Ellipse MicroLight HR

Operator’s manual

Ellipse® MicroLight

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Ellipse MicroLight HR operator's manual
Software version:

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Chapter 1 About this manual

1.1 The manual

Congratulations with your purchase of the **Ellipse MicroLight HR**. To get the most of your system it is important that you use the system correctly, so please read the manual thoroughly, before using the system.

The operator's manual is designed to provide you with the information needed to use the Ellipse MicroLight HR system safely and effectively. The manual is divided into the following chapters:

- **Chapter 1:** Introduction to the manual, explains the intended use of Ellipse MicroLight HR, gives background information and outlines treatment indications and contraindications.
- **Chapter 2:** Hair removal guide.
- **Chapter 3:** Day-to-day operation of Ellipse MicroLight HR.
- **Chapter 4:** System maintenance and hygiene.
- **Chapter 5:** System safety.
- **Chapter 6:** Technical specifications of the system and the applicator.

References to other sections of this user manual will be in *italic* text in the form: *chapter X.Y: Heading*.

1.2 Use of the manual

This manual uses **caution** or **warning** to indicate a possible safety risk if instructions are not carried out according to the manual.

Caution is used to identify conditions or actions for which a potential hazard may exist which will or can cause minor personal injury or property damage if the instructions are ignored.

Warning is used to identify conditions or actions for which a known hazard may cause severe personal injury, death or substantial property damages if the instructions are ignored.

In order to reduce the likelihood of injury or equipment damage, it is important to read the manual and specifically *chapter 5: System Safety* before using the equipment. Keep the manual nearby and review the procedures and safety precautions periodically. Contact your representative if you have any questions or feel that additional training is required.

Warning: This equipment is intended for use by qualified personnel only and then, only after they have been trained to use the equipment.

1.3 The system

Ellipse MicroLight HR is a console with a control board. An applicator is connected to the system by means of a flexible cable, providing power and circulation of demineralised water to the applicator.

1.4 Intended use

Ellipse MicroLight HR is intended to be used for cosmetic permanent hair reduction in clients of Fitzpatrick skin type I-V, with skin that is not suntanned or has a low degree of suntan.

Indications for use

Application	Treatment Variable	Fitzpatrick Skin Type					
		1	2	3	4	5	6
Hair removal HR-2 applicator	Hair thickness (thin, normal, thick)	✓	✓	✓	✓	✓	⦸
Note: Clients with darker Fitzpatrick skin types (4 or above) or who are suntanned should **always** be treated with extra care and attention. ✓ **Allowed; ⦸ Not allowed**							

Warning: Ellipse MicroLight HR has built-in parameters to prevent treatment of clients where the combination of skin type and degree of suntan exceeds the maximum allowed. Never try to treat clients above these limits; treatment will be ineffective and will possibly result in a skin burn.

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.

Caution: Take care if treating dark skin with high-energy settings! Darker skin contains more (light-absorbing) melanin. During treatment, melanin heats up the skin increasing the risk of epidermal burns. This should always be taken into account when treating suntanned clients or those with a Fitzpatrick skin type of 4 or higher.

Never attempt to perform a treatment outside specific intended use, or on a patient outside the approved patient's parameters.

Caution: Due to the reflection of the light from the bones, it is recommended to reduce energy when treating over bony areas. Attention should also be paid to areas with thinner skin. At all times, operator must monitor skin reaction and get feedback from client on comfort.

Never attempt to perform a treatment outside specific intended use, or on a patient outside the approved patient's parameters.

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.

Selecting degree of suntan

Degree of suntan is defined as a colour change in the skin due to exposure to sunlight.

0 NONE Would be the fairest possible colour of the chosen skin type.

1 LIGHT Would be slightly tanned colour of skin.

2 MEDIUM Would be a tanned colour of skin.

3 MED.HEAVY Would be a darker tanned colour of skin.

4 HEAVY Would be the darkest possible colour of the chosen skin type.

Chapter 2 Guide to hair removal

2.1 Hair anatomy

As seen in Figure 1, a human hair shaft consists of a cortex made up of cortical cells, in which the pigment **melanin** is located. The cortex is covered by a cuticle - a single layer of keratin cells. In addition, large hairs contain a medulla, a central (often hollow) core which gives strength to the hair.

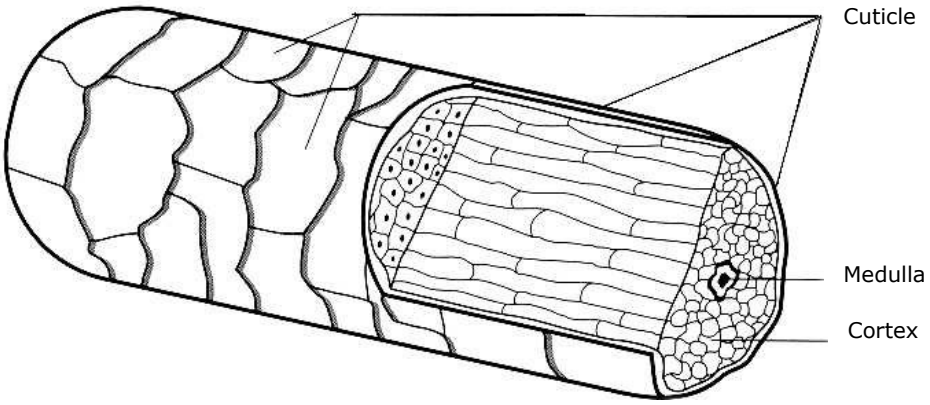


Figure 1 Cross-section through human hair

Within the skin (Figure 2) the hair shaft is surrounded by a hair sheath and is connected to the hair root, which is embedded in a pit in the skin called the follicle. The root is nourished by a small blood vessel. The follicle is typically located between 1mm and 5mm under the surface of the skin. This depth is dependent on the body site (1mm on upper lip; 5mm on bikini line). Follicles are often placed in groups of three (Figure 3). Normally only 1 of the 3 follicles is in the growing phase at any one time.

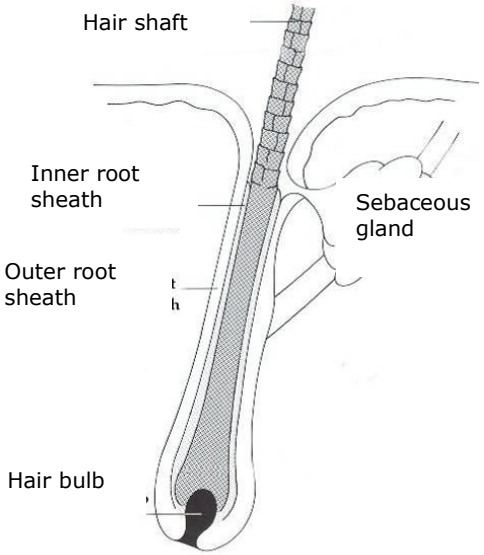


Figure 2 Cross section of hair in skin

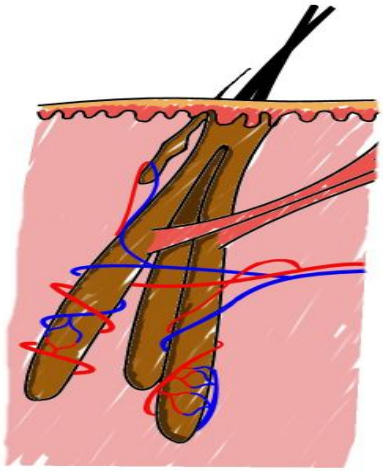


Figure 3 Hair follicles placed 3 together

2.2 Hair growth

The life cycle of the human hair has four phases. The hair follicles are not synchronised and therefore hairs that are close to each other may be in different phases at the same time. However, hormonal influences following a birth or severe infection may cause synchronisation of the hair growth cycle.

The four growth phases are:

- Anagen - the anagen phase is the growing phase of the hair. During early anagen, new hair grows from the hair follicle, pushing out old hair from the hair shaft.
- Catagen - in the catagen phase, when the hair bulb is degraded, cell growth and melanin production stops and the hair bulb is moved upwards to the skin surface.
- Exogen - when the hair falls out of the hair follicle.
- Telogen - is the typical resting phase. The length of the telogen phase depends on the anatomical site.

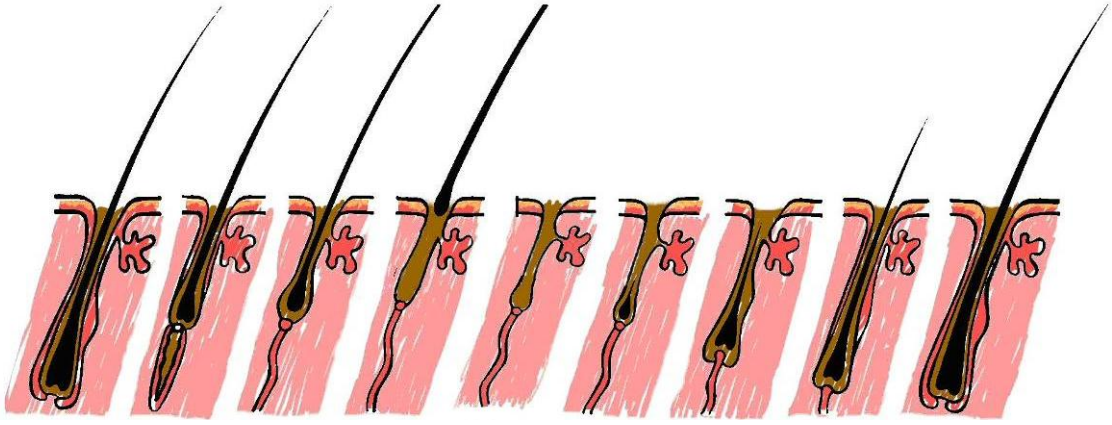


Figure 4 Life cycle of hair

Many different factors influence the growth of human hairs, such as age, ethnicity, medication, hormone levels and body site. Differences may be found in the length, coarseness and colour of body hair. Hair growth data for the various body sites is detailed in figure 4.

Head	Rest %	Growth %	Rest time	Growth time	No. of follicles per cm^2	Growth per day (mm)	No. of follicles	Depth of follicle (mm)	Expected no. of treatments	Results* from clinical papers
Scalp	15	85	3 – 4 months	2 – 6 years	350	0.35	Head and scalp total: one million	3 - 5	4 - 6	
Eyebrows	90	10	3 months	4 – 8 weeks		0.16		2 - 2.5		
Ear	85	15	3 months	4 – 8 weeks						
Cheeks	30 – 50	50 – 70			880	0.32		2 - 4		

Head	Rest %	Growth %	Rest time	Growth time	No. of follicles per cm^2	Growth per day (mm)	No. of follicles	Depth of follicle (mm)	Expected no. of treat-ments	Results* from clini-cal papers
Beard/ Chin	25	75	10 months	1 year	500	0.38		3 - 5		(1) 49% clear-ance 3tx
Mous-tache / Upper lip	35	65	6 weeks	16 weeks	500			2 - 4	5 - 6	
Body										
Axillae (arm-pits)	70	30	3 months	4 months	65	0.3		3.5 - 4.5	4 - 6	(4) 83% clear-ance 4tx (5) 64% 5tx
Trunk					70	0.3	425,000	2 – 4.5	4 - 6	(3) 74 -78% clear-ance 4tx
Pubic area	70	30	3 months	4 months	70			3.5 - 5	4 - 5	(2) 80.2% clear-ance 4tx
Arms	80	20	18 weeks	13 weeks	80	0.3	220,000	2 – 4.5	5 - 6	(3) 74 – 78% clear-ance 4 tx
Legs - Thighs	80	20	24 weeks	16 weeks	60	0.21	370,000	2.5 4	4 - 5	(3) 74 – 78% clear-ance 4 tx

Richard-Meharg hair growth table

*Results are taken at a period from 5-8 months after final treatment (varies according to study).

(1) Bjerring et al. Hair Removal using a New intense Pulsed Light Irradiator and a Normal Mode Ruby Laser. J Cutan Laser Ther 2000; 2; 63-71. Fitzpatrick Skin Types I –IV.

(2) Troilius A + C. Hair Removal with a Second Generation Broad Spectrum Intense Light Source – a Long-Term Follow-Up. J Cutan Laser Ther 1999; 1: 173-178 Fitzpatrick Skin Types II –IV.

(3) Stangl + Drosner. Comparison of Different Methods of Photo Epilation Med Laser Appl 17: 349 (2002). Fitzpatrick Skin Types I –III.

(4) Hee Lee et al. Photo-epilation results of axillary hair in dark-skinned clients by intense pulsed light Dermatol surg 2006 Feb; 32(2) 234-40. Skin Types III-IV.

(5) Internal Ellipse A/S Application note – 1APN7089 Hair Removal in Dark Skin Sept 2004. Skin Types IV-VI.

The number of visible hairs depends on the number of hairs being in their anagen/ catagen phase and the length in time of this phase. The longer the anagen phase lasts, the longer the hair can get. This is why the hair on the scalp grows much longer than the hairs on other parts of the body.

For example, at any time, 85% of the hairs on the scalp will be growing (anagen phase) and only 15% will be in the resting (telogen) phase. For scalp hair the anagen phase can be as long as 6 years while the resting period is only 3 – 4 months. In contrast, the hairs on the arms have a growing phase of only 3 months before they revert to a resting phase. At any one time, only 20% of those hairs may be growing.

2.3 Causes of unwanted hair

Most clients seek help for cosmetic reasons. Cultural norms and pressure from relatives or friends often require the removal of hair in certain regions such as the face, axillae (armpits), legs and bikini line for women and the chest and back for men. This system is intended for these cosmetic conditions.

If you observe one of the following two disorders, which are not cosmetic conditions, you need to advice the client to consult his/her own physician:

Hirsutism

Affects only females.

- Hair growth follows the male pattern, mainly facial hair in the beard and upper lip area. It is commonly seen as a secondary effect of endocrine (hormone) disorders or as an adverse effect of medication. Clients are often psychologically affected.

Hypertrichosis

- Excessive hair growth in either normal or abnormal locations.
- The cause is most commonly genetic or ethnic. Hypertrichosis can also occur as a secondary effect of hormone disorders, as an adverse effect of medication or in rare cases may result from tumours.

2.4 Hair removal – treatment information

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 Ellipse HR-2 applicator (REF 9APP7567) emits light with wavelengths of 600nm – 950nm that are highly absorbed in melanin. This gives high absorption in melanin. The penetration depth of these wavelengths is enough to reach even the deeper hair follicles.

Pulse duration

The pulse duration is dependent on the hair thickness. Although the pulse duration is not shown, Ellipse MicroLight HR automatically selects the appropriate pulse duration when the operator states the thickness of the hair. Thin hair needs less energy and shorter time to heat up and relatively low energy and short pulse to heat up and relatively low energy and short pulse duration are used. Thick hair needs more energy and longer time to heat up and a higher energy and long pulse durationd are used. In general the highest energies should only be used in connection with longer pulse durations (medium or thick hair).

The correct energy setting (fluence)

For a given wavelength and pulse duration, it is necessary to provide the light with enough energy to ensure that the hair follicle reaches a temperature of 70°C for at least 1ms.

If the energy setting is too high, too much energy will be conducted into the surrounding tissues (giving rise to a risk of burning). If the energy level chosen is too low the hair follicles will not be destroyed but will be damaged – this may mean that a thin white vellus hair may re-grow. Energy levels that are too low to destroy the hair follicles will sometimes synchronise the growth cycle. This results in the client experiencing an increased number of hairs entering the anagen (growing) phase at the same time.

Selection of the correct energy setting is dependent on the physical response of the client and the client's response to "pain".

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. This is entered on screen as (1).
- 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. This is entered on screen as (2).
- Thick hair - typically, beard, armpit, 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. This is entered on screen as (3).

Intervals between hair treatments

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

2.5 Pre-treatment information

It is important to inform clients about the entire treatment procedure. Information creates awareness of the treatment procedure and will give the client a realistic idea of what is achievable. Remember that the client is involved in the process and can influence the results positively or negatively. If the client has the right expectations before treatment, client satisfaction will be greater after it. Inform the client about:

- Treatment procedure.
- Achievable results (It is not possible to get 100% hair clearance) and the need for multiple treatments (because of the hair growth cycle).
- The "DO NOTS" – it is imperative the client obeys the following rules in the 30 days prior to treatment.
  - Do not pull out hair with tweezers, wax or use depilatory creams.
  - Do not bleach the hair.
  - Do not sunbathe, use solaria or use fake tan that dyes the epidermis.
- The client should not shave prior to treatment. Around 1mm of visible hair is needed for photo documentation, for evaluation of hair thickness and for marking the area to be treated. Depending on the body site this is the equivalent of 1 day (chin) to 6 days (eyebrow) hair growth. Inform the client that she will be shaved by the operator immediately before treatment.
- Contraindications to treatment, discussed in *chapter 2.9.*
- Possible adverse effects, discussed in *chapter 2.10.*
- Post-treatment care, discussed in *chapter 2.8*.

2.6 Pre-treatment care

Before treatment always:

- Remove client's make-up (to avoid skin burns).
- Take pictures of the treatment area for documentation purposes.
- Mark the treatment borders with a red or white pen. Do not use other colours, as they will absorb the light and cause 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 may lead to a skin burn and depigmentation of the permanent make-up and tattoo.
- Remember to shave the treatment area and remove all shaved hairs. Note the hair thickness. It is not possible to treat thin, normal and thick hairs in the same area in the same treatment session. If the area has hairs of mixed thicknesses, treat the thicker target first using a long pulse time. Thinner hairs can be targeted during subsequent treatment.
- 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: Ellipse Optical Coupling Gel – REF 2GEL0826 (5 bottles each of 250g) or 2GEL1342 (1 bottle of 5kg).

- Use eye protection (both operator and client). See chapter 5, Safety.

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:

- Perform test shots, max. 5 shots on a client before continuing the treatment. Make the test shots relevant to the treatment and to the treatment area. Allow sufficient time to evaluate the client reaction. Darker skin types take longer to react.

2.7 Treatment care

- Identify the skin type according to the Fitzpatrick skin type scale. Accurately enter this onto Ellipse MicroLight HR, which will adjust the default energy setting according to the skin type selected.
- Identify the degree of suntan. If necessary compare degree of suntan of the treatment site with an area not exposed to the sun. Accurately enter this onto Ellipse MicroLight HR, which will adjust the default energy setting according to the degree of suntan selected.

Note: Do not try to treat clients with a combination of skin type and degree of suntan outside the indications for use. See *chapter 1: Indications for use*.

- Accurately enter the Hair thickness onto Ellipse MicroLight HR, which will adjust the pulse duration according to the selected hair thickness.

Note: Default settings are placed in the lower end of the treatment 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 treatment window. This is found based on the operator's knowledge and by judging both the skin reaction and the client's tolerance of pain. Using treatment endpoints to determine the treatment window ensures continued effectiveness without compromising safety. The energy can be increased until perifollicular or general erythema (redness around the hair follicles or general redness) is observed; or perifollicular oedema (swelling around the hair follicles) or until the level of client discomfort is reached. If you need to treat the same area again (maybe using a higher energy), allow the skin to cool for at least 1 minute between shots.

A lack of skin reaction does not imply ineffective treatment, but usually indicates that a more effective result can be achieved by increasing the energy slightly. Test shots can also be made during the first consultation, allowing the operator to see the skin reaction over a longer period.

Figure 5 Perifollicular oedema and erythema

Figure 6 General erythema

Figure 7 Erythema in a skin type 4 client

Client response to pain is highly individual but normally clients find the treatment not to be painful. The scenario is comparable to the feeling of a rubber band snapping on the skin. Areas with greater hair density give rise to greater discomfort when treated and an individual client is also likely to respond differently to treatment in different body areas. Clients with naturally darker or tanned skin are likely to experience more discomfort as melanin concentration in the skin is higher.

When treating the upper lip a client with sensitive teeth could benefit from a piece of wet gauze placed between the teeth and the lip.

If a client is particularly anxious, it may help them to relax if they are first given a test shot in another area like the lower arm. Counting back from three to one generally has a beneficial psychological effect, as clients know when the shot will come, however, some clients respond negatively to the "countdown", so it is better to discuss this with the individual client.

EMLA cream or other topical anaesthetic preparations should not be used as they can influence the quality of the light penetration into the skin. A cool pack or cold damp cloth may be applied to the skin after treatment.

- Place the Light guide perpendicular to the skin surface to ensure maximum light penetration.
- 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 haemoglobins (haemoglobin and oxyhaemoglobin).

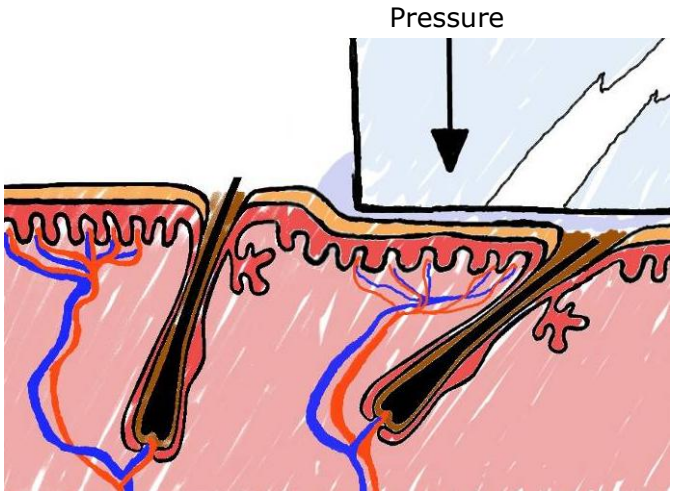


Figure 8 Applicator in contact with skin

Do not slide the applicator across the treatment site; lift it and place it down again. This ensures:

- That you leave a "footprint" of the area you have treated in the gel. This makes placing the subsequent shots easier and avoids the risk of either missing or double-treating an area of the skin.
- That the sides of the light guide are kept free from gel and reduces the risk of light being emitted from the side of the prism instead of the bottom of the prism. A build-up of gel on the sides can result in the client getting "zebra stripes" after treatment.

Figure 9 "Zebra striping" after treatment

2.8 Post-treatment care

- After the final shot remove the gel and dry the skin surface with a soft cloth.
- A cool pack placed against the skin may be comforting for the client, but is generally not required. A post-treatment soothing cream can also be applied.
- Do 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.

2.9 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 since this is a device for cosmetic purposes, 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:

- Clients with any disease or genetic condition causing photosensitivity; or clients exposed to photosensitizing substances.
- Clients undergoing treatment with anticoagulants (anti-clotting drugs) or any medication causing sensitivity to light.
- Clients suffering from long term diabetes or haemophilia.
- Clients tending to produce keloids (abnormal amounts of) or hypertrophic (raised red scars) scarring.
- Clients with suntanned skin or fever.
- Clients taking topical or systemic steroids or taking non-steroidal anti inflammatory drugs, as these actively work against the treatment.
- Clients with known or suspected malignant or pre-malignant pigmented lesions.
- Clients with an infection of the area to be treated.

Contraindication notes

Although not specifically contraindicated, clients who are pregnant or who have a heart pacemaker fitted are normally not treated. Treatment of pregnant clients is best deferred until 2-3 months after birth, as growth of body hair is synchronized at this time.

2.10 Adverse effects

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

- The client 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 clients (skin type 3 and especially types 4 and 5) 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 clients must be extra careful to avoid sun exposure.

- 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.

2.11 Further clinical information

Bleaching before treatment

Some operators who work with physicians use a bleaching cream prior to the treatment to bleach the skin. This also reduces the absorption of light energy in the epidermis during treatment.

4% hydroquinone can be used twice daily for 4 – 6 weeks, eventually combined with topical application of retinoic acid cream (0.025%). Both should be stopped 2-3 weeks before the next treatment. Use of such cream should be approved by a physician.

Pigmented areas

In case of pigmented lesions within the treatment area, consider the consequences of the treatment. The pigment will absorb the light as well. Try to position the applicator such that the pigmented lesion is not within the spot size, cover the lesion or reduce the energy.

Number of treatments

Client should normally expect at least 4 – 6 treatments. The final result and the number of treatments depend on a lot of different factors, such as:

- Skin type and degree of suntan.
- Hair thickness, hair growth cycle, hair colour and the depth of the hair follicles.
- Previous treatments, pre-treatment care, the treatment procedure, post treatment care and the experience of the operator.

It is therefore very difficult to predict treatment outcome in advance. However, setting the expectations correctly prior to treatment will increase client satisfaction after the treatment. Because the area is shaved, the effect is not immediately obvious.

Implants, permanent make-up and tattoos

Permanent make-up (dark colours in particular) will absorb the light energy and the client may feel a burning sensation (with burns in worst case). These areas must be excluded from treatment. This is also the case if the client has a tattoo in the treatment area.

Synchronisation of the hair growth cycle

The effect of light during the initial treatment will sometimes synchronise all hairs in the resting phases to an early anagen phase. The result is that more hair will grow after the initial treatment, which might be a disappointment for a client who is not informed of this possibility. The second treatment however, will be even more efficient, as more hairs are in the early anagen phase.

Note that the hair growth cycle naturally synchronises around 2-3 months after a client gives birth. It is therefore a good idea to postpone treatment of a pregnant client until this time.

Informed consent

No treatment is without risk and every treatment resulting in an effect can also cause adverse effects. Informed consent is an information document for the client that may be used to facilitate client awareness and acceptance of the risks associated with I^2PL treatments. The two-part form can be signed by both client and operator and both can keep a copy for their records. The next page is an example of such a document. Local legislation must be taken into account when a clinic makes its own consent form.

Consent Form for Treatment of Unwanted Hair Using the Ellipse system

I hereby authorise xxxxxxxx and any other associates or assistants selected by him, to treat me using the Ellipse system for the reduction of my unwanted hair. I understand that the reduction of unwanted hair may not be 100% and that multiple treatments are necessary based on the unique growth cycle of hair. I also understand that the treatment of unwanted hair using intense pulsed light may need to be performed in repeated sessions in the future to obtain the optimum result.

Intense pulsed light treatment is one method of treating unwanted hair. Unwanted hair may also be caused by medical conditions (hirsutism, hypertrichosis and other disorders). Treatments using the Ellipse system are not intended to cure any medical conditions causing unwanted hair.
The purpose of the treatment is to achieve cosmetic improvement by reducing hair growth using intense pulsed light to destroy hair follicles.

xxxxxxxx has informed me about alternative treatment possibilities and I understand that other forms of treatment or no treatment at all, are choices that I have. xxxxxxxx has explained to me that there are certain risks in any procedure and that in this specific instance such risks include, but are not limited to the following:

1. Post treatment discomfort, such as redness, erythema and follicular oedema, which may last up to 10 days.

2. Although uncommon, treatment with intense pulsed light may cause blisters or light burns to the epidermis.

3. Transient hyper - or hypo pigmentation may, occur and will normally fade in 3 to 6 months.

4. Regrowth or transformation of hair into vellus hair.

I agree to follow xxxxxx's post-treatment recommendations in order to ensure the best possible results. I understand that exposure to the sun and excessive heat must be avoided for 3 to 6 months after the treatment and a sun block of SPF 30 or greater must be used on the exposed skin areas. Otherwise it is possible that blotchy skin pigmentation, hyper- or hypo pigmentation might occur.

I agree to cooperate with the recommendations of. xxxxxxxx while I am under his care, realising that any lack of co-operation could result in less than optimum result.

I CERTIFY THAT I HAVE READ AND FULLY UNDERSTAND THE TERMS AND WORDS WTHIN THE ABOVE CONSENT TO THE PROCEDURE AND TO THE EXPLEANATIONS REFERRED TO or MADE. I HAVE HAD THE OPPORTUNITY TO ASK. XXXXXXXX ANY QUESTIONS REGARDING THE PROPOSED TREATMENT. I ALSO CERTIFY THAT I READ AND WRITE ENGLISH.

DATE	SIGNATURE OF CLIENT	SIGNATURE OF xxxxxxxx

Consent form

Chapter 3 Hair removal treatment

3.1 Before you start

This chapter provides step-by-step instructions for hair removal treatments using Ellipse MicroLight HR.

Please, note the information in chapter 3.4 regarding use of appropriate protection eyewear!

Warning: Before starting a treatment, it is important that the operator has understood the technical aspects of using the equipment. Please read the user manual especially *chapter 4: Maintenance* and *chapter 5: Safety*.

Warning: Safe and efficient client treatment requires suitable training.

Warning: The equipment should only be set up by your Ellipse A/S representative. As part of this he/she will:

- Unpack the system from its shipping crate and check that all components are present.
- Connect the applicator.
- Connect the power cable (supplied) to the mains input.
- Connect the system to the power supply and power up (switch on) the System. Software installation is carried out prior to delivery.
- Fill the system with demineralised water (Ellipse order number 9WAT7407) as described in *chapter 4.2: Water Supply*.

3.2 Operator start up

Note: An applicator must be connected to the Ellipse MicroLight HR on power-up. If you need to change applicators, follow the procedure shown in *chapter 4: Changing Applicators.*

Note: Numbers given in brackets refer to figure 13.

Procedure: The power supply to the Ellipse MicroLight HR is located at the rear of the cabinet. The control is a simple "rocker" switch.

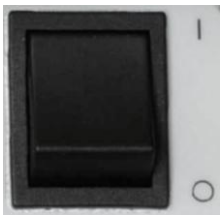


Figure 10 Power supply control switch

Press the switch at symbol "**I**" to power up and at symbol "**0**" to turn off the power supply.

When power is supplied, the system will start by showing a blinking standby/on light at the top of the control panel (1). This indicates that the system is getting ready to be used.

When this light stops blinking, press the button ⏻ (3) at the top of the control panel to move Ellipse MicroLight HR from standby mode to ready mode.

The Standby light will disappear and a display will show at the bottom of the Control panel (18) giving a software version number. Wait a couple of seconds for this number to disappear.

The ⚠ symbol (17) will appear. This means that you must read the Ellipse MicroLight HR operator's manual for the Ellipse MicroLight HR.

Press the start treatment ✓ symbol (10), when you have read the manual. The system will automatically perform a self-test. This is shown by the standby/on light blinking (1) and the display (18) panel giving a progress bar sign. When the panel is fully loaded (all squares are fully orange) the Ellipse MicroLight HR is ready for use.

Strictly follow the instructions regarding **filling water** in *chapter 4.2*, *water supply*. If these instructions are not followed, there is a small risk of creating an airlock in the system – you will see an error code 1400 advising this. To resolve the airlock issue, you will need to drain and then refill the system as advised in *chapter 4.2*.

The Ellipse MicroLight HR is designed to run at **normal room temperature** (15-25^{O}C). Please follow the instructions shown in *chapter 4.4 Temperature and storage precautions*.

Figure 11 System with the HR-2 applicator connected

Emergency stop

The Ellipse MicroLight HR has a red button located on the front of the console for emergency stop for all light emission.

Stop the system

Quickly press the emergency stop with the palm. An error code (18) shows code 1500 or 3000, when the emergency stop has been activated.

Reactivate the system

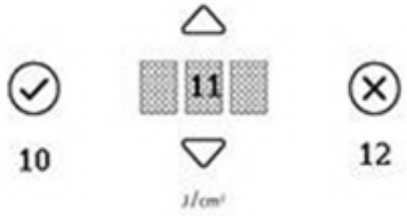
Turn the button clockwise to release the system to resume operations.

Figure 12 The emergency stop button

Keypad sound on or off

The Ellipse MicroLight HR **keypad** has two beep modes: **on** (beep) or **off** (silent).

To change the mode, press the standby button ⏻ and wait until the standby light is activated at the top of the system ⊙:



- Press △ to turn the **beep on**.
- Press ▽To turn the **beep off**.
- Press ⏻ to switch back to active mode.

3.3 Areas of the control panel

The Ellipse MicroLight HR control panel uses symbols and lights to control the console.

Figure 13 Guide to control panel

1 Standby/on light

2 Connected applicator name

3 Standby/on control

4 Parameter increase button

5 Parameter value

6 Parameter decrease button

7 Fitzpatrick skin type

8 Degree of suntan

9 Hair thickness

10 Start treatment button

11 Energy (J/cm^2) or beep on / off, see the previous page.

12 Stop treatment button

13 Shot counter

14 Button reserved for future applications

15 Clear counter button

16 Water pump button

17 Warning light

18 Error code display

19 Water error light

20 Temperature error light

21 Simmer not running light

3.4 Beginning the hair removal treatment

Warning: Ellipse MicroLight HR emits high energy, broad-spectrum light flashes that could cause severe eye damage. During treatment, the client must wear protective goggles (REF 2EYE0801 or 2EYE7140) and operator and bystanders, must wear green protection glasses (REF 2EYE0800 or 2EYE7138).

With the system in **ready mode** continue as follows:

- Enter the Fitzpatrick skin type – shown above 7 ( ) – by using the parameter Increase button (4) or parameter decrease button (6). The skin type is shown on the display (5).
- Enter the degree of suntan – shown above (8) – by using the parameter increase Button (4) or parameter decrease button (6). The degree of suntan is shown on the display (5). The numeric display for the degree of suntan is:

0	NONE	The fairest possible colour of the chosen skin type.
1	LIGHT	Slightly tanned colour of skin.
2	MEDIUM	Tanned colour of skin.
3	MED.HEAVY	Darker tanned colour of skin.
4	HEAVY	Darkest possible colour of the chosen skin type.

Enter the hair thickness shown above (9) by using the parameter Increase button (4) or parameter decrease button (6). Hair thickness is shown on the display (5). The numeric display for hair thickness is:

1: THIN

2: MEDIUM

3: THICK

- The default energy (J/cm^2) setting is automatically calculated and shown on the display in area 11. This energy is based on the skin type and degree of suntan.
- To increase or decrease the energy, press the up or down arrow (above and below area 11).
- You must check that the **energy setting** is safe and appropriate. Validate the data you have entered and press the start treatment button (10). A light at the base of the button will illuminate when the system is ready.
- When the System is charged (ready) you will hear an audible beep. Pressing the trigger of the applicator releases the pulse of light selected using the console.
- Use a test shot in an area relevant to the treatment area, but not too prominent. Judge both the skin reaction and the client's response (discomfort level). The time that should be allowed for skin reaction depends on the skin type of the client. Types 1 – 3 will usually react within a couple of minutes but for darker clients (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 oedema. 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 the **stop treatment button** (12).

- The number of shots used is shown on the display (13). This can be cleared by pressing the **clear shot counter** button (15).

Note: For hair treatment, the default energy is quite conservative (mild) and better results may be achieved by increasing the energy slightly. This is because quite a wide "treatment window" exists. Only adjust the settings after a test shot has been taken. Any adjustment should be governed by the skin reaction and client response.

3.5 Shut down

To close down the system, press the standby button (3). The standby/on light at the top of the display will illuminate. After, you can restart Ellipse MicroLight HR by pressing the standby Button (3) once more or turn off power to the Ellipse MicroLight HR by pressing the symbol **O** at the power supply control switch at the rear of the cabinet.

3.6 Moving Ellipse MicroLight HR

To move Ellipse MicroLight HR within a treatment room or along a corridor, ensure maximum stability by holding the front and back handles as you move it.

Always use the front and back handles when lifting the system, e.g. when the system is moved over a doorstep or moved stairways.

Chapter 4 Maintenance and error codes

4.1 Disclaimer

Ellipse A/S can only ensure continued compliance to required directives and standards, if repairs of the system or of the applicators and required periodic refurbishments of the applicators are performed by Ellipse personnel or by Ellipse trained and authorized personnel.

Use of high quality and original parts are crucial to ensure continued compliance. A number of parts are listed on critical component lists of the products' safety tests (according to *chapter 5 safety*). The safety test certificates are only valid as long as Ellipse uses the specified parts.

Ellipse A/S does not guarantee continued compliance and safety of the products if the above considerations are ignored.

4.2 Changing the applicators

Note: To prevent the risks of light discharge, ensure that any treatment is concluded by pressing the stop treatment button ⊗ (12) before changing the applicator.

- Physically release the cable relief holding the applicator in place (see figure 14). Unplug the electrical connector and the two cooling water fittings of the applicator to be changed (see chapter 1). A few drops of cooling water may leak from the fittings before the shut valve activates.
- 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. Make sure the water tubes are not bent. It might be necessary to turn the cable relief.
- Always re-position the cable relief after replacing the applicator in order to avoid damage to the applicator cable and connectors.

Note: You should follow the agreed return procedure with Ellipse when shipping an applicator for refurbishment/repair.

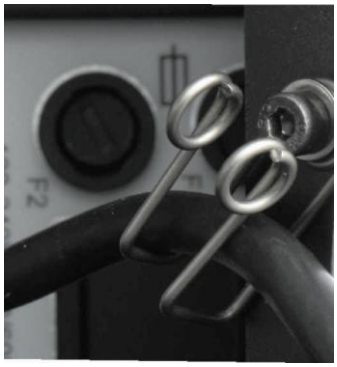


Figure 14 Cable relief

Figure 15 Fuses, switch and mains connection

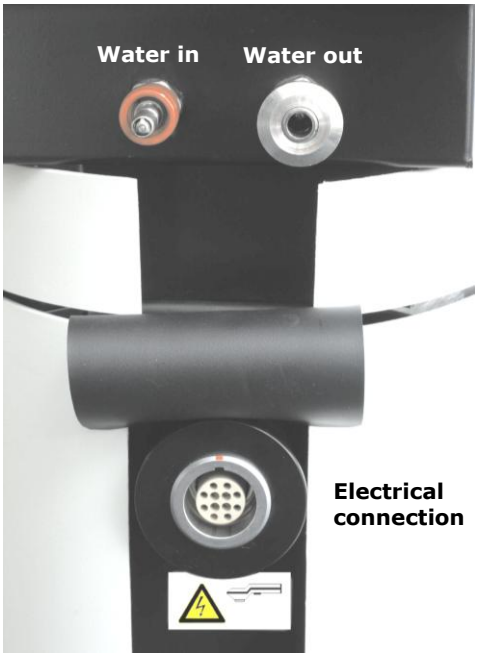


Figure 16 Electrical and water connections to applicator

4.3 Water supply

Warning: Take care no liquid falls onto the machine when disconnecting the water connector used for filling the water tank. In order to avoid this potential hazard place the water container on the floor to prevent spillage or dripping of water onto the machine.

Note: Only distilled or demineralised water should be used to fill Ellipse MicroLight HR. Custom-designed 5 litre bags of water are available from your Ellipse representative (Ellipse order number: 9WAT7407).

Filling the system

- Remove the cap from the water bag and screw on the water tubing found in your accessory kit.
- Ensure the applicator is connected to your Ellipse MicroLight HR and that the system is powered up.
- Remove the applicator handpiece from its holder at the back of the system and introduce the free end of the water tubing into the tank connector (see figure 16).

Figure 17 Tank connector and release catch

- Once connected, you can replace the applicator in its holder.
- Hold the water bag a little higher than the tank connector with the cap pointing downwards:

Figure 18 Correct position of water bag during filling

- Press the water pump button ⓦ. The pump will run for 1 minute. Apply gentle pressure to the water bag. The system will begin pumping water. The water level is visible in the window below the water tank filler cap. If the tank is not filled to the mark by the time the pump has stopped, then press the water pump button again to restart it.
- **Do not overfill!** Water level shall not exceed the top of the window. The tank has an overflow tube and water will leak onto the floor if the tank is overfilled. Place a kidney tray on the floor to hold the excess water. Immediately switch off the pump by pressing the same button ⓦ.
- When you have switched off the pump, release the tubing by pressing the release catch (see figure 16).

Draining the System

- Connect the drainage hose found in your accessories kit to the applicator water outlet shown in figure 15.
- Place the other end of the hose into a suitable container (2 litre bottle or jar).
- Power the system up.
- Wait until the system is in standby mode.
- Press the water drainage button. The water is now pumped out.
- The pump stops by itself when drainage is completed, which takes 20 seconds.
- Remove the drainage hose when completed.

4.4 System disinfection

Applicator disinfection

It is essential that any areas that come into direct contact with the client should be regularly inspected, cleaned and disinfected.

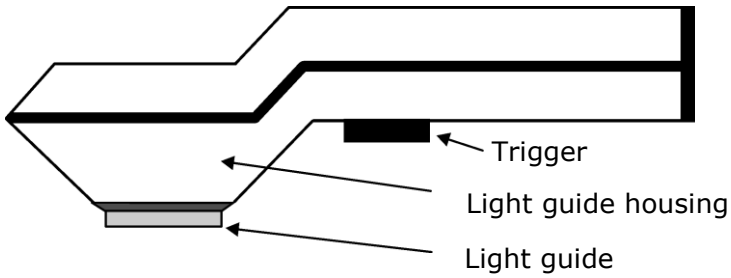


Figure 19 Position of light guide and housing

This applies particularly to the light guide and the applicator. Between treatments, the light guide and the light guide housing should be wiped with a mild soap solvent, followed by disinfection using a non-flammable disinfectant (for example peracetic acid) that is capable of killing bacteria, fungal spores and viruses. At least daily, visually inspect the applicator for any signs of damage. Once a week all applicator surfaces should be disinfected.

Cabinet cleaning

Cleanliness is a prime rule in maintaining equipment. At least once a month external metallic surfaces should be wiped to remove any foreign material that may have accumulated. Painted and plastic surfaces should be cleaned using a clean cloth moistened with a solution of soap and water. Clean the display using a clean cloth dampened with a mild window cleaning solution. Ensure that the cloth is not too wet, as no excess moisture should be allowed to run into the cabinet.

Cleaning the air intake

The air intake filter is located at the rear of the system. The filter must be cleaned with a vacuum cleaner once a week. Failing to do so will reduce the system capability to operate at room temperature, and may cause the system to pause during treatment for some cooling down period.

4.5 Technical requirements

Warning: If the ellipse MicroLight HR is to be connected to a 240V AC circuit, a centre-tapped circuit must be used.

Maintenance

An authorized representative should perform all system maintenance. To enhance the applicator lifetime and uptime of the system, maintenance should be performed every 12 months. Local conditions and dusty environment may shorten the intervals. Applicator lifetime may be reduced by lack of maintenance or lack of water.

Temperature

If the temperature in a clinic using Ellipse MicroLight HR drops below freezing point, damage can be caused to the cooling system. To prevent this, keep Ellipse MicroLight HR in a room above 5°Celsius or drain the cooling system of fluid. Note that the working temperature should be between 15 – 35° Celsius.

Storage precautions

For long time storage (more than 6 months) the shipping box can be used if it is available (if not consult your Ellipse A/S representative). The shipping box must be stored on a pallet. The storage temperature must be within 0° - 40° Celsius, 20 – 80% humidity, non condensing. Protect the system from dust and debris. Remove the applicator from the cabinet and store it separately.

Note: For long time storage (or if the temperature is likely to drop below 5°), the cooling system must be drained of fluid. – See *chapter 4.2: Draining the System.*

4.6 Error messages

If an error occurs during operation of Ellipse MicroLight HR, the warning symbol (17) will illuminate. If one of the following shows, check the error codes:

- Water error symbol (19).
- Temperature error symbol (20). This means that the circulating water has overheated.
- A numeric code in the error code area (18).

You can clear an error code by pressing the © button. If you are unclear as to the meaning of an error code, contact your Ellipse representative. Do not repeat the shot with the applicator on the client, until you are sure it is safe to do so. If you must repeat the shot, the applicator **must** be held away from the client's skin.

Code	Explanation	Action Required
1010	No applicator connected.	Connect the applicator to the system.
1020	No valid applicator connected.	Check that a valid applicator is connected. If the problem persists contact your Ellipse representative.
1030	Error in the USB stick.	The USB stick does not respond. Contact your Ellipse representative.
1040	Wrong USB stick.	The USB stick cannot be used with this system.
1050	USB stick is missing.	Insert the USB stick.
1060 – 1080	Applicator and system are not compatible.	Contact your Ellipse representative.
1100	Flow error.	Check flow tubes are correctly connected.

Code	Explanation	Action Required
1200	Modules not correctly placed.	Separate and reassemble the system.
1250	Applicator connected while modules separated.	Disconnect the applicator and try to separate the system again.
1300	Modules too cold.	Allow time for system to reach approved temperature.
1400	Water temperature too hot or too cold.	Allow time for system to reach approved temperature.
1500 - 2999	System module error.	Contact your Ellipse representative.
3000 - 4999	Prepare shot / shot error.	Reset the error and try to shoot again. If the problem persists contact your Ellipse representative.
5000	No Ellipse A/S dongle connected. A non-Ellipse A/S dongle is connected.	Connect Ellipse A/S dongle – if not available, contact your Ellipse representative.
5100 - 5200	Error on dongle type.	Contact Ellipse representative.
5300	No shot credits on dongle.	Replace the Ellipse dongle – if not available, contact your Ellipse representative.
6000	Upgrading error.	Contact your Ellipse representative.
6001 - 7999	System module error.	Contact your Ellipse representative.
8000	Display error.	Contact your Ellipse representative.
9000 - 9999	Self-test error.	Repeat the Self-test. If the error repeats, contact Ellipse your representative.
10130	Key switch is turned off.	Turn the key switch on.
10140	Applicator error.	Change to another applicator.
10000 – 11000	System module error.	Contact your Ellipse representative.
11001 – 99999	Reserved numbers.	Contact your Ellipse representative.

4.7 Software Update Procedure

New software versions are usually supplied by email in a file named emlfw.buf. Follow the procedure below to update the Ellipse system software.

Remember to read the **service note** issued with the software update.

1. Copy the file to a USB flash memory device. Save it in the root directory of the memory device.

2. Make sure that the Ellipse system mains switch is in position **O.** Insert the USB flash memory device in the USB connector (located under the Ellipse logo beneath the top plate).

3. Turn the mains power switch to position **I**. Do **not** touch the top plate and the buttons. The standby/on light is flashing for approx. 25 seconds while the computer is loading the operating system. The energy window shows "walking" LEDs while the software update is loaded. It may take several minutes.

4. A multi digit code is shown in the error code display when the walking LEDs stop. Check that the number displayed matches the number sent together with the software update.

5. Switch the mains power switch to position **O** and remove the USB flash memory device.

6. Start up the system following the usual procedure as described in chapter 2. The updated software is now in operation and the version is shortly displayed during start up. The service note enclosed with the software update may contain important information to be given to system operators.
7. Note that the system log files are automatically copied to the USB flash memory device during the software updating. Keep the files in your records for future reference.

Chapter 5 Safety

5.1 Introduction

This chapter contains important information concerning potential hazards and general safety precautions. The purpose of the safety instructions is to draw attention to potential hazards if instructions are ignored. These hazards may lead to accidents or serious injury to the client, operator or service personnel.

Ellipse MicroLight HR incorporates many safety features to protect the client and the operator. However, as with all electrical devices, safe use of Ellipse MicroLight HR relies on a "safe attitude" from a suitably trained operator. Do not use the system if a malfunction of the equipment or a safety problem is believed to exist.

Please, note the information in *chapter 3.4* regarding use of appropriate protection eyewear.

Please, note the information in *chapter 4.1* regarding repairs.

Restrictions on use

Warning: Certain hazards are associated with the application of intense light energy to the skin. For this reason it is important that Ellipse MicroLight HR is used only by suitably trained personnel, who understand both the clinical application and the dynamics of light-tissue interaction.

Warning: Injury to client can be caused by unintended flash release. Do not leave the equipment unattended in a condition ready to flash at any time.

5.2 Hazards

Caution: Proper evaluation of both client skin type and degree of suntan is of paramount importance for efficient operation; it is therefore vital that a thorough dermatological examination is carried out prior to any treatment.

Note: Dark skin, whether natural or due to suntan, will increase the risk of side effects such as burns and will also reduce the efficiency of the treatment. Be aware that degree of suntan may vary over the treatment area and that absorption will be affected by pigmented nevi or tattoos.

Eye protection

Warning: Ellipse MicroLight HR emits high energy, broad-spectrum light flashes that could cause severe eye damage. During treatment, the client must wear protective goggles (REF 2EYE0801 or 2EYE7140) and operator and bystanders, must wear green protection glasses (REF 2EYE0800 or 2EYE7138).

Caution: Never trigger the flash lamp without warning all personnel present.

Caution: Never leave a client unattended if the system is in the ready mode.

Warning: Never direct the light guide towards the eye. Aim away from the eye and regard the cheek bone as the highest point that can be treated. If necessary, move skin to be treated down over the cheek bone or up over the frontal cranial bone to use the bone as an additional shield.

Other client-related hazards

Injury to the client's eyes and skin may result from incorrect use of the equipment. Always take the following precautions:

Warning: Always follow the client parameters set-up instruction detailed in this manual.

Warning: No part of the area to be treated should be covered with any type of metal foil. When exposed to light radiation, foil may heat up and cause epidermal damage.

Warning: Do not use the applicator in the presence of a flammable anaesthetic mixture with air or oxygen or nitrous oxide.

Warning: Do not flash the light in the proximity of flammable materials.

Note that such materials may be liquid (e.g. alcohol swabs) or solid (e.g. dark clothing).

Warning: Do not use an applicator with a chipped or damaged light guide, as this may cause epidermal damage.

Caution: Only use approved and tested optical coupling gel: Ellipse optical coupling gel – REF 2GEL0826 (5 bottles each of 250g) or 2GEL1342 (1 bottle of 5kg).

Note: Abnormalities of the skin, such as pigmented lesions, birth marks and tattoos must be evaluated by a medical doctor or dermatologist with experience in photo-therapeutics prior to treatment.

The default settings are suggestions only. The operator is responsible for client safety and should only press the start button once satisfied that the settings are appropriate. No default settings should be accepted unless a thorough evaluation of the skin has been carried out.

Dark skinned clients should only be treated with extreme caution. Make a sample shot and evaluate reactions to this before continuing.

When performing hair removal over tattooed regions (including permanent make-up) the tattoo may be partly removed or discoloured or epidermal adverse effects may be noted. Therefore avoid treating such areas.

Operator related hazards

Severe injury to the operator could be caused by incorrect use of the equipment. Please ensure that the following precautions are observed:

Warning: Do not use a power cable other than that supplied with the system.

Note: The system must be connected to a 3-pin power point (i.e. a socket with protective earth). Contact a local electrician as necessary.

Warning: Never use the Ellipse MicroLight HR System if the System is wet or appears to be leaking water.

Warning: Due to electrical safety requirements, the applicator must only be refurbished by an Ellipse A/S authorized representative.

Warning: Ellipse MicroLight HR has covers to protect operators from electrical shock and mechanical hazards. Always contact qualified service personnel for your servicing needs. Do not attempt to service the equipment yourself and do not remove any covers.

Caution: The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- Use of the accessory in the vicinity of the client.
- Evidence that the safety certification of the accessory has been performed in accordance to the appropriate IEC 60 601-1 and/or IEC60 601-1-1 harmonised national standard.

Note: Do not lean anything against the equipment. Doing so could cause equipment damage.

Note: Do not connect any peripheral equipment other than that supplied by Ellipse to the USB port.

Fire hazards

Ellipse MicroLight HR emits high energy light flashes that, when absorbed in any material can cause a dramatic increase of temperature or even cause the material to catch fire. To prevent this take the following precautions:

Warning: Never expose flammable material to the radiation emitted from Ellipse MicroLight HR.

Note: Cleaning: never use flammable liquid like alcohol to clean or disinfect any part of Ellipse MicroLight HR. Ellipse A/S recommends cleaning the applicator with a mild soap solvent, followed by disinfection using a mild non-flammable disinfectant (see *chapter 4.3: System Disinfection*).

Warning: Do not use Ellipse MicroLight HR in the presence of flammable anaesthetic mixture or other flammable gases.

General precautions

Do not attempt to operate the Ellipse MicroLight HR System without the applicator connected.

Air bubbles trapped in the applicator must be removed before releasing the first shot - if not the applicator may stop working after a few shots.

Figure 20 Remove trapped air

To remove trapped air switch on the system and turn, gently shake, raise and lower the applicator. Continue this procedure until air is completely removed from the applicator. Visual inspection is possible through the light guide, as shown in the picture above.

Always reposition the applicator in the holder on the back of the cabinet when not in use. To avoid accidental light discharge, always press the stop treatment button .before replacing the applicator.

Warning: Do not attempt to use the Ellipse MicroLight HR System or applicator if a safety problem is thought to exist.

Warning: Do not attempt to use the Ellipse MicroLight HR System if an applicator is leaking cooling water.

Warning: All areas that come into direct contact with the clients should be regularly cleaned and disinfected. Improper cleaning may result in epidermal or equipment damage. This applies particularly to the light guide and the applicator. (See chapter 4: System disinfection).

Electromagnetic interference

Caution: Ellipse MicroLight HR generates and can radiate radio frequency energy. The equipment may cause radio frequency interference to other devices and to radio communications. To provide reasonable protection against such interference, the Ellipse MicroLight HR complies with the emissions limits as stated in EN 60601-1-2.

This electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual and accompanying technical information.

Portable and mobile RF communications equipment can affect electrical equipment. To ensure a high level of reliability when exposed to such interference, Ellipse MicroLight HR complies with the immunity requirements as stated in EN 60601-1-2. The operating conditions are classified on the basis of performance criteria as defined in EN61000-4-2.

Warning: Use of accessories, applicators and cables other than those specified, with the exception of accessories, applicators and cables, including the provided mains power cable sold by the manufacturer of Ellipse MicroLight HR, as replacement parts for internal and external components, may result in increased emissions or decreased immunity of the equipment. Use of cables not properly shielded and grounded may result in the equipment causing radio frequency interference in violation of the European Union Directive and FCC regulations.

Warning: Ellipse MicroLight HR should not be used adjacent to other equipment. If the system is used while positioned adjacent to other equipment, it should be observed to verify normal operation in the configuration in which it will be used.

5.3 CE conformity

CE

Ellipse MicroLight with applicator conforms to the requirements of 2006/95/EC Low Voltage Directive and therefore bears the CE mark of Conformity.

Safety Classification: The Ellipse MicroLight HR has the following classification:

Class I, Type B according to EN 60601-1 safety standard. This equipment requires a reliable protective earth connection.

5.4 IEC symbols used

Denotes protective earth point.

Alternating current.

Power ON.

Power OFF.

Type B equipment.

Manufacturer.

Date of manufacture.

Attention: consult accompanying documents for detailed instructions before proceeding.

This product should not be disposed of as normal waste, but should be sent to an authorized centre for recycling.

5.5 System safety labelling

Warning against Powerful Light radiation from the applicator. Avoid directly eye exposure.

Read the accompanying documentation.

Warning that a dangerous voltage may be present.

Applicator connection point.

Applicator cooling water output.

Applicator cooling water input.

Fuse.

Chapter 6 Technical specifications

6.1 General specifications

Dimensions (d x w x h)	Max 580 x 420 x 1120mm
Weight	Max 52kg
Shipping box dimensions (d x w x h)	Max 1230 x 670 x 750mm
Shipping weight	Max 96kg
Noise	Max 55 dBA
Electrical input	100-240 VAC
Maximum power consumption	1000 VA
Frequency	50/60 Hz
Fuse	T 10 A/250 VAC
Pressure	700-1060 hPa
Working temperature	15°C – 25°C
Relative working humidity (non-condensing)	10 – 75%
Storage temperature (drained)	0°C – 40°C
Relative storage humidity (non-condensing)	20 – 80%

6.2 Output

Light source	Intense pulsed light (I^2PL)
Charge time	2 seconds
Number of pulses before the system runs hot	Unlimited within working temperature

6.3 Applicator

Type	Hair applicator type HR-2
Pulse time (min-max)	15-40ms
Foot print (spot size)	10 x 48mm
Wavelength range (min-max)	600 – 950nm
Energy range	8 J/cm^2 – 21 J/cm^2 (note 1)

Accessories

Optical coupling gel – REF 2GEL0826 (250g) or 2GEL1342 (5kg)

Note: technical specifications are in accordance with GEN15406-1 and are subject to change without notice.

*Note 1: For regulatory reasons the maximum limit will be 18 J/cm^2 in Japan.

Chapter 7 Guidance and manufacturer's declaration EMC topics

7.1 Guidance and manufacturer's declaration – electromagnetic emissions

Ellipse MicroLight HR is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	Ellipse MicroLight HR uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Ellipse MicroLight HR is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions	Complies	

Ellipse MicroLight HR is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%RH.
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines ± 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV differential mode ± 2kV common mode	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

7.2 Guidance and manufacturer's declaration – electromagnetic immunity

Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec.	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec.	Mains power quality should be that of a typical commercial or hospital environment. If the user of Ellipse MicroLight HR requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field. IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: UT is the AC mains voltage prior to application of the test level.

Ellipse MicroLight HR is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 3V/m 	Portable and mobile RF communications equipment should be used no closer to any part of the Ellipse MicroLight HR, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80M to 800MHz $d = 2.3\sqrt{P}$ 800M to 2.5GHz where *P* is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Ellipse MicroLight HR is used exceeds the applicable RF compliance level above, the Ellipse MicroLight HR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Ellipse MicroLight HR system.

[b]Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Ellipse MicroLight HR system

The Ellipse MicroLight HR is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Ellipse MicroLight HR system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Ellipse MicroLight HR as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter / W	Separation distance according to frequency of transmitter / m		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	**80MHz to 800MHz** $d = 1.2\sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CE

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