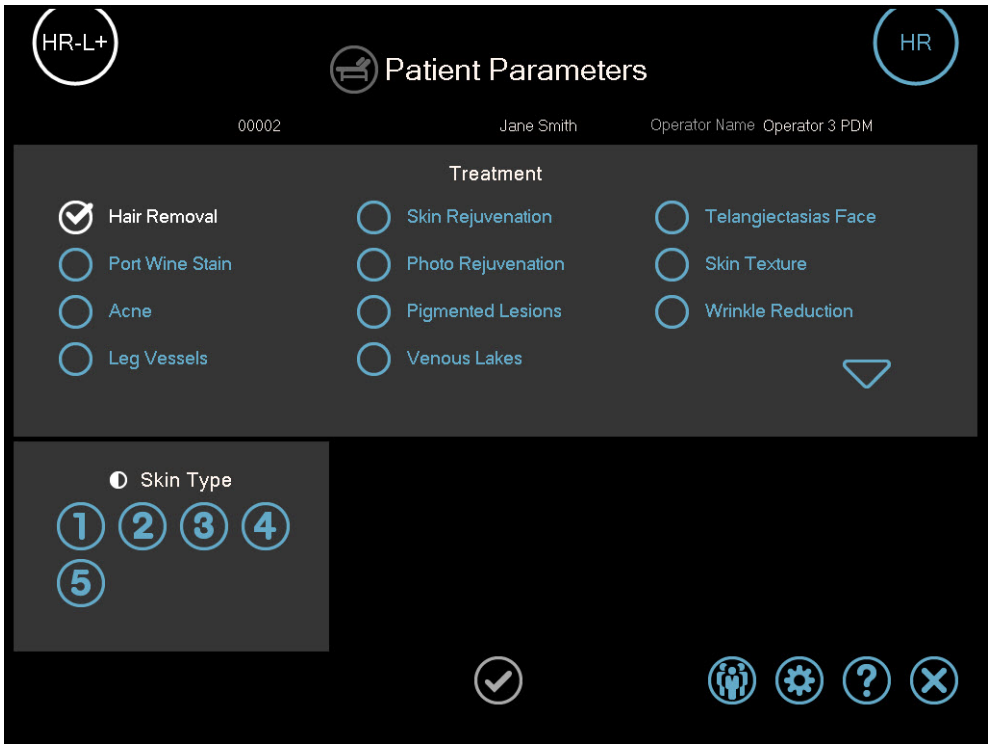


Fig 26. Patient Parameters Screen – Skin Type (International to be replaced with US Version)

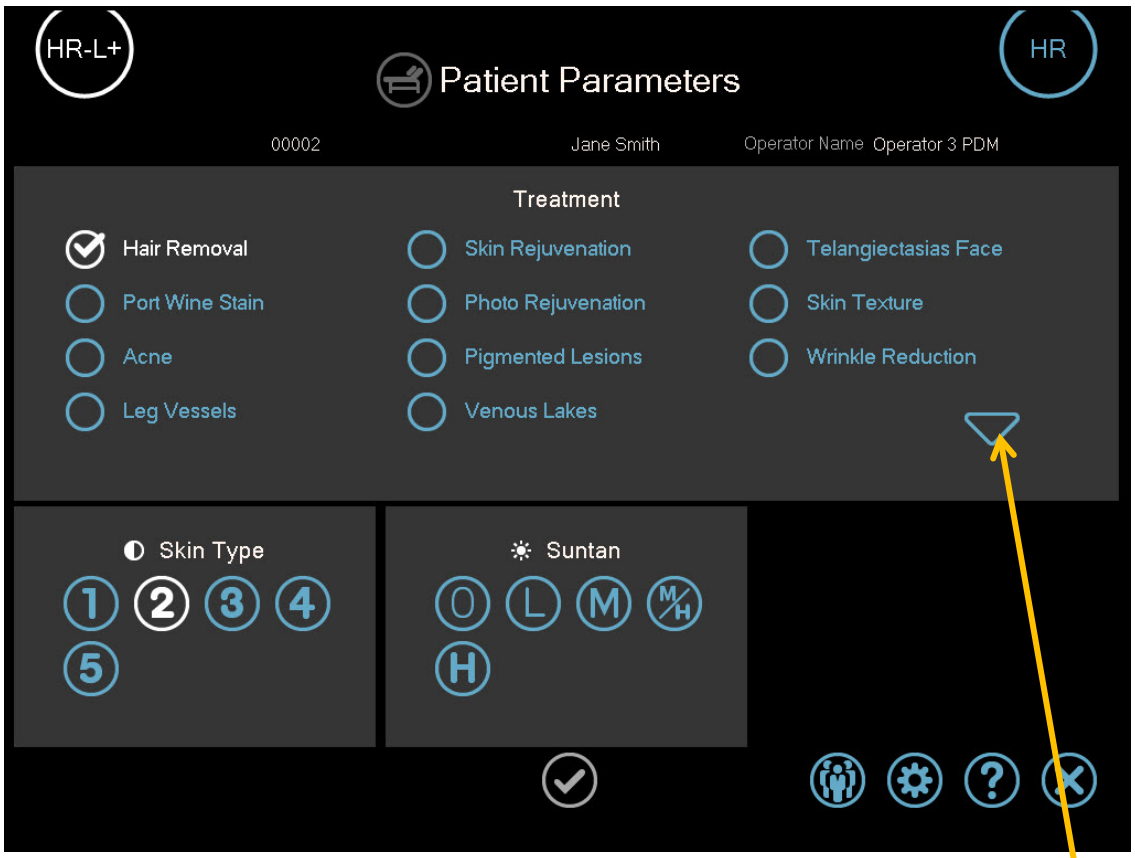


Fig 27. Patient Parameters Screen – Suntan (International to be replaced with US Version)

The list of treatments can always be expanded again by pressing the arrow

Note: Normally, only Skin Types and Degrees of Suntan where recommended settings are available are shown. If a combination of Skin type and Degree of Suntan is not recommended, it is normally hidden and cannot be accessed. I^2PL^+ system users working in Expert Mode and MultiFlex$^+$ users in Expert or Pulse Definition Mode (see Chapter 3) will see the missing combinations in orange. Treatment is not recommended on non-standard skin type and suntan combinations as there is an increased risk of adverse reaction to treatment; an on-screen reminder will be shown and the energy will be greatly reduced.

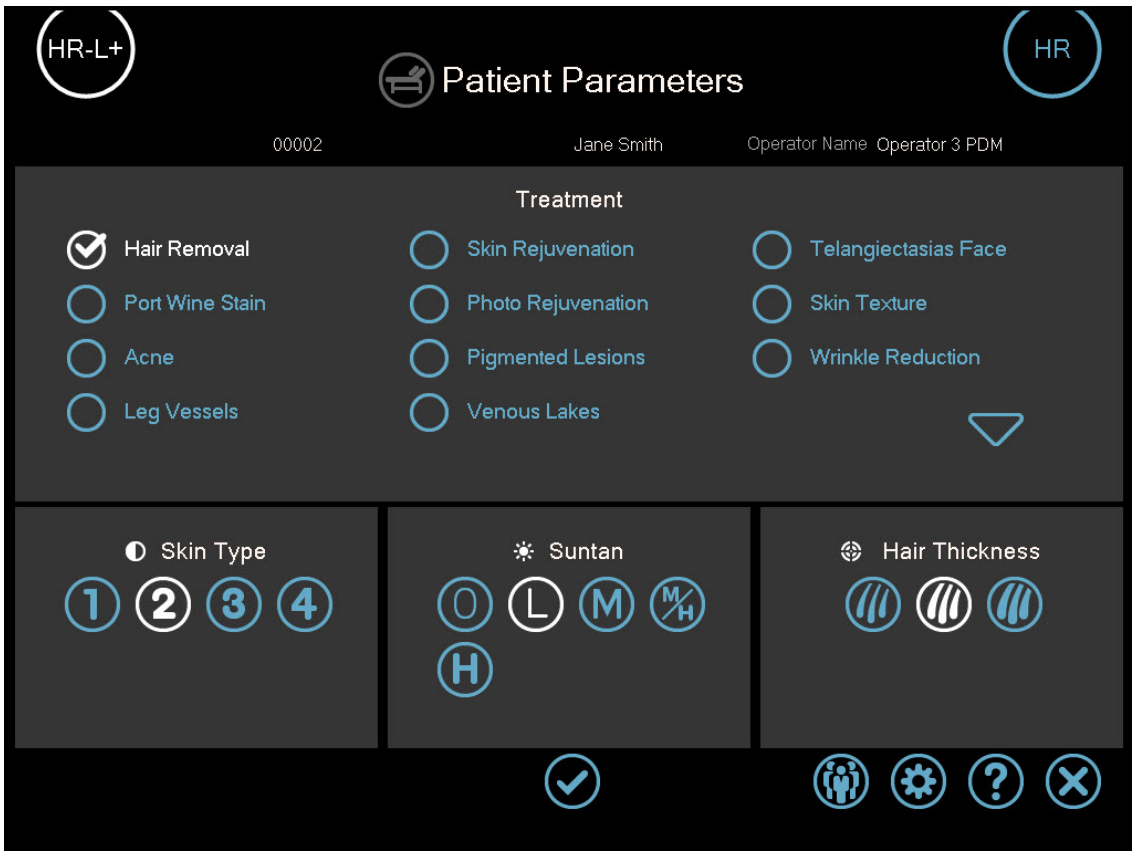


Fig 28. Patient Parameters Screen – Hair Thickness(International to be replaced with US Version)

Your Ellipse system recognizes the applicators (Hand Pieces) connected to the System, and shows the appropriate treatment screen after the user has confirmed the details by pressing  . If the treatment requires an applicator that is not attached, you will be reminded to change applicators in the status bar at the bottom of the screen. For example if you had selected pigmented lesions with the applicators connected as shown above, you would see the following warning.

Fig 29. Change Applicator Error Message

You can connect 2 applicators to your Ellipse system at the same time, or run with only one applicator connected. The applicators connected are shown at the top of the treatment screen.

Fig 30. One Applicator Connected

The image above shows one (HR+) applicator connected at Connection B. The letter "A" shows that Connection A has no applicator attached.

If two applicators are attached, (in this example HR+ and VL+), you will see the following

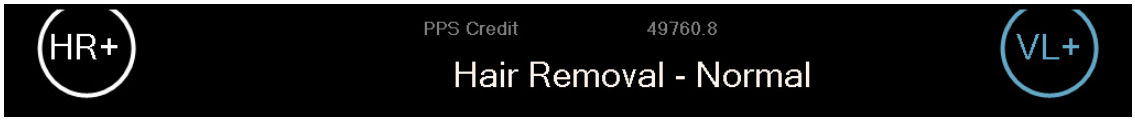


Fig 31. Two Applicators Connected

If both connected applicators are capable of performing the treatment you will be able to change between them by pressing the button. The applicator chosen will be highlighted. If only one applicator is capable of performing the treatment, then this will be automatically highlighted – it will not be possible to change across to an unsuitable applicator.

If you want to connect a different applicator, you need to follow the process shown in Chapter 4 Changing applicators. Your Ellipse system will automatically detect a new applicator when connected.

If you wish to carry out a different type of treatment on the same patient with an existing applicator follow the same basic procedure of selecting treatment, and patient parameters.

Note: if you change applicators when your Ellipse system is shut down, the system will detect the change when you start the System again.

When you are sure that the patient and treatment parameters are correct, press accept treatment to begin treating. In the example given in Fig 28, press  to go to the following treatment screen.

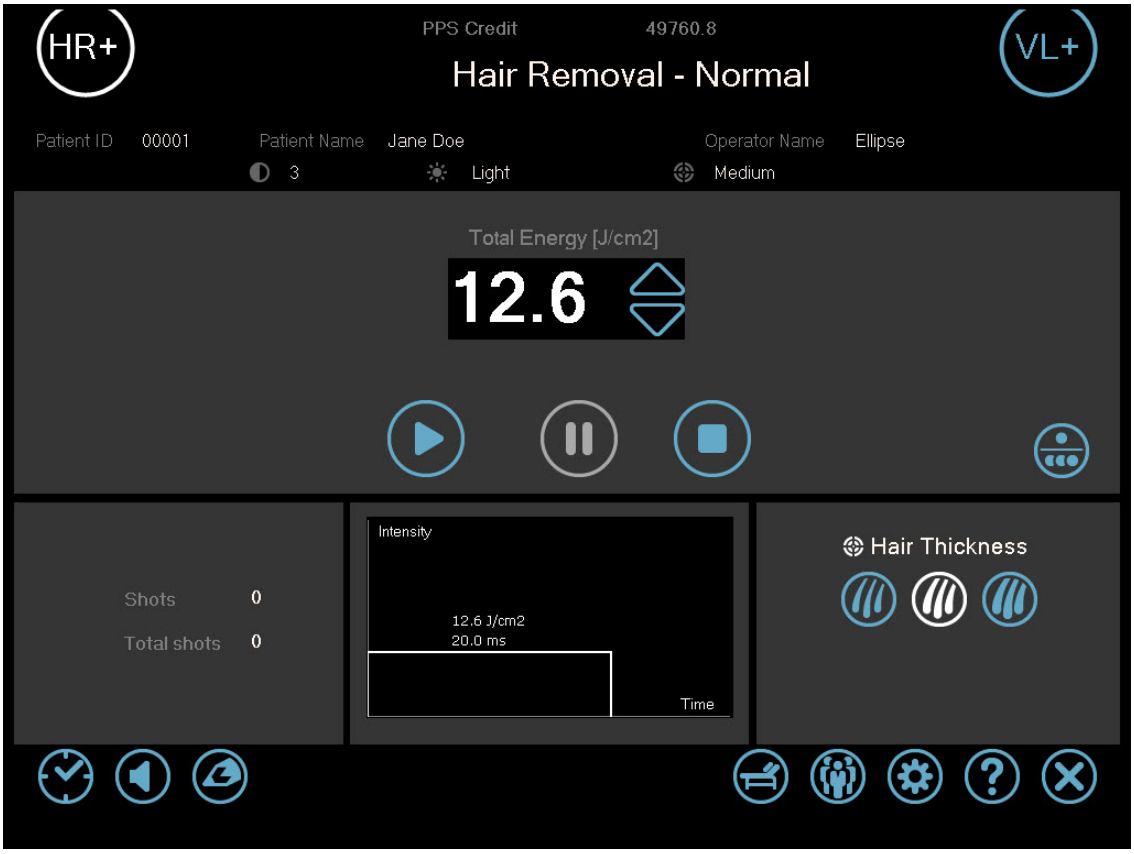


Fig 32. Example Treatment Screen

2.7 Treatment Screens

Background

The Treatment Screen confirms the patient parameters selected earlier, and present these with a default treatment for the parameters selected.

Sections 2.9– 2.19 show the treatment screen for each individual treatment available using your Ellipse system. Not every treatment may be available on your individual system. Each treatment screen has the same basic layout – the screen is divided into 8 areas.

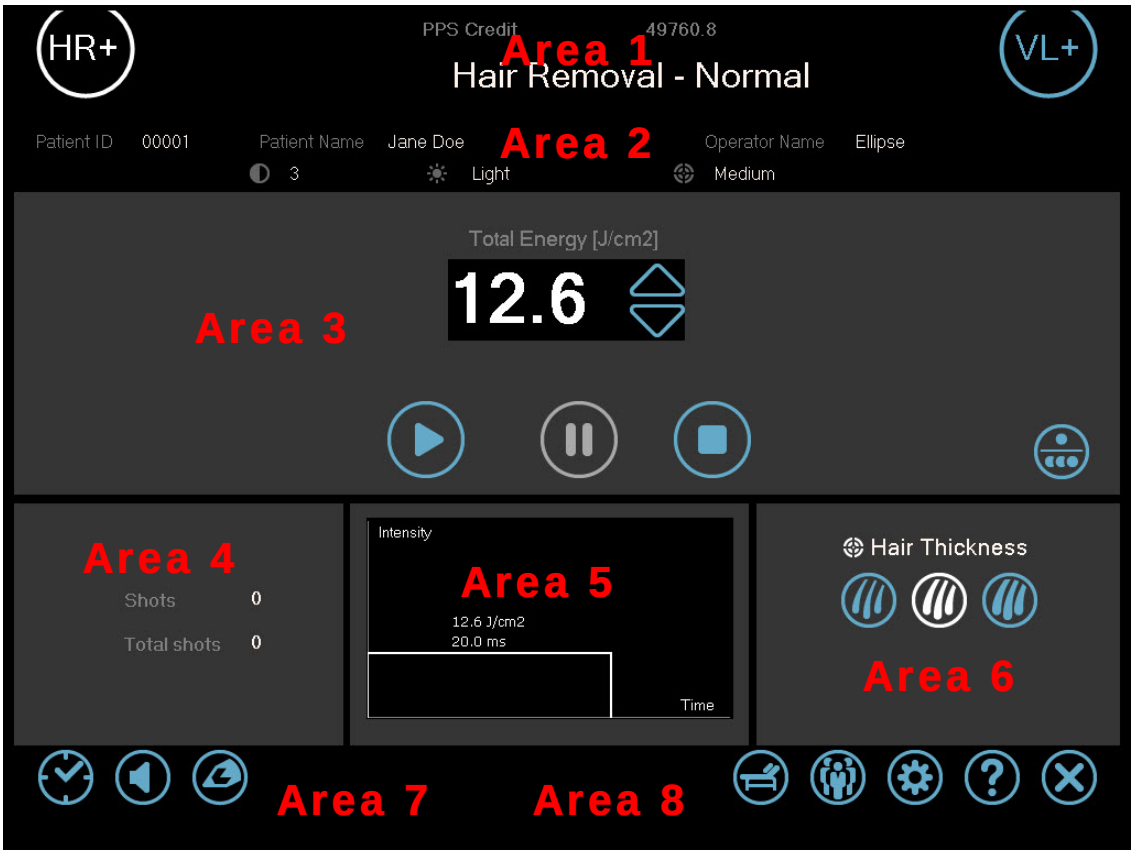


Fig 33. Areas of Treatment Screen

- Area 1 confirms you are in the Treatment screen, and shows the Applicators connected. It also shows the number of credits left on your PPS Dongle.
- Area 2 shows the Patient Data and Patient Parameters you have selected before treating.
- Area 3 shows the energy used to perform the treatment. In expert mode, it will also show you the number of pulses, pulse length and pulse delay. This is also the area where the main instructions are given: to start  , pause  or stop  the treatment; to cycle between normal and expert mode, or normal, expert and pulse definition mode  .

- Area 4 shows the number of shots (flashes of light) released using the current settings, and also the total number fired for this treatment.
- Area 5 gives a pictorial display of the pulse length and energy used to perform the treatment.
- Area 6 allows you to change treatment parameters, when treating the same patient – in the example shown, you could switch from normal to thin or thick hair
- Area 7 allows you to make minor system changes - to the minimum interval between shots  , to the volume of the beep given as an audible signal that the applicator is ready to fire  and also gives you the opportunity to make a comment about the treatment  .
- Area 8 is the area where you can choose to the main screens: all patients  , all treatments  , access settings options  or the help menu  . It is possible to log off or shutdown the system from here  .
- Any error messages or warnings will be shown in areas 7 / 8.

2.8 Treatment of a Patient (All treatments)

Treatment of a patient is always accessed by

- selecting an existing patient, or entering a new one, as detailed in Section 2.5 Patients Screen
- selecting the appropriate treatment parameters as detailed in 2.6 Treatment Selection
- ensuring the applicator appropriate to the treatment is connected.

If the combination of Skin Type and Degree of Suntan can be treated with the chosen applicator, the default Energy (J/cm^2) setting is automatically calculated. This is based on the Skin Type, Degree of Suntan and treatment parameter you have selected.

- To increase or decrease the energy, press the up or down arrow on screen.
- If you change the Energy setting from the default, the white Energy field changes colour.

Fig 34. Example of (left) default and (right) increased energy

- You can select a different target variable (hair thickness, vessel size, vessel colour or pigment colour within the treatment screen. Clicking on the treatment variable (Area 6) will restore the default energy for the treatment variable (based on the patient parameters you have selected).
- Use of the various applicators is similar. They are chosen according to the treatment, the patient Skin Type and Suntan combination. Note that the default energies and maximum energies vary according to the applicator in use.
- You must check that the Energy setting is safe and appropriate.

  Validate the data you have entered and press  .
- You will see a note at the bottom of the screen that informs the System is charging. When the System is charged (ready) you will hear an audible beep. (At the same time a message appears at the bottom of the screen to advise the System is ready.) Pressing the trigger of the applicator releases the pulse of light selected using the console. Note that the time between shots can be adjusted using the Timer Control.
- Use a test shot in an area relevant to the treatment area, but not too prominent.
- Judge both the skin reaction, and the patient's response (discomfort level). The time that should be allowed for skin reaction depends on the Skin Type of the patient.
- If you have to adjust the Energy, this is done by pressing the up/down buttons as before.

- To terminate the treatment press  . To take a break, press  and then  to recommence treatment.

Note: Always stop the treatment before exiting the treatment page. Always pause or stop the treatment before selecting a different applicator.

2.9 Treatment of a Patient (Hair Treatment)

For Hair Removal, choose the HR$^+$, HR-D$^+$, HR-S or HR-L$^+$ applicator. On the Patient Parameters screen  , you choose Hair Removal, the Skin Type and Suntan and the thickness of hair to be treated.

Note:

SPT$^+$ and I^{2}PL$^+$ (Standard Operator):Only combinations of Skin Type and Degree of Suntan that are approved for treatment are shown.

Skin Type	Maximum Suntan Allowed (HR$^+$, HR-S, HR-L$^+$)	Maximum Suntan Allowed (HR-D$^+$)
4	Medium	Medium
5	None	Light
6	Not Allowed	None

Fig 35. Maximum Skin Type & Suntan Combinations – Hair Removal

If you are treating a small area of hair (in the nose, ears, or between eyebrows) use of the HR-S Applicator is recommended. Large areas, such as back or full legs are most efficiently treated using the HR-L$^+$ applicator.

When you have selected the correct patient parameters, press  .

I^{2}PL$^+$ or MultiFlex$^+$ (Expert Operator)

If you choose a combination of Skin Type and Degree of Suntan that requires use of the HR-D$^+$ applicator, you will see a warning message:

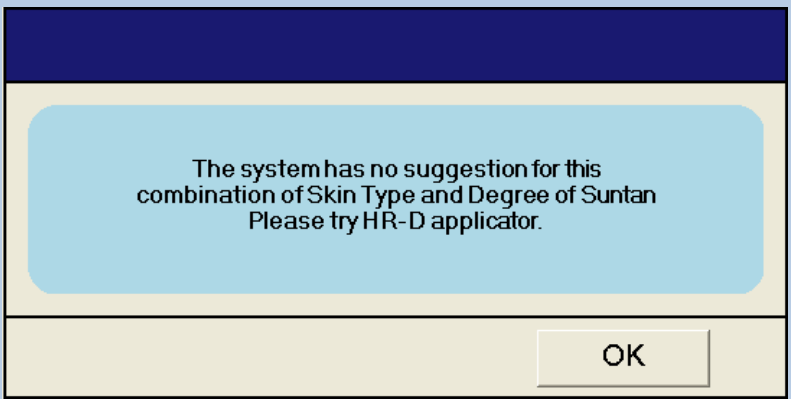


Fig 36. Patient Parameters Exceeded – use HR-D$^+$

Note that even with the HR-D$^+$ applicator, it is not permitted to treat patients for hair removal if they are too tanned. (See Fig 35). A further on-screen reminder will be shown and the energy will be greatly reduced Treatment is not recommended as there is an increased risk of adverse reaction to treatment.

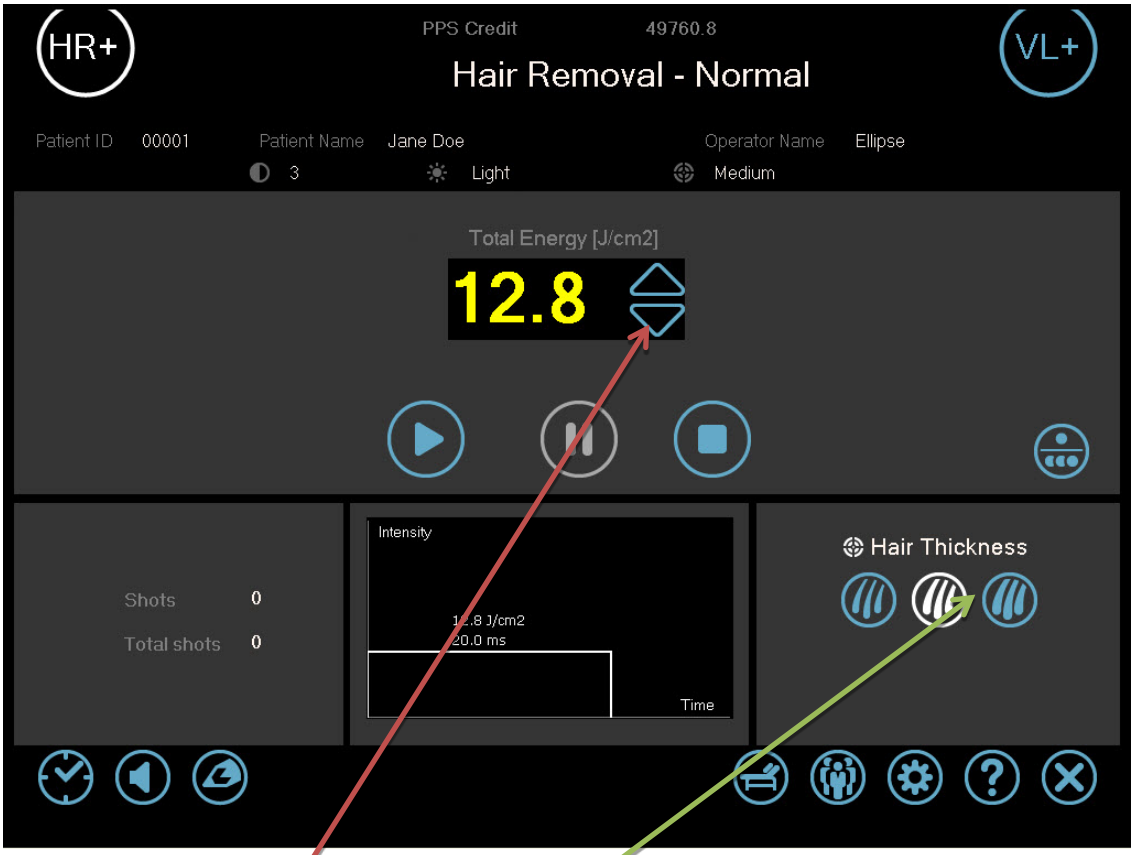


Fig 37. Treatment Screen – Hair Removal

- Follow the pre-treatment procedure and treatment procedure listed in Section 1.6 Hair Removal.
- To increase or decrease the energy from the default, press the up or down arrow on screen.
- You can select a different hair thickness within the treatment screen Area 5).
- Use of the various applicators is identical. They are chosen according to the patient Skin Type and Degree of Suntan combination. Note that the default energies and maximum energies vary according to the applicator in use. The HR-D$^+$ applicator uses slightly longer pulses of light than the HR$^+$, HR-L$^+$ and HR-S applicators.
- Press  to begin the treatment.
- After a test shot in an area relevant to the treatment area, but not too prominent, judge both the skin reaction, and the patient's response (discomfort level). The time that should be allowed for skin reaction depends on the Skin Type of the patient. Types 1 – 3 will

usually react within a couple of minutes but for darker patients (Skin Type 4 – 6) it is advisable to wait at least 15 minutes before proceeding with the actual treatment. The desired response is light erythema, perifollicular erythema or perifollicular edema. Based on the reaction and response, it must now be decided if the suggested setting is safe and appropriate.

- If you have to adjust the Energy, this is done by pressing the up/down buttons as before. Note: for hair treatment, the default Total Energy is quite conservative (mild) and better results may be achieved by increasing the energy slightly. This is because quite a wide "Therapeutic Window" exists. Only adjust the settings after a test shot has been taken. Any adjustment should be governed by the skin reaction and patient response.

- To terminate the treatment press  . To take a break, press  and then  to recommence treatment.

2.10 Treatment of a Patient (Telangiectasia Face)

I2PL+ users can choose the VL+ or PR+ applicator. The PR+ applicator is used for small or medium (pink or red) vessels in patients with a low degree of suntan, and lighter skin (Types I-III). The VL+ applicator is used to treat thick (more blue) vessels or patients who have slightly more suntan or naturally darker skin (Type IV).

SPT+ users can only use the VL+.

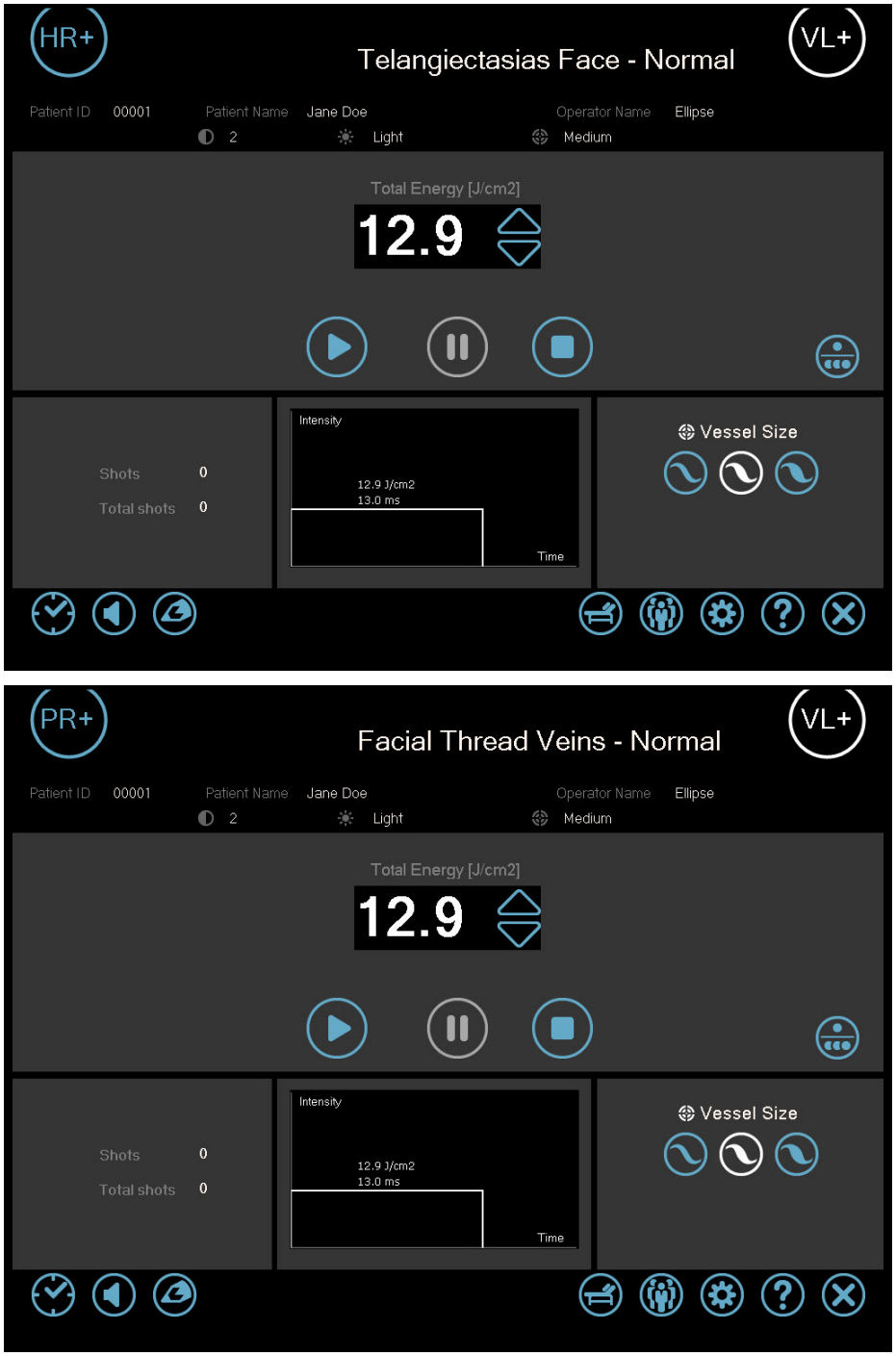


Fig 38. Treatment Screen – (top) Facial Telangiectasias, (bottom) Facial Thread Veins

- Follow the pre-treatment procedure and treatment procedure listed in Section 1.7.
- The default Energy (J/cm^2) setting is automatically calculated. This is based on the Skin Type, Degree of Suntan and vessel thickness you have selected. To increase or decrease the energy from the default, press the up or down arrow on screen– See Fig 34. If you change the Energy setting from the default, the change is highlighted.
- You can select a different vessel thickness within the treatment screen).
- Use of the various applicators is identical. They are chosen according to the patient Skin Type and Degree of Suntan combination. Note that the default energies and maximum energies vary according to the applicator in use.
- Note: The PR$^+$ applicator needs less energy because its waveband results in higher absorption in hemoglobin. The PR$^+$ applicator waveband also has a higher absorption by melanin, making it less suitable for darker skinned or suntanned patients.

Applicator	Highest Treatable Skin Type
VL$^+$	4
PR$^+$	3

- Press  to begin the treatment.
- You will see a note at the bottom of the screen that informs the System is charging. When the System is charged (ready) you will hear an audible beep. (At the same time a message appears at the bottom of the screen to advise the System is ready.) Pressing the trigger of the applicator releases the pulse of light selected using the console.
- After a test shot in an area relevant to the treatment area, but not too prominent, judge both the skin reaction, and the patient's response (discomfort level). The desired response is a temporary darkening (bluish colour) of the brightest red vessels. This typically lasts less than 1 second, and is followed by general erythema (redness). If the skin turns a greyish colour, then the energy setting is too high and should be reduced.
- The time that should be allowed for skin reaction depends on the Skin Type of the patient. Types 1 – 3 will usually react quickly but for darker patients (Skin Type 4) it is advisable to wait at least 15 minutes before proceeding with the actual treatment. Based on the reaction and response, it must now be decided if the suggested setting is safe and appropriate.
- If you have to adjust the Energy, this is done by pressing the up/down buttons as before.

- To terminate the treatment press  . To take a break, press  and then  to recommence treatment.

Note: vascular treatments have a relatively small "Therapeutic Window". Only adjust the settings slightly between test shots. Any adjustment should be governed by the skin reaction and patient response.

2.11 Treatment of a Patient (Port Wine Stains)

For Port Wine Stains, choose the VL$^+$ or PR$^+$ applicator. PR$^+$ applicator is used for small or medium (pink or red) vessels in patients with a low degree of suntan, and lighter skin (Types I-III). The VL$^+$ applicator is used to treat large (more blue) vessels or patients who have slightly more suntan or naturally darker skin (Type IV).

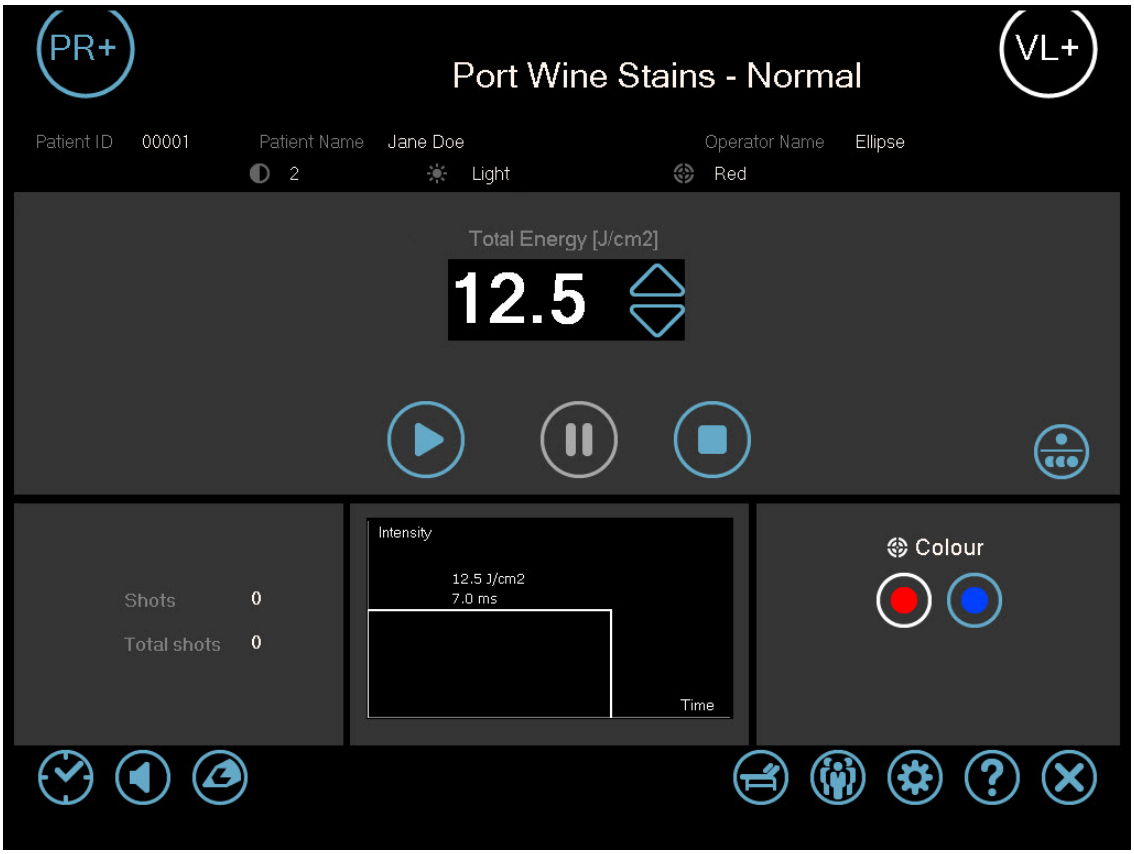


Fig 39. Patient and Treatment Parameters – Port Wine Stain

Follow the pre-treatment procedure and treatment procedure listed in Section 1.7 Vascular Treatments (Telangiectasias - Face, Port Wine Stains.

The default Energy (J/cm^2) setting is automatically calculated. This is based on the Skin Type, Degree of Suntan and vessel colour you have selected. To increase or decrease the energy from the default, press the up or down arrow on screen (Area 5) - See Fig 34. If you change the Energy setting from the default, the change is highlighted.

You can select a different vessel colour within the treatment screen.

Use of the various applicators is identical. They are chosen according to the patient Skin Type and Degree of Suntan combination. Note that the default energies and maximum energies vary according to the applicator in use. The PR$^+$ applicator needs less energy because its waveband results in higher absorption in hemoglobin. The PR$^+$ applicator waveband also has a higher absorption by melanin, making it less suitable for darker skinned or suntanned patients. The VL$^+$ applicator uses higher wavelengths, which have a greater penetration depth; this makes it more suitable for treatment of deeper (blue) Port Wine Stains.

Applicator	Highest Treatable Skin Type
VL$^+$	4
PR$^+$	3

- Press  to begin the treatment.
- You will see a note at the bottom of the screen that informs the System is charging. When the System is charged (ready) you will hear an audible beep. (At the same time a message appears at the bottom of the screen to advise the System is ready.) Pressing the trigger of the applicator releases the pulse of light selected using the console.
- After a test shot in an area relevant to the treatment area, but not too prominent, judge both the skin reaction, and the patient's response (discomfort level). The desired response is an immediate darkening of the vessels. This typically is followed by general erythema (redness). If the skin turns a greyish colour, then the energy setting is too high and should be reduced.
- The time that should be allowed for skin reaction depends on the Skin Type of the patient. Types 1 – 3 will usually react quickly but for darker patients (Skin Type 4) it is advisable to wait at least 15 minutes before proceeding with the actual treatment. Based on the reaction and response, it must now be decided if the suggested setting is safe and appropriate.
- If you have to adjust the Energy, this is done by pressing the up/down buttons as before.
- To terminate the treatment press  . To take a break, press  and then  to recommence treatment.

Note: vascular treatments have a relatively small "Therapeutic Window". Only adjust the settings slightly between test shots. Any adjustment should be governed by the skin reaction and patient response.

2.12 Treatment of a Patient (Diffuse Redness and Pigmentation)

I2PL+ users can choose the VL$^+$ or PR$^+$ applicator. The VL$^+$ applicator is used initially to treat areas of pigment or patients who have slightly more suntan or naturally darker skin (Type IV). PR$^+$ applicator is used for patients with a low degree of suntan, and lighter skin (Types I-III).

For SPT+ users, only the VL$^+$ is permitted.

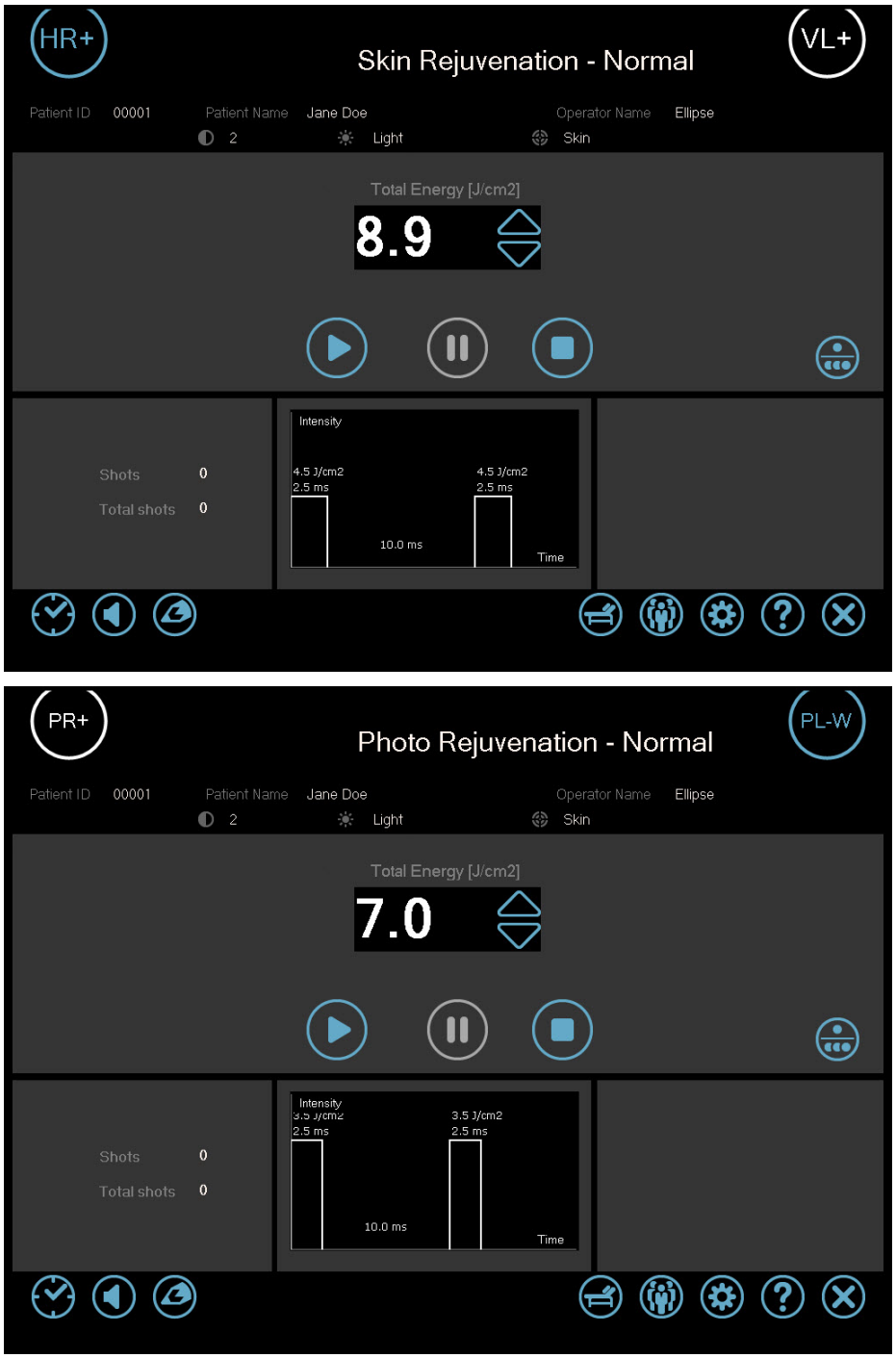


Fig 40. Treatment Screen – (International to be replaced with US Version)

Follow the pre-treatment procedure and treatment procedure listed in Section 1.8 Diffuse Redness and Pigmentation.

The default Energy (J/cm^2) setting is automatically calculated. This is based on the Skin Type, Degree of Suntan and vessel colour you have selected. To increase or decrease the energy from the default, press the up or down arrow on screen. If you change the Energy setting from the default, the change is highlighted.

Diffuse redness and pigment is treated before treatment of individual vessels, first since these act as a mask over the larger vessels. Individually visible telangiectasias are treated at a later treatment session using Telangiectasia Face.

Use of the various applicators is identical. They are chosen according to the patient Skin Type and Degree of Suntan combination. Note that the default energies and maximum energies vary according to the applicator in use. The PR$^+$ applicator needs less energy because its waveband results in higher absorption in hemoglobin.

Applicator	Highest Treatable Skin Type
VL$^+$	4
PR$^+$	3

- Press  to begin the treatment.
- You will see a note at the bottom of the screen that informs the System is charging. When the System is charged (ready) you will hear an audible beep. (At the same time a message appears at the bottom of the screen to advise the System is ready.) Pressing the trigger of the applicator releases the pulse of light selected using the console.
- After a test shot in an area relevant to the treatment area, but not too prominent, judge both the skin reaction, and the patient's response (discomfort level).
    - For pigment, the desired response is the pigment will turn darker within a few minutes. Treatment of diffuse redness will be successful if general erythema is seen over the treatment area
    - If the skin turns a greyish colour, then the energy setting is too high and should be reduced.
- The time that should be allowed for skin reaction depends on the Skin Type of the patient. Types 1 – 3 will usually react thin a few minutes, but for darker patients (Skin Type 4) it is advisable to wait at least 15 minutes before proceeding with the actual treatment. Based on the reaction and response, it must now be decided if the suggested setting is safe and appropriate.
- If you have to adjust the Energy, this is done by pressing the up/down buttons as before.

- To terminate the treatment press  . To take a break, press  and then  to recommence treatment.

Note: rejuvenation has a relatively small "Therapeutic Window". Only adjust the settings slightly between test shots. Any adjustment should be governed by the skin reaction and patient response.

2.13 Treatment of a Patient (Pigmented Lesions)

For Pigmented Lesions, choose the PL, PL$^+$ or PL-W applicator, depending on the size of the lesion. Protect surrounding skin with gauze.

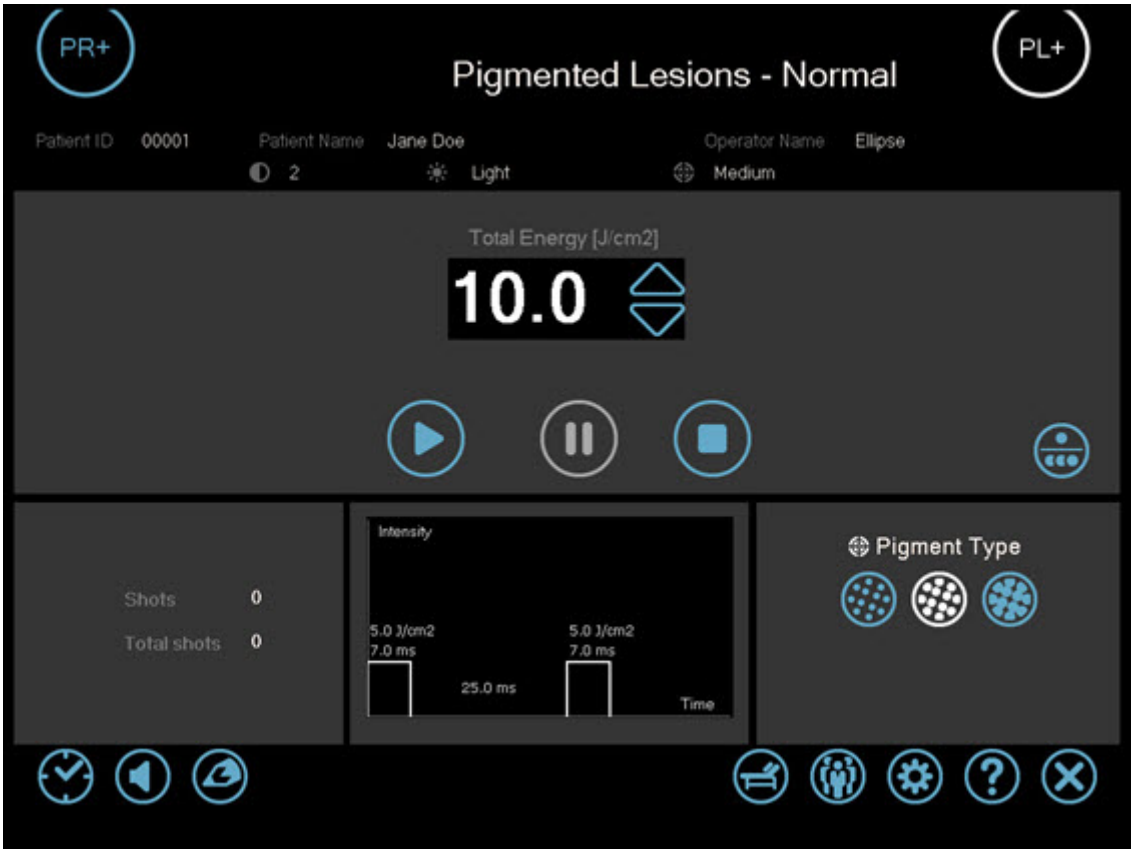


Fig 41. Treatment Screen – Pigmented Lesions

Follow the pre-treatment procedure and treatment procedure listed in Section 1.9 Pigment Treatments (Epidermal)

The default Energy (J/cm^2) setting is automatically calculated. This is based on the Skin Type, Degree of Suntan and pigment colour you have selected. To increase or decrease the energy from the default, press the up or down arrow on screen– See Fig 34. If you change the Energy setting from the default, the change is highlighted.

You can select treatment of areas of different colored pigmentation within the treatment screen (light:  medium:  or dark: ).

- Press  to begin the treatment.
- You will see a note at the bottom of the screen that informs the System is charging. When the System is charged (ready) you will hear an audible beep. (At the same time a message appears at the bottom of the screen to advise the System is ready.) Pressing the trigger of the applicator releases the pulse of light selected using the console.
- After a test shot in an area relevant to the treatment area, but not too prominent, judge both the skin reaction, and the patient's response (discomfort level). For pigment, the desired response is the pigment will turn darker within a few minutes. If the pigment can be wiped from the skin, then the energy setting is too high and should be reduced.
- The time that should be allowed for skin reaction depends on the Skin Type of the patient. Types 1 – 3 will usually react within a few minutes, but for darker patients (Skin Type 4) it is advisable to wait at least 15 minutes before proceeding with the actual treatment. Based on the reaction and response, it must now be decided if the suggested setting is safe and appropriate.
- If you have to adjust the Energy, this is done by pressing the up/down buttons as before.
- To terminate the treatment press  . To take a break, press  and then  to recommence treatment.

Note: treatment of pigment has a relatively small "Therapeutic Window". Only adjust the settings slightly between test shots. Any adjustment should be governed by the skin reaction and patient discomfort.

2.14 Treatment of a Patient (Inflammatory Acne Vulgaris)

For Acne Vulgaris, choose the PR+ applicator.

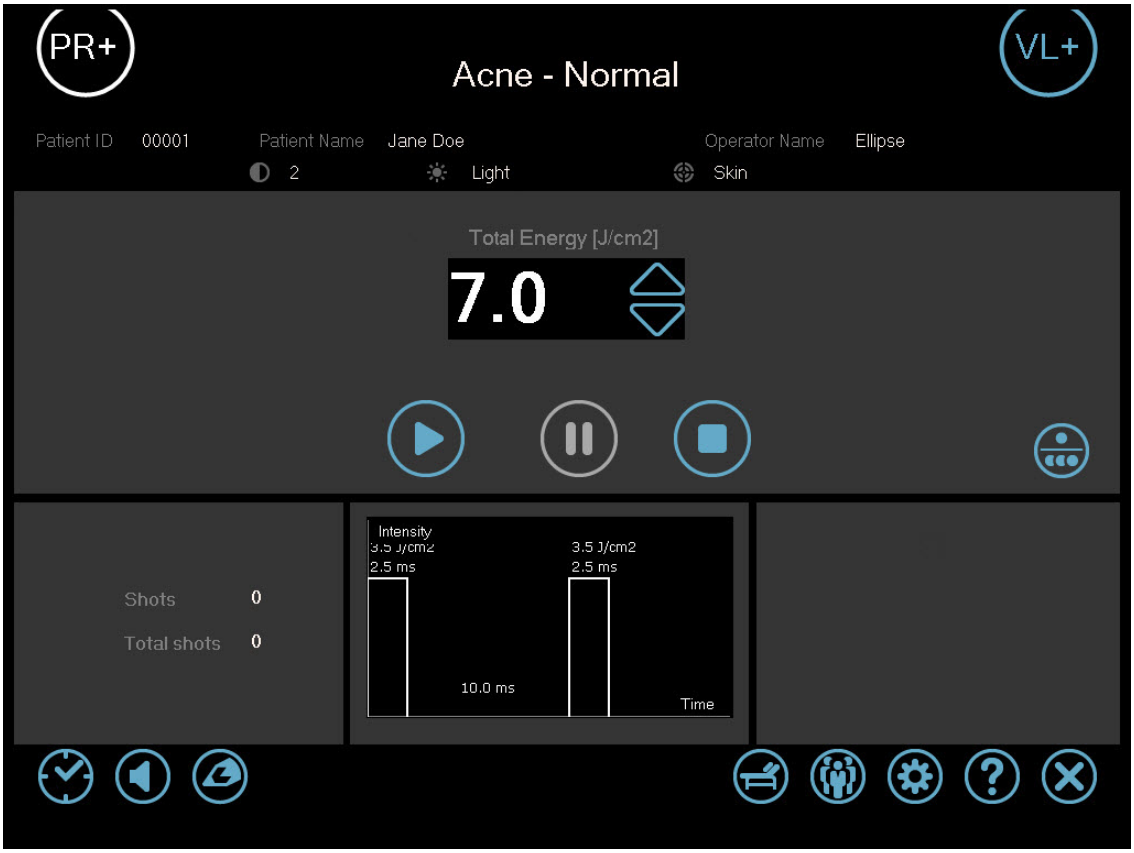


Fig 42. Treatment Screen – Acne

Follow the pre-treatment procedure and treatment procedure listed in Section 1.10 Acne Vulgaris Treatment

The default Energy (J/cm^2) setting is automatically calculated. This is based on the Skin Type, and Degree of Suntan you have selected. To increase or decrease the energy from the default, press the up or down arrow on screen. If you change the Energy setting from the default, the change is highlighted.

- Press  to begin the treatment.
- You will see a note at the bottom of the screen that informs the System is charging. When the System is charged (ready) you will hear an audible beep. (At the same time a message appears at the bottom of the screen to advise the System is ready.) Pressing the trigger of the applicator releases the pulse of light selected using the console.
- After a test shot in an area relevant to the treatment area, but not too prominent, judge both the skin reaction, and the patient's response (discomfort level). For acne vulgaris, the desired response is that any pigment in the area will turn darker within a few minutes. If the pigment can be wiped from the skin, then the energy setting is too high and should be reduced. If there is no excess pigment, then

the desired response is general erythema (redness) within a minute of the shot.

- The time that should be allowed for skin reaction depends on the Skin Type of the patient. Types 1 – 3 will usually react within a few minutes, but for darker patients (Skin Type 4) it is advisable to wait at least 15 minutes before proceeding with the actual treatment. Based on the reaction and response, it must now be decided if the suggested setting is safe and appropriate.
- If you have to adjust the Energy, this is done by pressing the up/down buttons as before.
- To terminate the treatment press  . To take a break, press  and then  to recommence treatment.

Note: treatment of acne vulgaris has a relatively small "Therapeutic Window". Only adjust the settings slightly between test shots. Any adjustment should be governed by the skin reaction and patient discomfort.

2.15 Treatment of a Patient (Poikiloderma of Civatte – subset of Diffuse Redness and Pigment)

For Poikiloderma of Civatte, choose the VL$^+$ or PR$^+$ applicator. The VL$^+$ applicator is used initially to treat areas of patients who have slightly more suntan or naturally darker skin (Type IV). PR$^+$ applicator is used for patients with a low degree of suntan, and lighter skin (Types I-III).

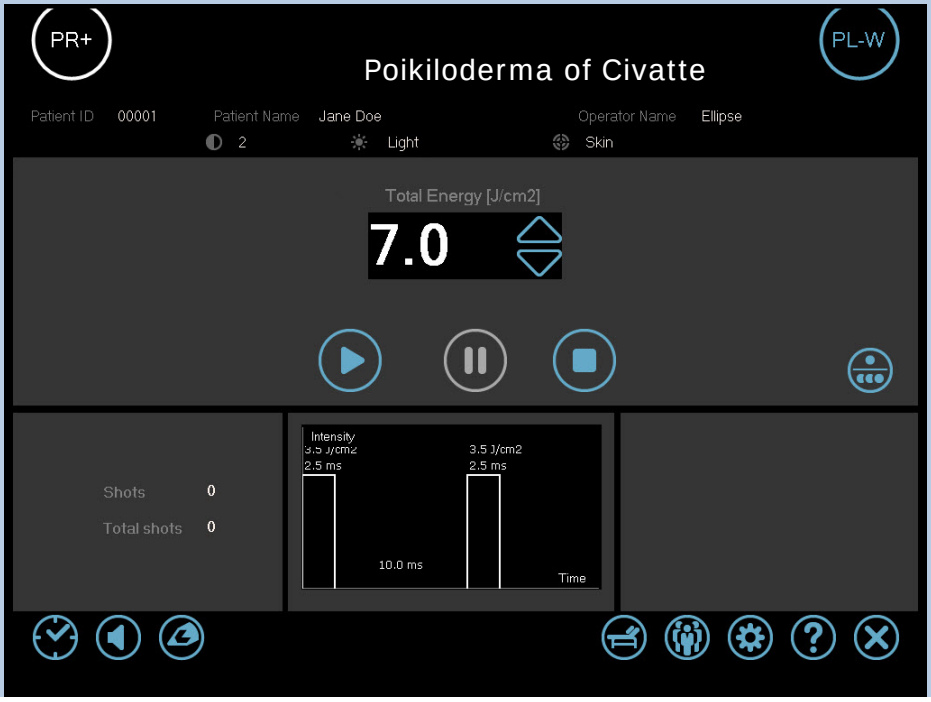


Fig 43. Treatment Screen –Poikiloderma of Civatte

Follow the pre-treatment procedure and treatment procedure listed in Section 1.7 Diffuse Redness and Pigmentation - Intense Pulsed Light.

The default Energy (J/cm^2) setting is automatically calculated. This is based on the Skin Type, Degree of Suntan and vessel colour you have selected. To increase or decrease the energy from the default, press the up or down arrow on screen. If you change the Energy setting from the default, the change is highlighted.

Individually visible telangiectasias are treated at a later treatment session using Telangiectasia Face.

Use of the various applicators is identical. They are chosen according to the patient Skin Type and Degree of Suntan combination. Note that the default energies and maximum energies vary according to the applicator in use. The PR$^+$ applicator needs less energy because its waveband results in higher absorption in hemoglobin.

Applicator	Highest Treatable Skin Type
VL$^+$	4
PR$^+$	3

- Press  to begin the treatment.
- You will see a note at the bottom of the screen that informs the System is charging. When the System is charged (ready) you will hear an audible beep. (At the same time a message appears at the bottom of the screen to advise the System is ready.) Pressing the trigger of the applicator releases the pulse of light selected using the console.
- After a test shot in an area relevant to the treatment area, but not too prominent, judge both the skin reaction, and the patient's response (discomfort level).
    - o General erythema is expected over the treatment area
- Based on the reaction and response, it must now be decided if the suggested setting is safe and appropriate.
- If you have to adjust the Energy, this is done by pressing the up/down buttons as before.
- To terminate the treatment press  . To take a break, press  and then  to recommence treatment.

Note: Poikiloderma of Civatte has a relatively small "Therapeutic Window". Only adjust the settings slightly between test shots. Any adjustment should be governed by the skin reaction and patient response.

2.16 Treatment of a Patient (Telangiectasias and Reticular Vessels - Nd:YAG)

For treatment of leg vessels use the ND:YAG. Treatment parameters are similar to those for Intense Pulsed Light Treatment

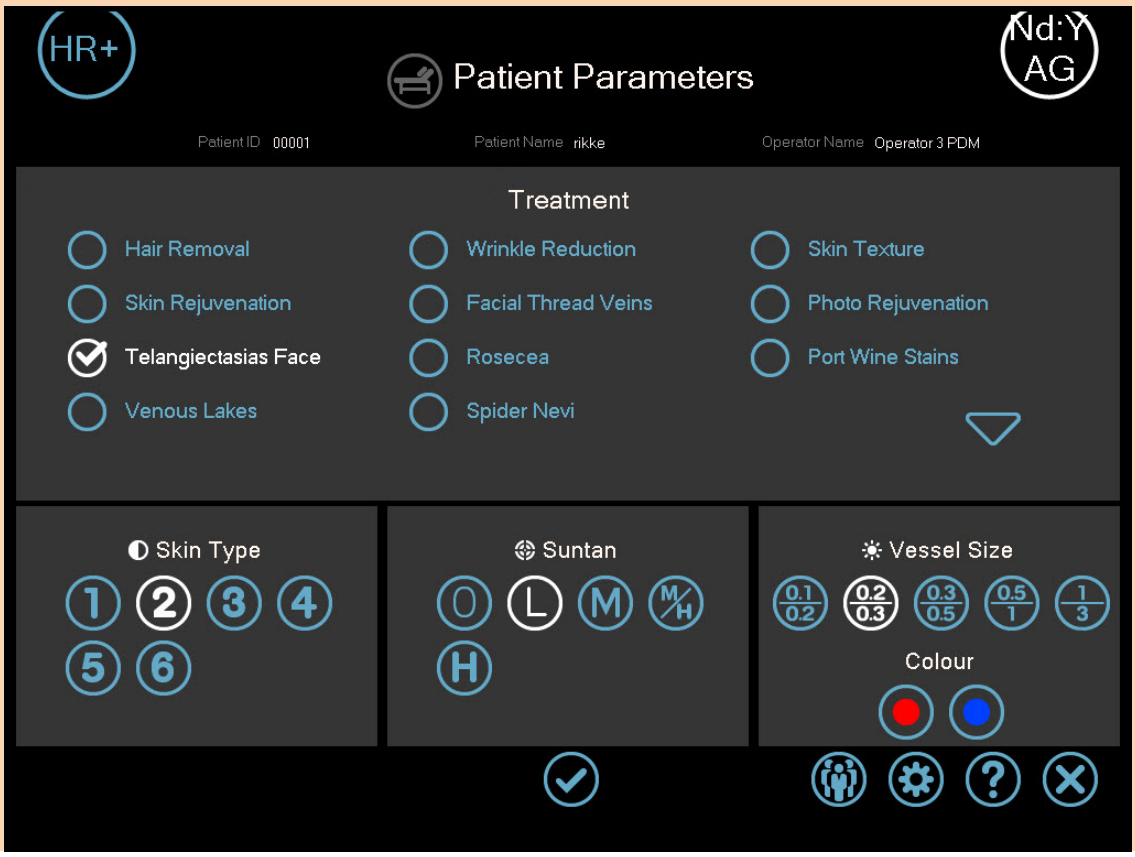


Fig 44. Nd:YAG treatment parameters for leg vessels (International to be replaced with US Version)

Follow the pre-treatment procedure and treatment procedure listed in Section 1.11 Telangiectasias and Reticular Vessels (Nd:YAG Treatment)

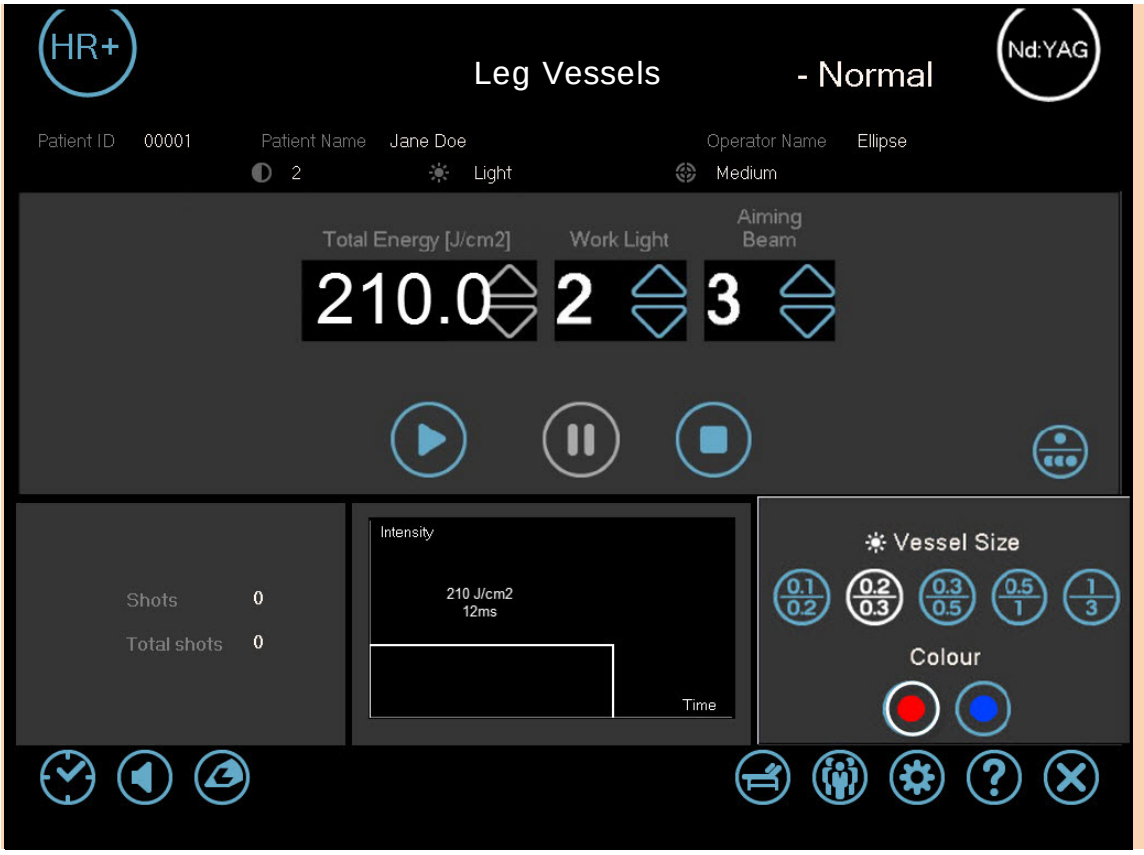


Fig 45. Treatment Screen ND:YAG Telangiectasias

The default Energy (J/cm^2) setting and pulse time are automatically calculated based on the Vessel Size and Colour you have selected. To increase or decrease the energy from the default, press the up or down arrow on screen. If you change the Energy setting from the default, the change is highlighted.

- Press  to begin the treatment.
- You will see a note at the bottom of the screen that informs the System is charging. When the System is charged (ready) you will hear an audible beep. (At the same time a message appears at the bottom of the screen to advise the System is ready.) Pressing the trigger of the applicator releases the pulse of light selected using the console.
- After a test shot in an area relevant to the treatment area, but not too prominent, judge both the skin reaction, and the patient's response (discomfort level and clinical endpoint covered in Section 1.13) Based on the reaction and response, it must now be decided if the suggested setting is safe and appropriate.
- You can select a different vessel thickness or colour within the treatment screen
- If you have to adjust the Energy, this is done by pressing the up/down buttons as before.

- To terminate the treatment press . To take a break, press and then to recommence treatment.
- As laser treatment has a small therapeutic window then adjustment of the settings has to be taken in small steps. Any adjustment should be governed by the skin reaction and patient response. Never repeat shots on the same treatment area, as this can lead to tissue damage or scarring

2.17 Settings

Settings are most easily accessed from the Log On or Patients Screen. At first glance, the screen can seem intimidating, but Settings are an easy to use method of running the non-standard tasks on your Ellipse system.

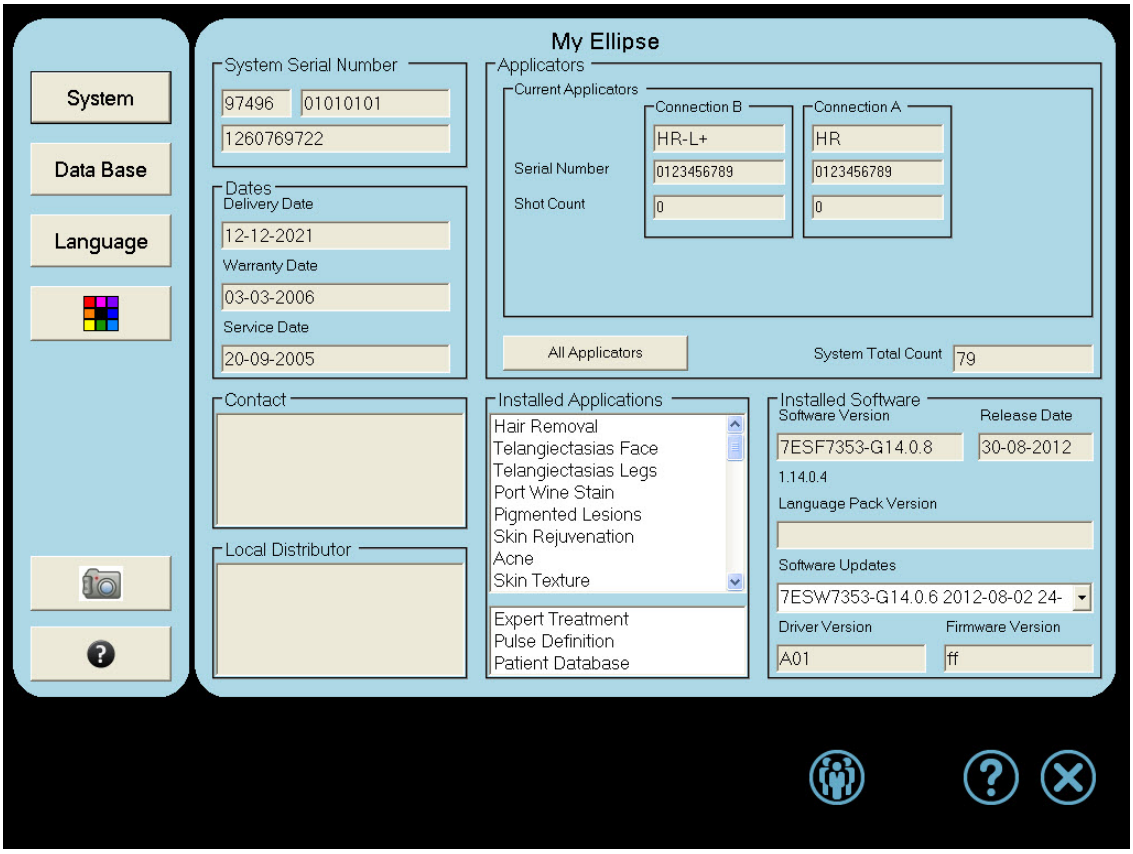


Fig 46. Settings Screen

The screen divides into 2 parts – left and right. On the left are the buttons you need to perform certain tasks. On the right is all the information you will need should you have to call your Ellipse distributor about service or related issues. The right hand side also shows how many shots you have performed with your applicators, which treatments are installed, and when your next service date is due.

The Settings Page also provides the gateway to do many of the extra tasks offered by your Ellipse system. These are broken down into 4 main areas. – System, Data, Language and Colour Scheme.

Finally, the Settings page offers a link to the on-screen before and after pictures and the on-screen manual.

System Button

Pressing the <System> button brings up the following screen:

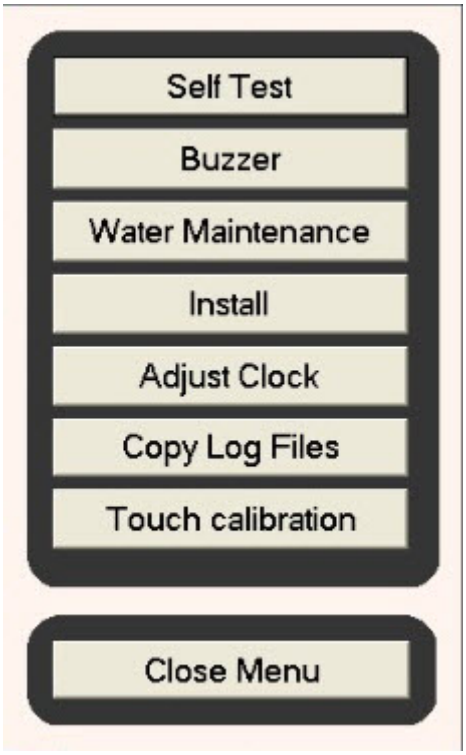


Fig 47. System Screen

Self Test - Allows you to carry out a self test. This should normally be done only at the request of a Service Technician.

Buzzer - Allows you to set the length of the sound that tells you the system is ready to carry out a treatment pulse. Use the slider control to adjust the length of the sound.

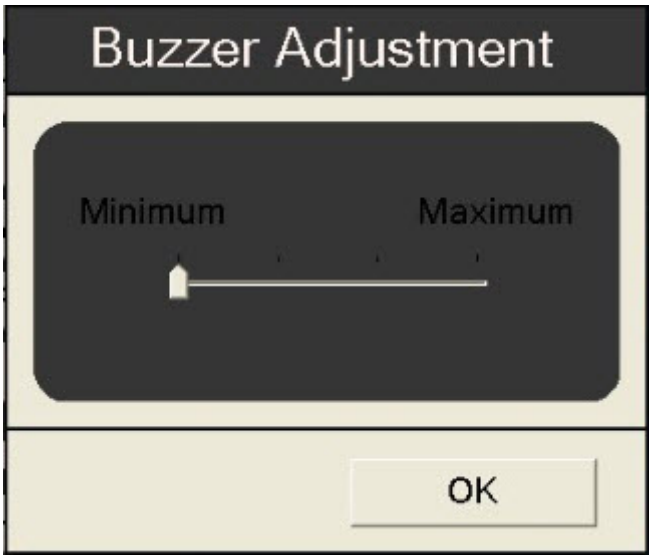


Fig 48. Buzzer Adjustment

Water Maintenance - This is used to check the water level in your System. See **1MAN8438-Ellipse Plus Range - Essential Information** if you need to fill or drain water.

Install – Software is updated from time to time, for example as new treatments are introduced or to add treatments you did not choose to buy at the time of initial purchase of your Ellipse system. The install button allows your Ellipse system to handle these updates. Often this work will be done by your distributor's service department. There are 4 items on the Install Menu:

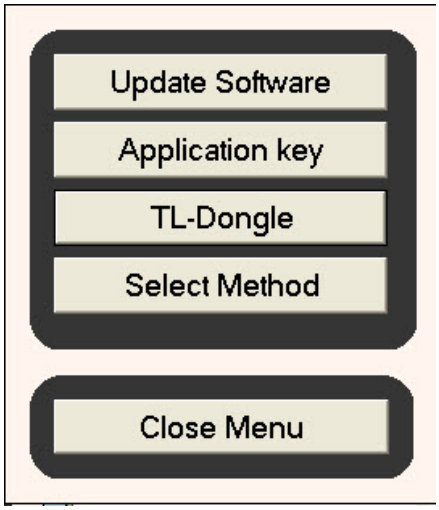


Fig 49. Install Menu

1) Update Software is used for updates to system software.

Fig 50. Update Software

Select <**Update Software**>, insert USB memory drive containing the update and follow the on-screen instructions. Updating the Software is often

carried out by a Service Technician. If not, you will be supplied full details of how to install the update.

2) Application Key is used to increase treatment options

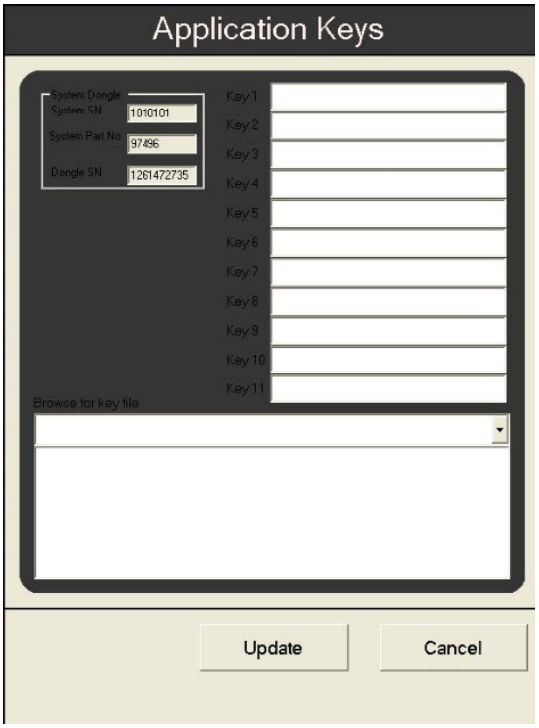


Fig 51. Application Keys

Select <**Application Key**>, insert the USB memory drive containing the key and follow the on-screen instructions. This is often carried out by a Service Technician. If not, you will be supplied full details of how to install the key.

3) A TL Dongle is used if you have been supplied with a system that allows an unlimited number of shots to be fired within a set period of time.

4) Select Method enables you to select a TL-Dongle or a PPS Dongle. For more details, please refer to 1MAN8403

Adjust Clock

The clock is used to set times for the log files recorded by your Ellipse system. Each component can be adjusted and the resultant time can be accepted or cancelled by pressing the appropriate button.

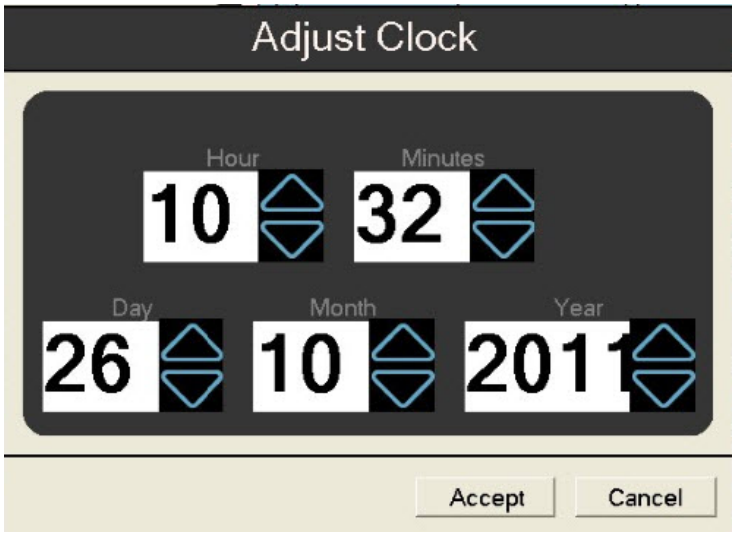


Fig 52. Adjust Clock.

Copy Log Files – Pressing <Copy> will copy the system log files to a USB memory stick (recommended). The <Select file destination> button allows you to choose an alternative file destination.

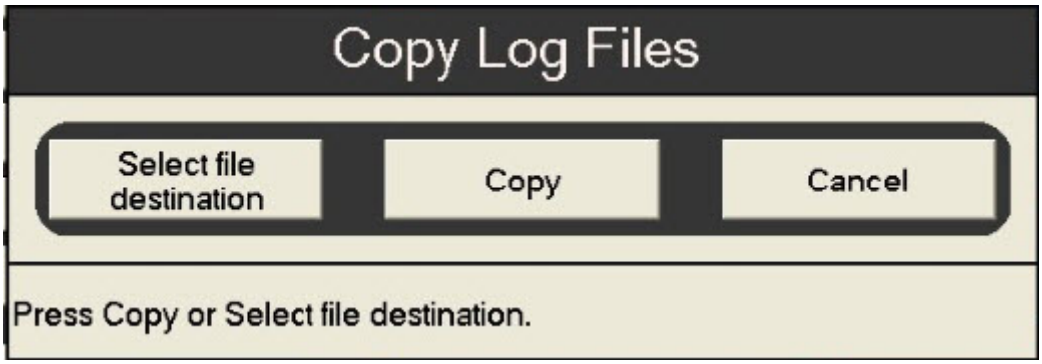


Fig 53. Copy Log Files

Touch Calibration – Your Ellipse system has a touch sensitive screen. If you find that the mouse or cursor has drifted (so that pressing the screen over a button no longer activates that button, you can recalibrate the touch screen.

Press <Touch Calibration>. The following screen opens:

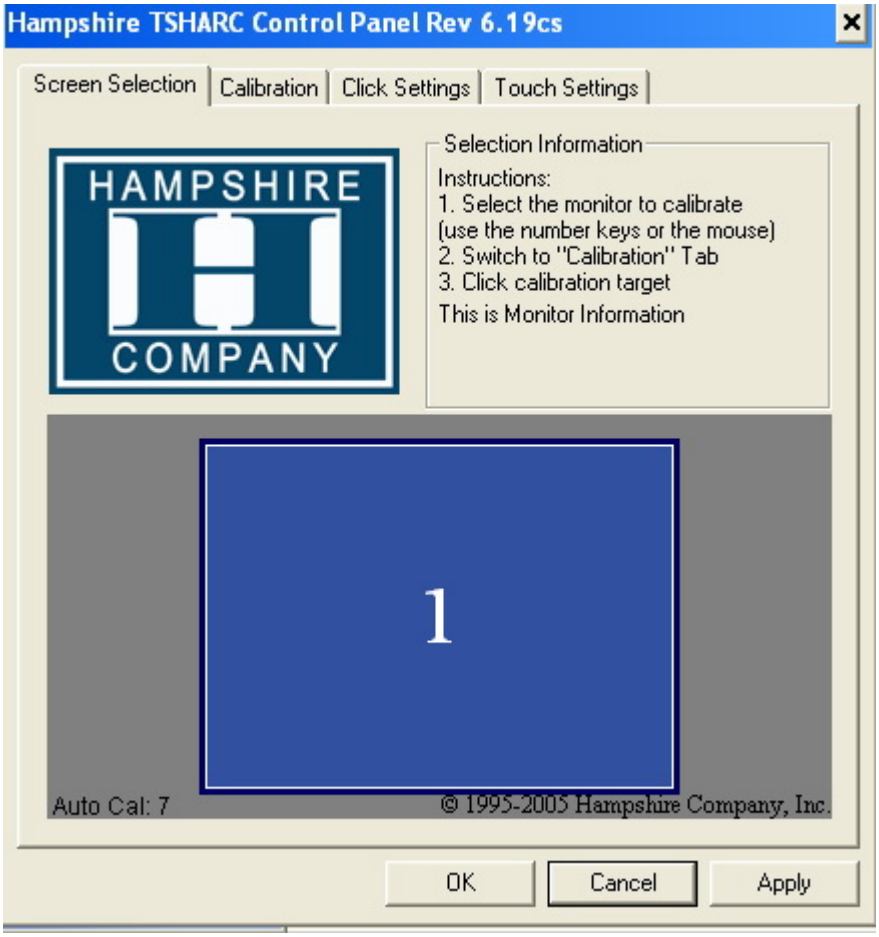


Fig 54. Touch Calibration Opening Screen

Press the Tab marked <**Calibration**>.

You will be asked to point to various areas of the screen.

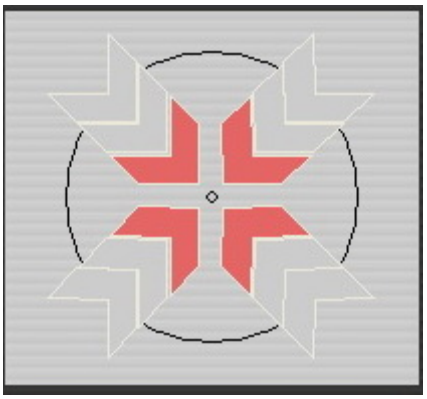


Fig 55. Calibration Screen

Follow the on screen instructions.

Color Selection

It is possible to use various colour schemes on your Ellipse system. Press the colour selection  icon to open the following screen:

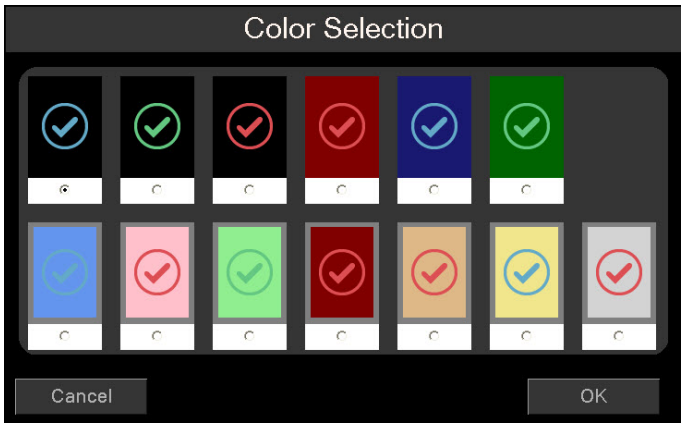


Fig 56. Color Selection

Simply click on the button under one of the colour schemes to choose it. Press <**OK**> to close the box and apply the colour scheme.

Data Base - This gives a menu with 5 items

Fig 57. Database Menu

Import Patient Data - This will allow you to import any patient data stored elsewhere. If there are duplicate patients stored, you will have the choice of merging the existing patients or changing the patient ID.

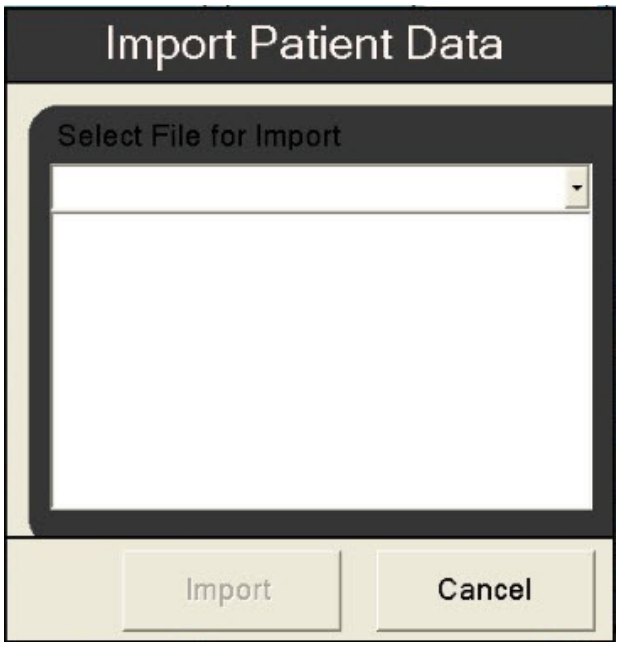


Fig 58. Import Patient Data

Export Patient List - When this is selected a dialogue box opens asking you to choose the destination of the files. It allows you to export patient address list. No treatment data is exported using this function.

Fig 59. Export Patient List

Allow the system time to find the memory stick or transfer device (this will often be shown as drive D:\). Select the drive by pressing the downward arrow shown in the image above. When you have selected the drive, press it and then press <Export>.

Export Treatment Data - Select the directory as detailed above (Patient List). It allows you to export both patient data and associated treatments.

Choose between exporting all treatment data and that for certain dates

Fig 60. Export Treatment Data

Backup Database - When this is selected a dialogue box opens asking you to choose the destination of the files. It allows you to make a copy (on USB memory drive) of all patient and treatment.

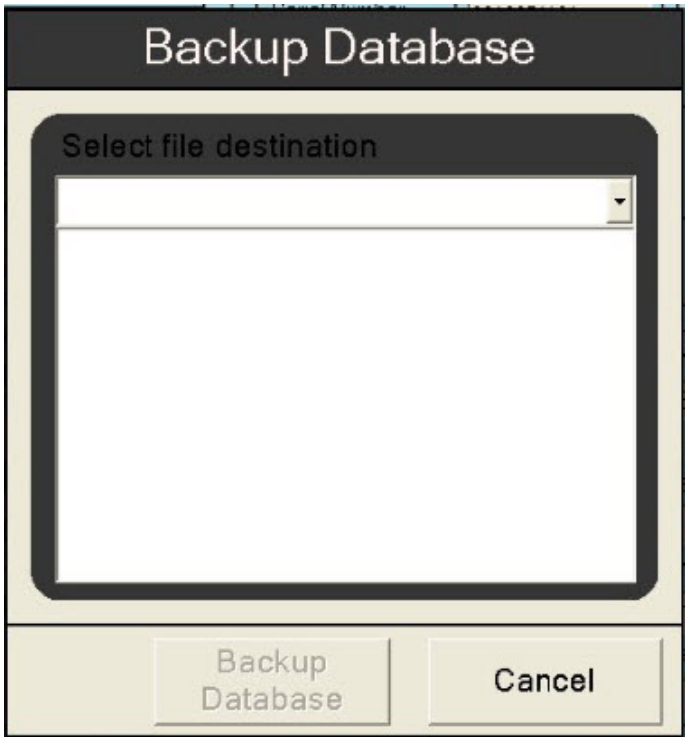


Fig 61. Backup Database

Select the destination as above, and press <**Backup Database**>. Your original data is unaffected.

Advanced Database – opens a new menu with 5 options

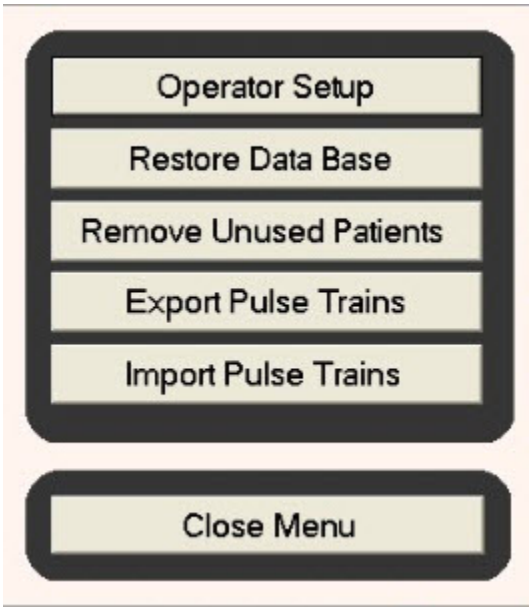


Fig 62. Advanced Database

Operator Setup

Note – you must be logged in as an administrator in order to add, delete or edit operators. Access Operator Setup by choosing <Settings>, then <Database>, then <Advanced Database> then <Operator Setup>.

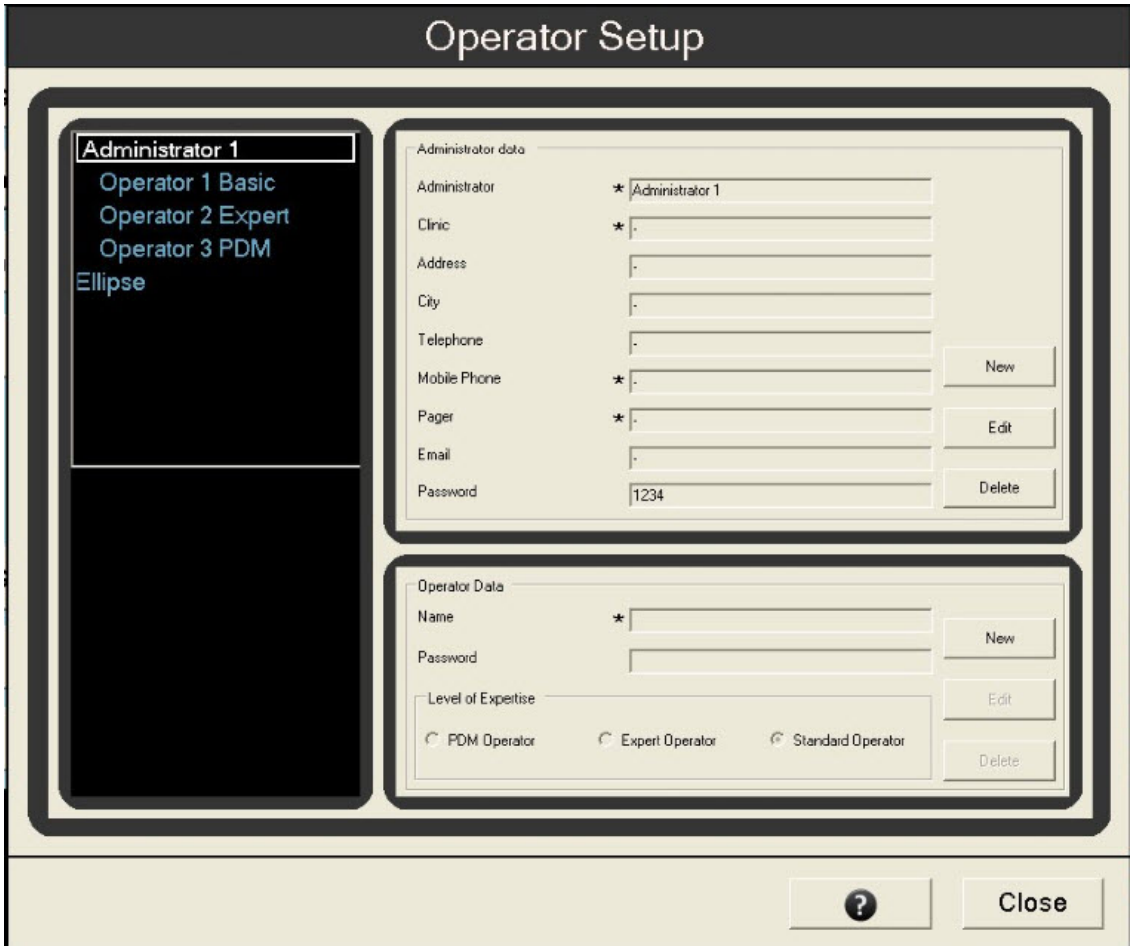


Fig 63. Operator Setup

Your Ellipse SPT+ system allows standard operators only. Standard Operators can undertake treatments and adjust energy, but cannot alter pulse settings nor create a pulse.

An Ellipse I²PL+ system allows two levels of operators.

- Standard Operators can undertake treatments and adjust energy, but cannot alter pulse settings nor create a pulse.
- Expert Operators can undertake treatments, adjust energy, pulse times & delays, and alter the number of pulses.

An Ellipse MultiFlex+ system allows three levels of operators.

- Standard Operators can undertake treatments and adjust energy, but cannot alter pulse settings nor create a pulse.
- Expert Operators can undertake treatments, adjust energy, pulse times & delays, and alter the number of pulses.
- Pulse Definition Mode Operators can create a unique series of pulses

For safety reasons, your Ellipse system separates the ownership of the system from the operation of the system. The main feature of this separation is that an operator cannot change the level of his own expertise.

Adding a new operator, or changing the level of expertise of the operator, is done by logging in as an ADMINISTRATOR. Administrator can make administrative changes but not perform treatments.

Changing Details of Operator 1

If a clinic is operated by a single person, then there is no need to add an operator. Instead you can edit Operator 1. Log in as Administrator 1 (this name may have been changed to your own name during installation).

Select Operator 1 by clicking on the name "Operator 1" on the left of the screen.

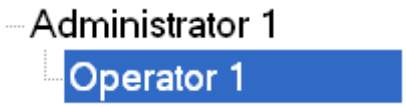


Fig 64. Operator Setup - Operator Name

Press <**Edit**> (bottom right).

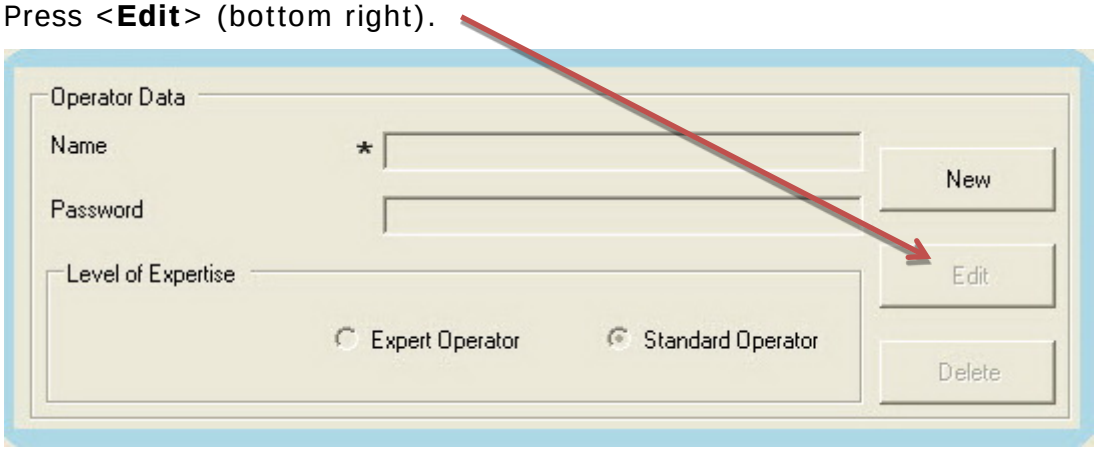


Fig 65. Operator Setup - Operator Edit

The Operator Name, Password and (for I2PL+ and MultiFlex+) Level of Expertise can now be set. The default level is a Standard Operator. Press <OK> to confirm or <Cancel> to cancel changes.

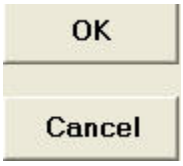


Fig 66. Operator Setup - Confirmation

Adding an Extra Operator

To add an Operator, simply press the <**New**> button. (See Fig 67)

The Operator Name, Password and Level of Expertise can now be set. The default level is a Standard Operator. Press <OK>. The list of users and operators will be updated. Press <Cancel> to cancel the addition.

Deleting an Operator

To delete an operator press the <Delete> button. You will be asked to confirm the deletion. The list of users and operators will be updated.

Administrators

Adding, editing or deleting an administrator is done in exactly the same way.

Restore Database – You will be cautioned that this will replace your existing data with that previously exported. You will be asked to confirm your decision.

Fig 67. Database Restore

If you agree, you will be prompted for the drive containing the stored database.

Fig 68. Database Restore (Location)

Remove Unused Patients - This will allow you to remove any patients for whom treatments have not been carried out for the last two years from the patient database. You will be asked to confirm this – if you agree, the task will be carried out automatically.

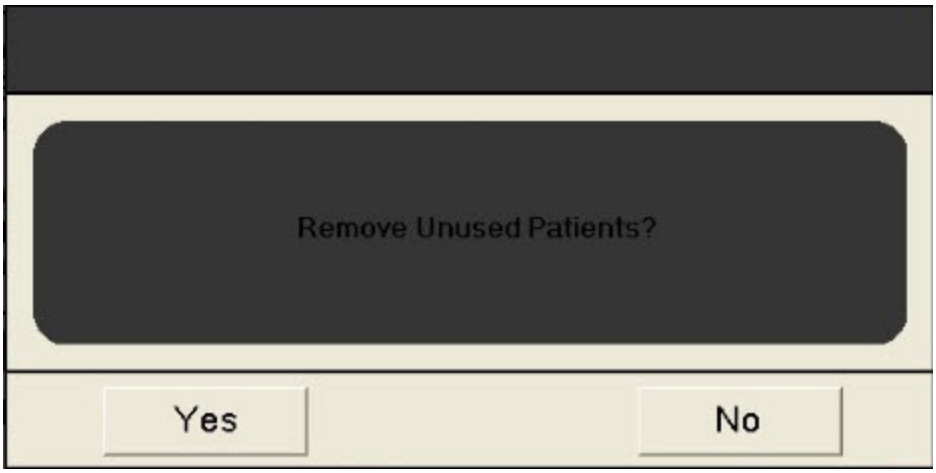


Fig 69. Remove Unused Patients

Language Button

This allows you to choose a system language from the list available.

Additional Items

There are 3 additional icons on the settings page:

Icon	Action
	Opens a Before and After Treatment document, which includes Clinical Endpoints (desired treatment effects).
	Opens the onscreen manual and Clinical Workbook– See Section 2.4 Help and Error Messages

2.18 Shut Down

To close down the system, press  from any screen. This will terminate the program and close down the operating system. The ATX Button on the front of your Ellipse system will turn from green to orange. After, you can restart your Ellipse system by pressing the ATX button once more, or turn off power to your Ellipse system by pressing the switch next to the symbol O at the rear of the cabinet.

If there is a critical need to switch off your Ellipse system, this can be done by pressing the ATX Button on the front of the system for 4 seconds. Note that your Ellipse system contains a computer operating system. Switching off the machine, without following the exit procedure above may cause errors in the computer operating system to occur. On Ellipse MultiFlex^{+} it is also possible to stop the system by pressing the red emergency button.

Chapter 3: EXPERT and PULSE DEFINITION MODE

This Chapter Applies to I²PL⁺ and MultiFlex⁺ systems only

Expert mode is an option for experienced users with in-depth clinical expertise. In special clinical cases and for research use, these users can over-ride the default settings. Such operators must be set up from the Operator Setup screen (Settings).

Do not attempt to use Expert Mode unless competent to do so.

3.1 Expert Mode

In the Expert Mode each "shot" can be "tailored" so that it consists of one or more light pulses (Pulses per Shot), each with its own selected time duration (Pulse Time) – and a chosen delay period (Pulse Delay).

It is always recommended to use the default settings regarding the compositions of the shots as these are settings which have been proven to work during Clinical Trials.

Extended Treatment Parameters

In Expert Mode, combinations of Skin Type and Degree of Suntan that cannot be treated with the chosen applicator are shown in yellow. It is recommended not to treat these patients.

If you proceed with treatment of this patient, the System shows the message:

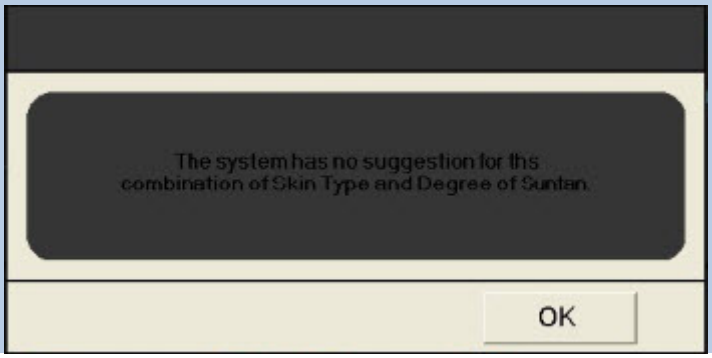


Fig 70. Patient Parameters Exceeded

After you have pressed <**OK**> to acknowledge the warning, the system will set the energy to the lowest possible energy.

Adjustment of the Pulse Time (Experienced users only!):

- We recommend always basing the adjustment of the Pulse Time on correctly chosen patient parameters according to the normal procedure.
- If the target is between two standard settings always chose the one that gives a less aggressive pulse (the thicker hair, darker lesion colour or larger vessel), DO NOT CHOOSE A TARGET PARAMETER LESS THAN THAT OBSERVED IN THE PATIENT.

- Press the <Expert> Button  .
- If the target size is judged to be less than one of the selection options in the Parameters, then decrease the Pulse Time accordingly. Decreasing the Pulse Time will automatically reduce the Energy, ensuring the energy output will still be below the upper limit of the therapeutic window.
- Perform test shots and wait a couple of minutes. Increase the Energy level until skin reaction is seen or the pain threshold of the patient is reached. Note that in treatment of vessels, a visible reaction will normally occur in less than 1 second after the shot.

For some special treatments, the practitioner can speed up the treatment procedure by using two or more pulses in a single shot. Ellipse I^2PL^+ system allows this by enabling selection of more than one pulse per shot. Performing this kind of treatment dramatically increases the risk of skin burns, and we do NOT recommend practitioners to do so, unless they have a deep understanding of light-skin interactions.

The standard setting for treating Pigmented Lesions is an example of a double pulsed treatment.

The Pulse Time is set to 7.0 ms, the Number of Pulses is set to 2 and the Delay Time is 25 ms. This leads to two pulses each of 7 ms Pulse Time, released with a Pulse Delay time of 25 ms, which is much longer than the Thermal Relaxation Time (TRT) of the target (the keratinocytes).

The total active light emission time for this pulse train is therefore 2 x 7 ms = 14 ms, and the total Pulse train duration is 2 x 7 ms + 25 ms = 39 ms (Fig 73).

The Pulse delay does not change the active light emission time – it simply spaces the individual pulses in the pulse train.

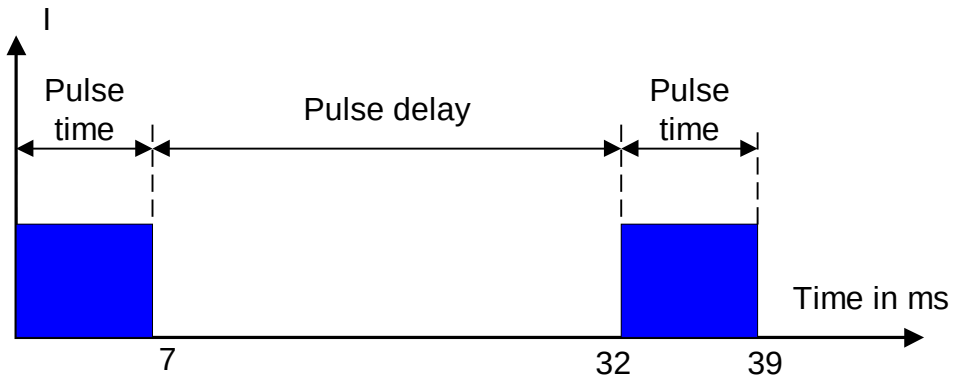


Fig 71. Standard pulse timing for treating pigmented lesions

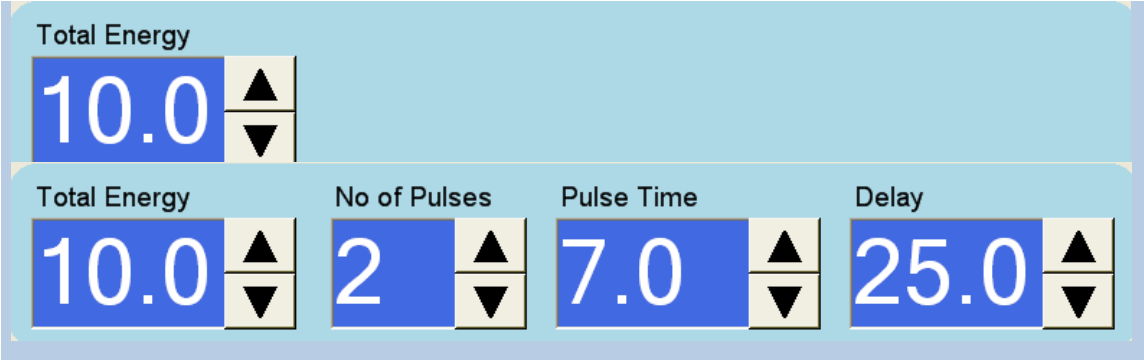


Fig 72. Pulse timing for treating pigmented lesions (top: in Normal Mode; bottom in Expert Mode)

How to perform multiple pulses per shot:

- Always base the Energy setting on correctly chosen patient parameters from the Treatment Screen.
- Adjust to give a lower Energy setting than shown – the setting can then be increased slightly to provoke the correct reaction in the pigmented lesion.
- If the target is between two standard settings always chose the one that gives a less aggressive pulse (the thicker hair, darker lesion colour or larger vessel), DO NOT CHOOSE A TARGET PARAMETER LESS THAN THAT OBSERVED IN THE PATIENT.
- Carefully note the suggested Energy setting.
- Press <  >.
- Select the decided number of pulses. It may be necessary to lower the Energy setting to reach the required number of pulses.
- Adjust Pulse Delay (the time between the pulses). Be aware that the Pulse Delay should be selected according to the TRT of the target (typically 10- 50 ms). If the Pulse Delay chosen is too short, the risk of skin burns will increase. Adjusting the Pulse Delay may marginally increase the Energy.
- To ensure a safe starting point for the treatment, the Energy setting should be adjusted according to the previously noted setting from the system. The displayed Total Energy is the sum of energy for all the released pulses.
- Perform some test shots and wait a couple of minutes (more for darker skinned patients or any Degree of Suntan). Increase the Energy level until skin reaction is seen or pain threshold for the patient is reached.

Clinical implications of the pulse duration and energy parameters

Energy

The total energy level in J/cm^2 should be selected according to the maximum tolerance of the patient. (Consider both clinical skin reaction and pain threshold).

Pulse Time

The Pulse Time should be selected according to the TRT, which is related to the size of the target. Also, the pulse duration should be selected in order to minimize the temperature increase of the epidermis.

Pulses/Shot

The biological significance of the assembly of individual pulses can be compared to manually firing several shots on the same area of skin.

Pulse Delay

The Pulse Delay defines the pause between the individual pulses in a pulse train. Be aware that the Pulse Delay should be selected according to the TRT of the target (typical 10- 50 ms). If the Pulse Delay chosen is too short, the risk of skin burns will increase dramatically. We do NOT recommend practitioners to use multiple pulses unless they have a deep understanding of skin-light interactions.

Note

The Expert Mode enables the practitioner to perform many other special constructed pulse trains. For example, some manufacturers use a pulse train consisting of 2-3 pulses spaced with a short Pulse Delay of 2-5 ms. The idea is to protect small "non-target" structures (e.g. the short TRT melanosomes in the epidermis) in-between individual pulses in a pulse train. Larger target structures (like hair bulbs or vessels with high TRT) only lose relatively little energy in this short delay, and therefore the temperature of the bulb or vessel only drops a little before the next pulse in the pulse train is emitted.

Your Ellipse system is able to perform this kind of treatment, but Ellipse does NOT recommend doing so, because of the risk of skin burns. In both theory and practice, it is safer to use one single pulse with a Pulse Time adjusted according to the relaxation time of the target.

Please be aware, that in Expert Mode, the manipulation of Pulse Time and Pulses/Shot will lead to automatic change of the Energy level in J/cm^2. Therefore it is extremely important to perform test shots and to monitor skin reaction before engaging in treatments via the Expert Mode!

To confirm the settings press  . At all times, the user has the responsibility for the treatment based on clinical / dermatological insight and experience gained from previous treatments.

3.2 Pulse Definition Mode

Ellipse MultiFlex allows an operator with PDM status (set by the Administrator) to create an enhanced Pulse Train, where each part of the Pulse Train can have a different energy, and where the Pulse Times and pulse delays can vary. The Cautionary Notes given for Expert Mode are even more important when using Pulse Definition Mode, so please read them again.

Pulse Definition Mode can only be entered from Expert Mode  . Press  on the Expert Treatment screen. The Pulse definition screen appears. This screen allows you, amongst other things, to

- Edit existing pulses by their Energy Time boxes and/or Delay by using the up and down arrows situated at the side of the relevant box
- Save and/or select previously saved Pulses using the My Pulse Trains.

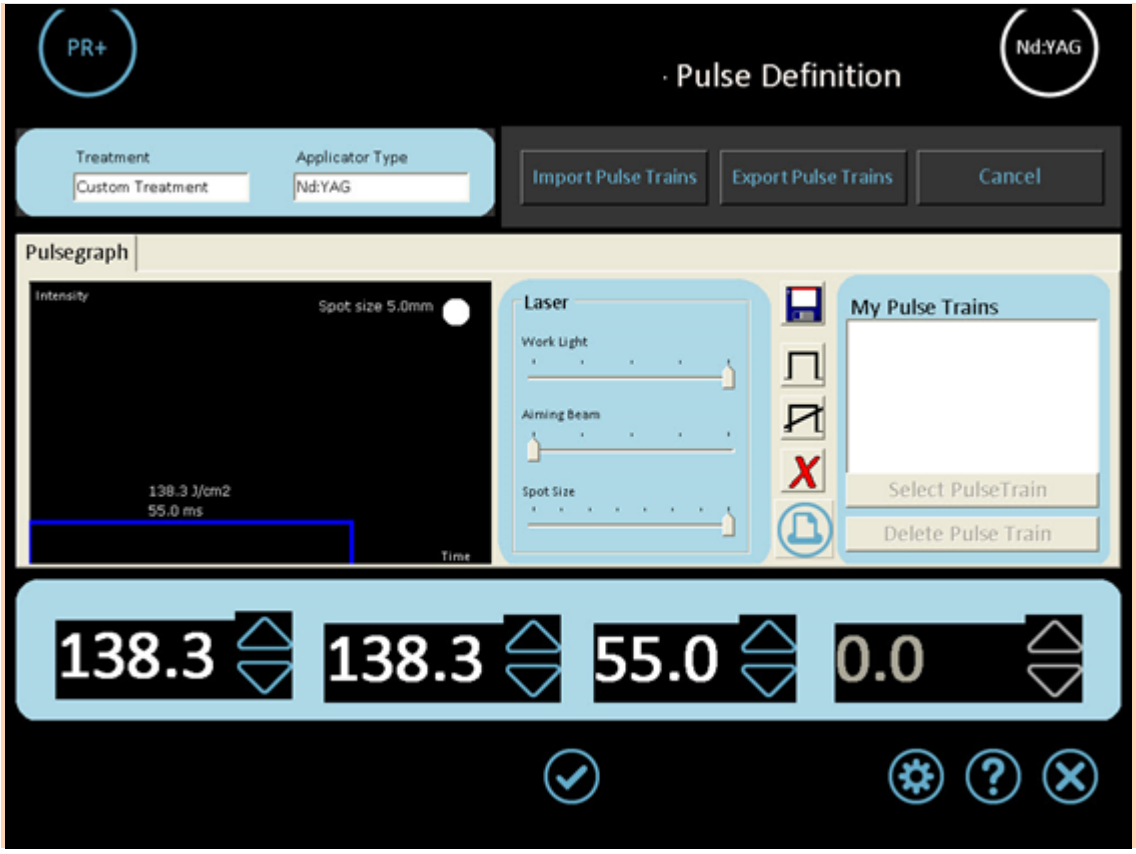


Fig 73. Example PDM Mode (with ND:YAG Applicator connected)

Special screen features for PDM	Function
Import Pulse Trains	This function will allow you to import a Pulse Train sent as a file from Ellipse or a colleague. Browse to select the Pulse Train file(s) you wish to import. These Pulse Trains will normally be saved onto a memory stick (USB) or disk which should be inserted into your system for this function to work.
Export Pulse Trains	Press to open the Export Pulse Trains box. Open the drop down box and browse to where you wish to export the Pulse Trains data to. Select Pulse Trains. You can select all or some of the trains to export. Use <**Select all>** to select all or if you only wish to select one or more, hold down the CTRL key while pressing the Pulse Trains you wish to export. Pulse Trains are stored in alphabetical order. The system records the name of the applicator as part of the file name, so treatments using the same applicator will be grouped together. Press <**Export**> to complete the procedure.
Pulse graph	This visually depicts the format of the pulse.
	Press the Save icon to save the pulse.
	Use the Add pulse icon to add an extra pulse.
	Use the Delete pulse icon to delete the last Pulse in the Pulse Train.
	Press to delete all pulses showing in Pulse graph
	Print the pulse
My Pulse Trains field	This will show previously saved pulse trains, made for the same type of applicator that is currently selected. To choose a previously saved pulse, select and press the required pulse. To choose between previously saved pulse trains press the entry in the "My Pulse Trains" list and then <**Select Pulse**> and then <**Accept Treatment**> to use the pulse train for treatment.
Total Energy Number of Pulses Pulse Time Delay	The numerical values of the pulses and delays can be changed as required. Use up and down arrows to implement any change. **Note:** it is possible to highlight a previous pulse by pressing it. Once highlighted, you can change the pulse length or pulse energy. The same way, it is possible to alter a pulse delay after you have pressed it.

Note: there is no patient name displayed. The applicator to be used is highlighted on the top of the **Pulse Definition Screen**.

PDM treatment procedure

1. Set the Total Energy, Number of Pulses, Pulse Time and Delay and Press 

   If you have chosen to use a previously saved Pulse Train, ensure that the patient parameters have not changed since the Train was first created.

2. The Custom Treatment Screen appears. On this screen you can, for example, change the Spot size if you are working with the Nd:YAG. Example:

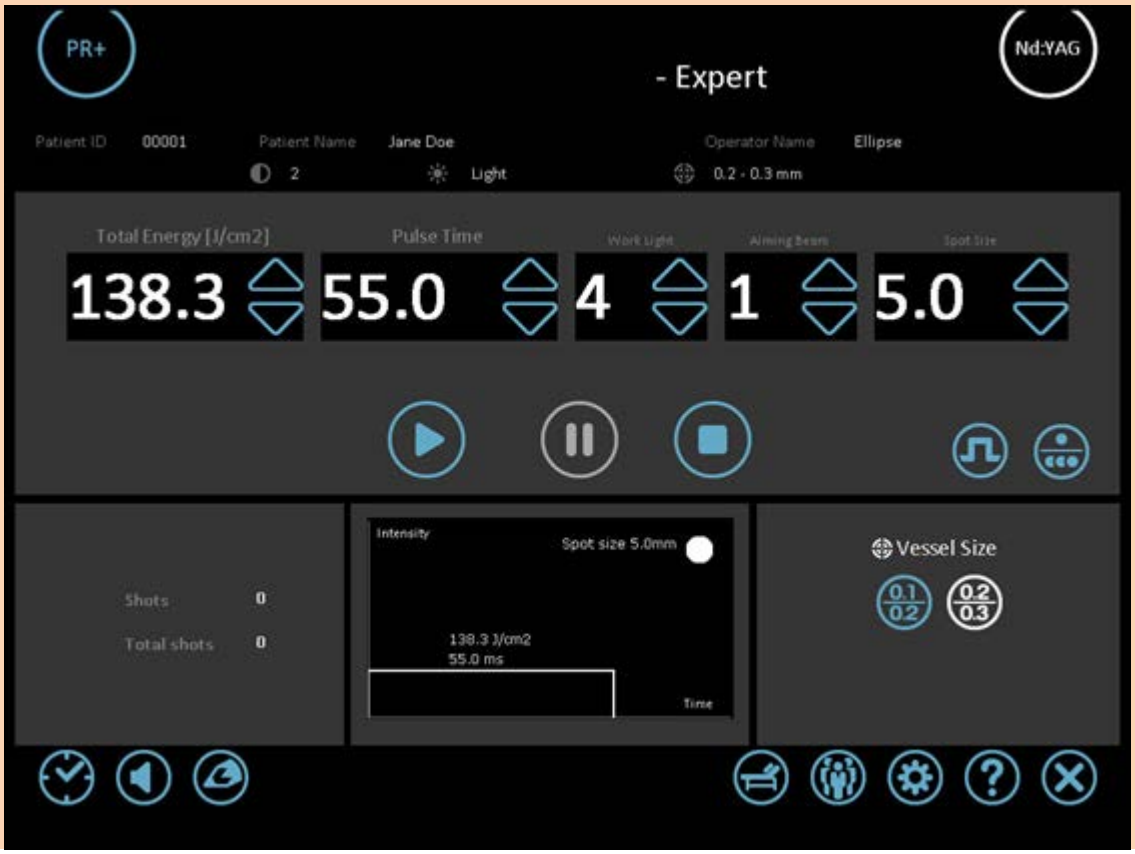


Fig 74. Example of Custom Treatment

3. If required, select a previously saved Pulse Train by touching the required train in the My Pulse Trains box and touching <Select Pulse Train>.

   Press <Start>. The system will ask you to wait until it is ready. This may take up to three minutes.

How to save a pulse train

In the Pulse Definition screen it is possible to save a custom made pulse train.

1. Press  if you wish to save the pulse you have created for future use.
2. Enter a name into the Enter Pulse Train Name box which appears.

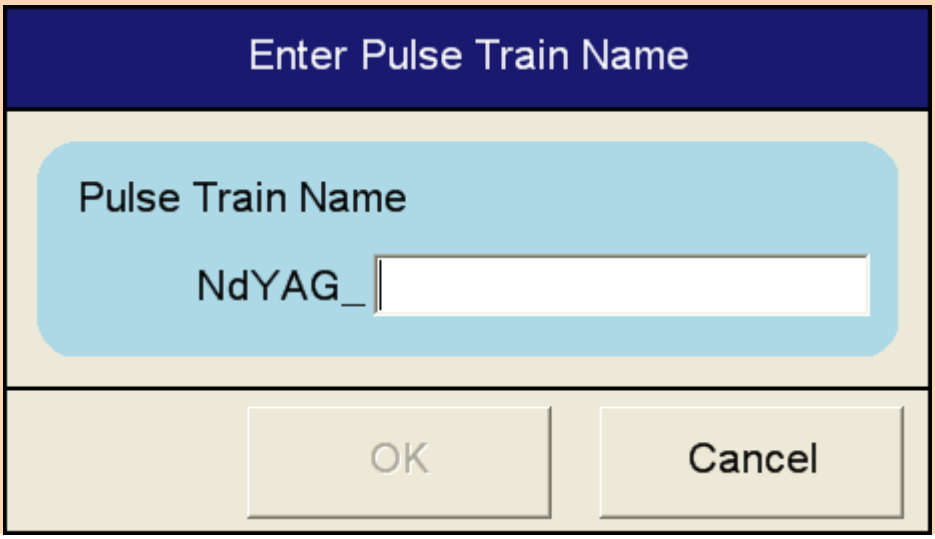


Fig 75. Saved Pulse Train

3. Press <OK>. If you press <Cancel> your pulse train will not be saved.

Chapter 4: CHANGING APPLICATORS

4.1 Physical Change of Applicators

Your Ellipse system allows two applicators to be connected at the same time. If you are changing from one applicator to another to perform a different treatment, you should follow steps 1 to 3.

Note: To prevent the risks of light discharge, ensure that any treatment is concluded by Pressing  on the treatment screen, before changing the applicator.

1. Physically release the cable relief at the back of the cabinet. (See Fig 78 Position of cable relief) unplug the electrical connector and the two cooling water fittings of the applicator to be changed (See Fig 79 Position of electrical and water connections). A few drops of cooling water may leak from the fittings before the shut valve activates.
2. Remove the "old" applicator and attach the "new" by reconnecting the two cooling water fittings and the electrical connector. The red markings on the male and female ends of the electrical connections should be aligned. Reposition the cable relief. Make sure the water tubes are not "kinked". It might be necessary to turn the cable relief.

Note: it is important to connect the electrical and water connections to the same group – a single applicator should use electrical connection A and water connections A, or electrical connection B and water connections B.

3. Always reposition the cable relief after replacing the applicator in order to avoid damage to the applicator cable and connectors.

Note – to avoid damaging the pump, ensure that at least one applicator is connected before turning on the system.

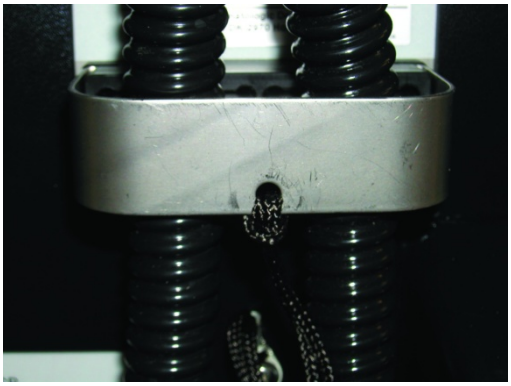


Fig 76. Position of cable relief

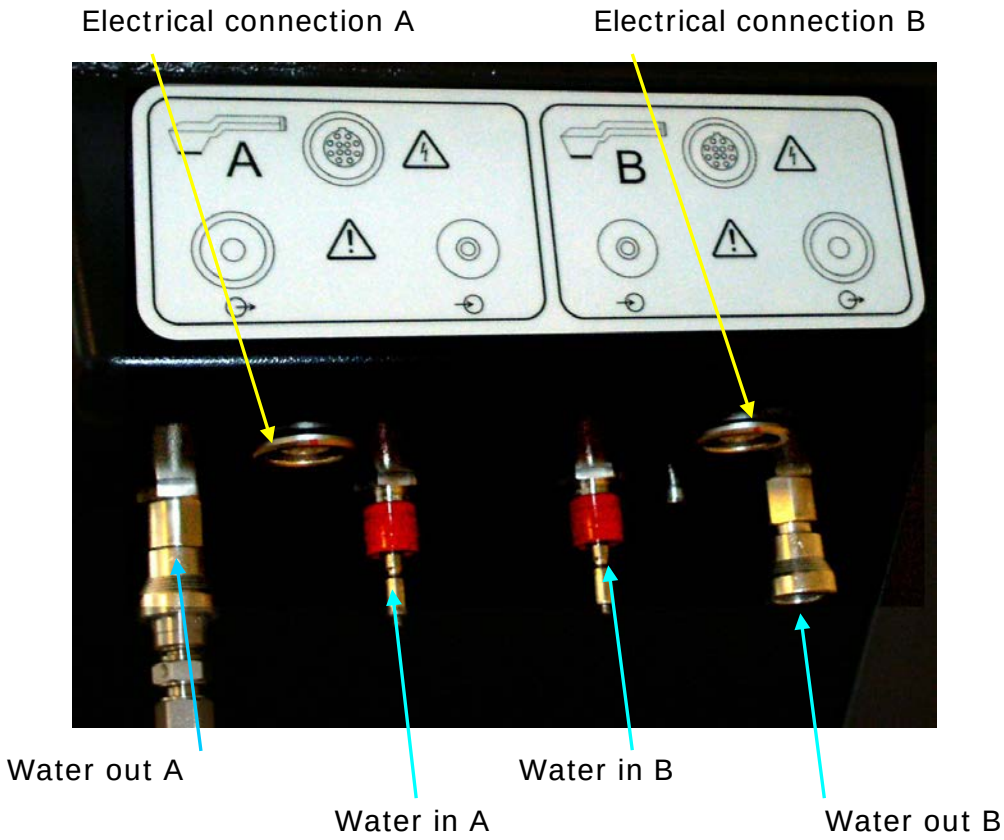


Fig 77. Position of electrical and water connections (SPT+ and I2PL+)

Fig 78. Position of electrical and water connections MultiFlex+ Systems

1 Water out A	**2** Electrical Connection A	**3** Water in A	**4** Air out and condensed water return.	**5** Laser electrical connection
6 Interlock plug insertion point (door)	**7** Water in B	**8** Electrical Connection B	**9** Water out B	

Note: It is very important that the electrical connector and the water connector are connected to the same output group (A or B). Connect the IPL applicator cables to 1, 2, and 3 *OR* to 7, 8, and 9.

Connect the laser applicator cables to 1, 2,3,4,5.

Interlock Plug - the Ellipse MultiFlex^{+} interlocking feature can be used for deactivation of laser emission when a door is accidentally opened to the treatment area.

If remote interlocking is not required the special interlock dummy plug must be inserted in the interlock plug insertion point (6).

Fig 79. Interlock Dummy Plug

If remote interlocking is required to ensure a safe entry to the treatment area, a switch may be mounted on the doorframe in a way that ensures contact closure when the door is closed.

Warning: Always use a shielded cable when establishing an interlock circuit. Otherwise, the EMC properties of this device cannot be guaranteed fulfilled.

Caution: The interlock circuit must be installed and tested by a qualified technician. The function of the installed circuit will be tested at service.

4.2 Applicator Lifetime and Dongles.

Applicator Lifetime

Your Ellipse system works on a Pay per Shot principle. This means that you pay a fixed amount per shot (flash of light) on the "Plus Series" applicators, as shown below.

Payment	Applicator	Credits charged per shot
Pay Per Shot Basis	HR^{+}, HR-D^{+}, VL^{+}, PR^{+*}, PL^{+*}	1.0
"	HR-L^{+}	1.8
Refurbishment Basis	HR-S, PL*, PL-W*; Nd:YAG**	-

Applicators marked * are available on the I2PL+ and MultiFlex+ only. The Nd:YAG applicator** is only available on the MultiFlex+

The Pay per Shot (PPS) charge for the Plus Series applicators includes standard refurbishment (but excludes damage caused to the light guide by misuse). These applicators must be returned to Ellipse for refurbishment when they have fired their maximum number of allowed shots, xxx.xxx. Your sales representative will advise the current number. The maximum is set to ensure that all applicators remain within output specifications.

In order that you can plan the refurbishment, your Ellipse System will display a count-down "Refurbishment in XXXX" when the number of remaining shots for that applicator is XXXX (less than 10 000).

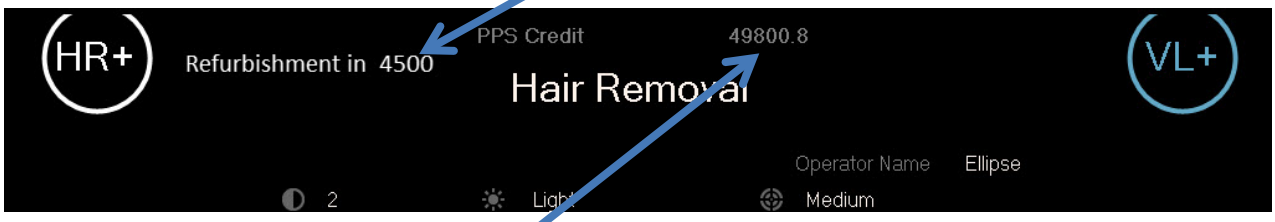


Fig 80. Screen showing countdown to refurbishment of HR^{+} and number of credits on dongle

Credits are purchased using a pre-paid "dongle", a USB device that is connected to your Ellipse system, via the USB port on the rear of the system. Dongles can be purchased with different numbers of credits. All standard size applicators use 1 credit per shot, but the larger HR-L^{+} applicator uses 1.8 credits. The number of credits remaining on the dongle is shown.

The system will warn you when the number of credits reduces below 5000 to allow you time to purchase a new dongle.

Note it is possible to remove the dongle to prevent unauthorized use of the system, but the removed dongle should be stored in a safe place so it is available when next required.

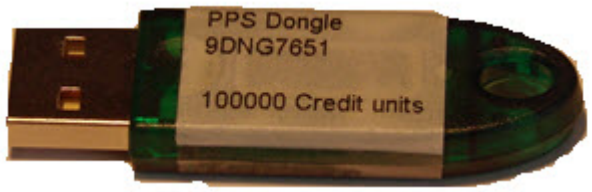


Fig 81. Example Dongle

Dongles are colour coded to show the systems they work with.

Blue	HR-3 only (systems other than Microlight)
Red	HR-3 or + Series Applicators (Microlight Systems)
Green	+ Series Applicators (systems other than Microlight)

It is only possible to use a green dongle on this system.

The HR-S, PL and PL-W applicators do not work on a PPS basis. These applicators will not take credits from the PPS credit "bank" when used, but give a lower number of guaranteed shots.

CE 0543

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