25 June 2008

Complaint: Mrs A
Our ref : 07/09713

I write further to my letter to you of 30 May 2008 about Mrs A's complaint concerning the service provided to her by a beauty therapy clinic (the Clinic) and beauty therapist Ms B. Mrs A complained that Ms B performed an ELOS (Electrical Light Optical Synergy) treatment on her face on 10 May 2007, which resulted in blistering and scarring, and that she was not adequately advised of the risks associated with this treatment.

You and Ms B were notified of this investigation on 21 November 2007 and were asked to provide specific information by 14 December 2007. This deadline was subsequently extended, at your request, until 7 January 2008. However, despite repeated reminders from this Office, we did not receive a formal response from you. Ms B provided a response on 19 May 2008.

On 30 May I provided you with my provisional opinion on this case and invited you and Ms B to comment on my findings. Ms B stated that she was regretful of the stress she caused Mrs A. She said that she tried to provide Mrs A with a great experience and had always followed proper procedures, and is sad that Mrs A was disappointed. Ms B provided Mrs A with an apology. You telephoned my Office and explained you had experienced some personal difficulties recently. You were reluctant to respond in writing, but said you would provide a letter of apology. This will be sent to Mrs A.

Having reviewed all the information on file, I have made my final decision that you and Ms B breached the Code of Health and Disability Services Consumers' Rights.

Information reviewed
I reviewed the information you provided initially in response to Mrs A's complaint letter (which you were sent on 18 June 2007). I have also considered further information obtained from: Mrs A; dermatologist Dr C; general practitioner Dr D; the Association of Beauty Therapists NZ Inc. President; the Association Secretary; the Manager of a second beauty therapy Clinic; a Clinical Sales Specialist; President of the New Zealand College of Appearance Medicine, Dr John Barrett; and ACC.

You were advised of my investigation on 21 November 2007 and informed that it would cover the appropriateness of the service provided to Mrs A on 10 May 2007 by you, as the employer and co-owner of the Clinic, and Ms B as the provider. You were also advised that the investigation would include the adequacy of the information Ms B provided to Mrs A about the proposed treatment on 10 May 2007.

On 26 November, two HDC staff visited you at work to explain the reason for the investigation and the additional information requested. I have considered the

information you provided at that time, as well as Ms B's subsequent response of 19 May 2008.

What happened?

Background

On 8 May 2007 Mrs A telephoned the Clinic to make an appointment for herself and her daughter. She spoke to Ms B and requested laser treatment for dark patches on her cheeks. She planned to attend a family wedding in September 2007 and wanted to improve the appearance of her skin.

The Clinic is a beauty therapy clinic that provides a variety of treatments including ELOS hair reduction and skin rejuvenation. You advised that all treatments provided at the clinic were performed by qualified beauty therapists with New Zealand Qualifications Authority (NZQA) recognised certificates.

Treatment

On 10 May, Mrs A attended an appointment at the Clinic. She was seen by Ms B, who assessed her facial scarring and recommended ELOS treatments. Ms B used a Syneron ELOS machine.

As you know, the ELOS machine differs from a straight IPL (Intense Pulsed Light) machine in that it delivers a radio frequency as well as light. The proportions of light and radio frequency are varied depending on the client's skin type. The machine emits an optical pulse and an electrical pulse at the same time and the electrical energy is forced towards the areas of skin heated by the light pulse. It produces a greater and more focused thermal effect than the IPL machines, which are also used by the beauty therapy sector. The less intense light energy produced by ELOS, means there is less chance of burning and the pulses can be delivered for longer periods than the straight IPL machines.

Before treatment, Ms B completed a Skin Rejuvenation Consultation form for Mrs A. Under the section listing "complications for medical history" it was indicated that Mrs A had a pigmentation disorder. The consultation form also listed a number of possible "contraindications" to ELOS/IPL treatment, which stated "Any abnormal or undiagnosed pigmentation should be avoided". This was not identified as a factor for Mrs A.

Ms B stated that she talked to Mrs A about her pigmentation disorder and asked her if she was seeing a dermatologist, using sun block or any other treatments, medications or traditional remedies. Ms B noted under the heading "Skin Type Assessment" that Mrs A had a Fitzpatrick Skin type IV.[1]

Mrs A had previously been treated for acne by her doctor and given the antibiotic Minocycline.[2] However, it was not recorded that Mrs A was receiving treatment from

[1] Skin type can be categorised according to the Fitzpatrick skin type scale, which ranges from very fair (skin type I) to very dark (skin type VI). Fitzpatrick Skin type IV is the highest risk skin type for ELOS/IPL treatment.

[2] Minocycline is a semi synthetic derivative of tetracycline (oral antibiotics often used to treat skin diseases), which may cause photosensitivity: www.medsafe.co.nz profs/datasheet/m/minotabtab.

her doctor for acne. The second page of the consultation form listed precautions for the use of ELOS/IPL treatment. It warned, "Treat with caution if patient has any of the following risk factors", which included "Medications that may cause photosensitivity to light 580-980mm." This was not identified as a risk factor for Mrs A.

The consultation form listed possible side effects from the treatment as:

"
- Temporary mild discomfort from treatment, may feel warmth or tingling
- Temporary swelling, redness sin treatment area
- Temporary 'darkening' of pigmented lesions before becoming light
- Superficial scabbing, crusting or blister
- Transient or permanent dyschromia from epidermal injury."[3]

Ms B stated that she explained ELOS treatment to Mrs A; that she would feel a bit of heat as a side effect; and that it might cause some redness. She performed a patch-test on the back of Mrs A's hand and asked if she wanted to proceed with the treatment.

In contrast, Mrs A stated that Ms B did not provide her with any information. She said that Ms B gave no reason for performing the test on the back of her hand and told her that when she came back for a second treatment there would be twice the amount of heat. Mrs A said Ms B "took all the shortcuts".

Mrs A signed a Clinic Treatment Form which stated "I have read and fully understand the contents of this consent and authorise the performance of ELOS treatment". This form also stated that she accepted "any liability associated with complications from ELOS procedures", and that she was satisfied with the information provided to her in the consultation. She did not record any medication or fill in the section requesting any "relevant information that may assist us with treating you".

When Ms B treated Mrs A's face, she recorded the short pulse light energy level she used was 16, the radio frequency level was 18 and "ISM%": 10% 13%. These were all within the guidelines used by the Clinic staff.[4]

Mrs A advised that the treatment hurt straight away, like being burnt with hot water. However, Ms B told you that Mrs A had tolerated the treatment and allowed her to treat her whole face.

Mrs A reported experiencing a stinging sensation overnight. The following morning she found that her eyes were swollen and her face blistered.

Follow-up actions

On 11 May 2007, Ms B telephoned Mrs A to see how she was, and advised that blistering was "natural". Ms B offered to perform a facial but Mrs A declined this. Mrs A reported that Ms B called a number of times over the next two weeks offering to visit, which Mrs A declined.

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[3] Dyschromia is a disorder of the pigmentation of the skin or hair.

[4] The guidelines used by the Clinic are attached as Appendices 1 and 2.

On 20 May Mrs A consulted a doctor at her medical practice about the blisters on her face. The doctor noted that she had multiple dark spots mainly over her forehead and cheeks, but there was "no overt redness or swelling". Mrs A asked the doctor to provide her with the fade out cream (1% ascorbic acid + 0.5% HC) that one of the other doctors at the practice had prescribed for her in the past. Mrs A also asked the doctor for a further prescription for Minocycline. He prescribed the cream and Minocycline tablets and advised her to return to the Clinic for further advice on her skin problems.

On 21 May, Mrs A attended another beauty therapy clinic (Clinic 2). The Clinic 2 Manager stated that Mrs A was "very distraught" when she arrived at the clinic, and asked them to use "anything and everything to fix it". Photographs were taken of the scarring and Mrs A was given a light dermabrasion (procedure used to smooth facial skin by removing the superficial layers). The Manager advised Mrs A that certain products might make the problem worse and provided her with some "lightening products". The Manager advised Mrs A to return to the first Clinic. However, she returned to Clinic 2 the next day and asked for further lightening products. Mrs A also telephoned her medical practice that day and was given a further prescription for her skin.

On 23 May, Mrs A contacted the Clinic and complained about the treatment she had received on 10 May. She was offered a schedule of skin treatments, "soothing dermatological products to optimise the health of the skin", and a refund of the cost of the treatment ($95.00). Mrs A refused the offer of skin treatments.

On 28 May, Mrs A returned to Clinic 2 for another light dermabrasion. She was also provided with a Vitamin K skin product.

On 30 May, Mrs A returned to see her usual general practitioner Dr D. Dr D completed an ACC treatment injury claim for Mrs A and referred her to skin specialist Dr C.

On 31 May, Mrs A saw Dr C. Dr C noted the history of the burns to her face. He photographed Mrs A's cheek and forehead, which he stated "clearly show deep pigmentation, which is post-inflammatory, from the burn which has resulted from the laser on her hands, face and cheeks". Dr C noted that Minocycline can often increase pigmentation, so prescribed Doxycycline (a broad spectrum antibiotic) for her acne.

In June 2007, Mrs A travelled overseas to visit her family. While there, Mrs A's mother applied herbal treatments to her face.

Dr C saw Mrs A again on 29 June 2007, when he noted that the pigmentation lines were lighter. By letter dated 29 June, Dr C applied to ACC for approval for Fraxel laser treatment for Mrs A, which he believed was the best type of laser to treat her "post-inflammatory hyper pigmentation". In this letter, Dr C stated:

> "In summary, the patient was probably treated with an intense pulsed light machine (this is not a laser), but we have never been given any information with regards to what the actual machine was that treated her. The test spot

should have been observed for at least four to six weeks to see whether there was improvement or any complications from the test spot."

Additional information

Standard training

The Association of Beauty Therapists NZ Inc. (the Association) advised that training and ongoing education in the use of ELOS and IPL machines is the responsibility of the machine distributors.

The Association Secretary advised that the Association has a number of members who distribute ELOS machines and they conduct "extensive and continued" training to the beauty therapy clinics they supply. The Association believes this training and follow-up should be mandatory.

The President of the Association stated that any complaints should be directed back to the distributor.

The Clinical Sales Specialist for the new Syneron machine distributors advised that therapists purchasing their machines are provided with two days training on site and one further day of training (usually three to four months later) to assess operator competence.

She said that some distributors have failed to provide adequate training and support and there have been reports of burning. However, while darker pigmented skins are more liable to burn, problems are generally caused by operator error.

Ms B's training and experience

The Syneron ELOS machine used for treating Mrs A was imported from the USA by a company which was taken over in March/April 2007.

The Clinic team, including Ms B, was trained by a trainer. Ms B stated that that her training included comprehensive coverage of the use of the ELOS machine, treatment expectations, contraindications, skin analysis, pain tolerance and patch testing for compatibility for treatment options. The trainer said that therapists were also advised about adverse reactions that included redness and swelling, blistering and crusting and darkening of pigmentation.

Ms B received 75 hours training in ELOS therapy using the Syneron ELOS machine. She holds a certificate in Beauty Therapy from England and has achieved NZQA qualifications through the New Zealand Beauty Therapy College. Ms B does not belong to the New Zealand Beauty Therapists' Association (the Association), but I note you do.

Ms B said that it is usual following skin rejuvenation treatments for freckles, pigmentations, capillaries and spider veins to darken in the two weeks following a treatment, but that this resolves and is a normal part of the process. She had conducted approximately 230 ELOS/IPL treatments on 80 clients before Mrs A. You reported that no other clients were known to have had an adverse reaction.

Expert advice
Dr John Barrett, President of the New Zealand College of Appearance Medicine advised that, in his view, beauty therapists should be subject to the same rigour as members of the New Zealand College of Appearance Medicine and their nurses with respect to IPL treatments. However, he said that in his opinion this is not possible, because to cover off all safety issues, beauty therapists would require a high level of skill in this area which could not be easily taught without background knowledge of pathology or adequate continuing supervision.

Recent developments

Code of Practice
The fact that IPL treatment involves a risk to the consumer, and should only be performed by those with appropriate training, expertise and experience, has been recognised by both the Association of Beauty Therapists and the Medical Council of New Zealand (the Council).

In October 2005, the Association issued the seventh edition of the *Code of Practice for Beauty Therapy Clinics, Spas and Training Establishments* (the Code). This did not include any reference to IPL treatment. However, in September 2007, the Code was revised and the eighth edition states:

> **"17. HEALTH AND SAFETY POLICY FOR IP LIGHT**
>
> The management and distributor of any IPL will have an active consultative commitment to continuous improvement in all areas of health and safety management in the work place…
>
> 5. To educate all staff, students, visitors and contractors as far as reasonably practicable as to the potential dangers and hazards that exist within the business and the appropriate steps to take in order to ensure the safety of all staff and visitors."

Medical Council statement
Clearly you and Ms B are not doctors and cannot be expected to meet the same standards. However it is pertinent to note that in terms of doctors using this equipment, the Medical Council of New Zealand has made it very clear that these procedures should only be performed by providers with the appropriate training, expertise, and experience.

In October 2007, the Council published a statement on cosmetic procedures, which includes reference to intense light treatment in category 2 of activities regulated by the statement.[5] It clearly defines that "treatment should therefore only be provided if you have the appropriate training, expertise and experience" and goes on to say that the provider should be able to "deal with all routine aspects of care and any likely complications".

[5] Medical Council of New Zealand "Statement on cosmetic procedures" (October 2007)

Action taken since the complaint

I also note the following:

- the Clinic has refunded the treatment cost to Mrs A ($95.00).
- ACC has accepted Mrs A's claim as personal injury, and is funding remedial treatment.
- the Clinic was removed from the Companies Register on 13 June 2007. You are now trading under another name.

Relevant rights

I consider you and Ms B to be health care providers under section 3(k) of the Health and Disability Commissioner Act 1994 (the Act) when providing ELOS treatments to Mrs A. In particular, I note that the ELOS treatment was intended to treat acne (a common inflammatory disorder of the sebaceous glands). Furthermore, medical history is taken before treatment to identify medications and conditions that may increase the chance of skin damage. In light of these factors, I am satisfied that you and Ms B provided "health services" in accordance with the definition in section 2 of the Act and you are therefore obliged to comply with the Code of Health and Disability Services Consumers' Rights (the Code).

Under the Code, Mrs A had the right to services of an appropriate standard, including that services be provided with reasonable care and skill (Right 4(1)). She also had the right to be given information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including an explanation of her condition, and the options available and expected risks (Right 6(1)). Furthermore she had the right to make an informed choice and give informed consent, and services should not have been provided without this consent (Right 7(1)).

Final opinion

My decision is made in accordance with the power delegated to me by the Commissioner.

Breach – Ms B and her employer

Information provided to Mrs A
The Clinic had information and consent forms for ELOS/IPL treatment which were designed to protect the client and the operator. Mrs A signed the consent form stating that she was satisfied with the information provided by Ms B about the treatment and acknowledging that she accepted any liability associated with complications from ELOS treatments. However, the information form completed by Ms B and Mrs A contains contradictory information. On the one hand, the form shows Mrs A indicated that she had a pigmentation disorder (which was listed as possible medical complication). In the next section of the form, "abnormal or undiagnosed" pigmentation is not noted as a possible contraindication. This suggests to me that neither Mrs A nor Ms B may have understood the importance of what they were recording.

It appears that Mrs A was not fully aware of the implications of signing the consent form. Mrs A does not recall any discussion about the risks or side effects of the IPL treatment. It is not clear that Mrs A's use of acne medications was satisfactorily explored. There is also discrepancy about the information Ms B provided to Mrs A about how her skin type and pigmentation disorder might effect her treatment, or any additional risks it posed.

While it is common for the public to sign waivers without reading what they sign, and consumers are often reminded of the need for "buyer beware", the Code requires the provider of a service to fully inform the consumer. This includes providing information which clearly advises of the risks, side effects and benefits of a treatment. I am not satisfied that by filling in the personal information form with Ms B and signing the consent form, Mrs A was fully informed of the risk that ELOS treatment posed to someone with her skin type and problems. Therefore, in my opinion, Ms B breached Right 6(1)(b) and Right 7(1) of the Code of Rights.

As Ms B's employer and co-owner of the Clinic, you also had a responsibility to ensure that Mrs A was given adequate information and was appropriately informed. Although the Clinic provided consent forms for clients considering ELOS treatment, it is clear that Mrs A was unaware of the risks of ELOS treatments, particularly in relation to her individual circumstances. Having a document in place to obtain treatment consent is of little use if steps are not taken to ensure that staff are aware of their responsibility to the client — that clients are provided with full information about the risks, possible complications and counter-indications, and understand what they are consenting to. Furthermore, the information on the forms needs to be readily understood. Reference to possible side effects such as "permanent dyschromia from epidermal injury" are unlikely to leave clients any the wiser about this risk. Accordingly, it is my opinion that you are vicariously liable for Ms B's breach of Right 6(1)(b) and Right 7(1) of the Code.

Provision of treatment

It is clear that the treatment Mrs A received from Ms B at the Clinic on 10 May 2007 burnt areas of skin on her cheeks and forehead, although it is difficult to determine the extent of the burns as Mrs A subsequently pursued various forms of treatment.

Ms B is a qualified beauty therapist who, at the time of these events, appears to have received two days initial on-site training by the ELOS/IPL machine distributor, with a further one-day's training and supervision three to four months later. From the personal information form it seems that she did not know that Mrs A was being treated with Minocycline for her acne. Even if she had known, it is unclear whether she would have been aware that this could increase skin photosensitivity. However, Ms B clearly did know that Mrs A was at some risk. As previously discussed, she was aware that Mrs A had a pigmentation disorder. She had also noted that Mrs A had a Fitzpatrick Skin type IV, which is the highest risk skin type for ELOS/IPL treatments.

While Ms B may have complied with accepted beauty therapy practice when she performed a skin test on the back of Mrs A's hand immediately before treating her face, this practice does not seem appropriate. In his letter to ACC, Dr C recommended that beauty therapists should test and observe the client's skin for any adverse reaction to IPL treatment four to six weeks prior to treatment. The Consumers' Institute

website recommends that there should be a one month wait between the test run of IPL treatment and the actual treatment.[6]

Ms B was aware that Mrs A's skin type put her in a high risk category and the personal information form warned the ELOS/IPL operator to proceed with caution if the patient had risk factors. Mrs A reported that the treatment hurt straight away (although the blistering to Mrs A's face and hand did not appear until some 12 hours after the treatment). In my view, greater care was needed. Ms B did not proceed with due caution in providing Mrs A with treatment, and accordingly breached Right 4(1) of the Code.

As previously discussed, you provided appropriate training for Ms B in the use of ELOS/IPL machines. You had also adapted the Syneron guidelines for the use of the machines to instruct staff on safe ELOS/IPL treatment. However, I am not satisfied that you took all reasonably practicable steps to ensure Ms B provided services with reasonable care and skill. In particular, you have provided no evidence of any guidance given to staff about when treatment should be refused or delayed for clients in a high risk category. In these circumstances, I consider you are vicariously liable for Ms B's breach of Right 4(1) of the Code.

Other comment

In the course of this investigation it has become apparent that the beauty therapy industry relies on the machine distributors to ensure that operator training is adequate. I do not accept that the responsibility for safe use of ELOS or IPL treatment is solely that of the machine distributor. In my view, clinics and therapists have an obligation to ensure client safety during treatments. This includes the therapists being trained in all aspects of the treatments offered and machines used, according to accepted standards. It includes ensuring that therapists have a good understanding of the relevance of the information sought from clients about their medical history and the implications it has for treatment. Clinics and therapists need to understand the informed consent process and provide written material to inform clients of potential risks.

I note that the Association's Code of Practice now includes a health and safety policy regarding the use of IPL. However, it is of concern that the policy appears to focus more on workplace safety than managing risk to the client. It appears that there is a need for adequate guidelines/standards regarding the use of ELOS and IPL equipment across the whole sector.

Actions to be taken

I recommend that you reflect on the lessons from this complaint and report back to me on changes you have made to ensure clients are fully informed before consenting to treatment. You have also agreed to provide Mrs A with an apology. Your report on changes to your practice and the apology should be sent to my Office by **21 July 2008**.

[6] www.consumer.org.nz.

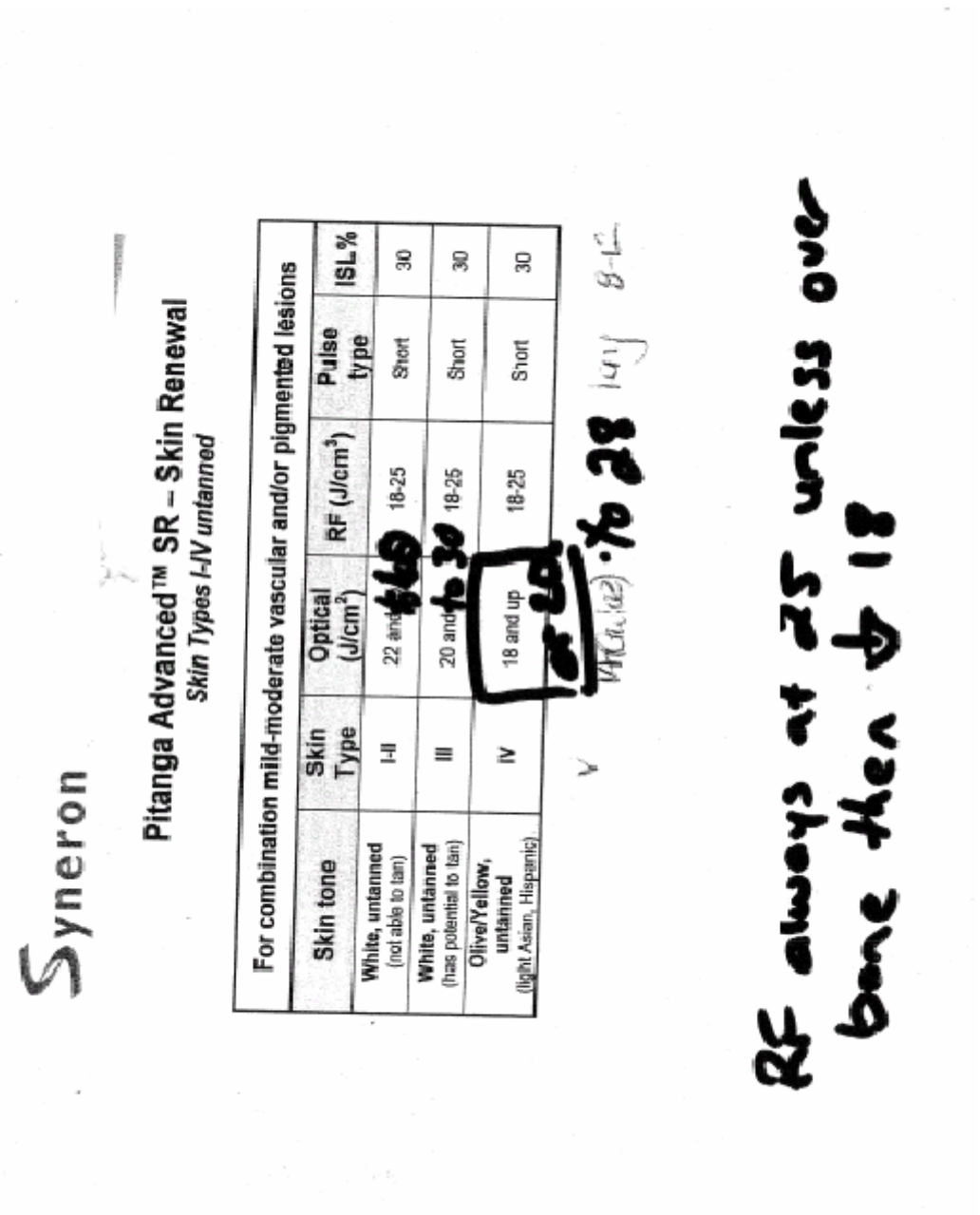
I will send an anonymised copy of this letter to the Association of Beauty Therapists NZ, and suggest that it reviews the Code of Practice in relation to ELOS and IPL treatment and consider formulating standards for this treatment, and guidelines for their members on informed consent. This is in light of the concerns expressed by the Association about the training available in the use of ELOS/IPL machines.

Furthermore, I will also send an anonymised case study taken from my final letter to the Ministry of Health (including Medsafe), the Ministry of Consumer Affairs, the New Zealand College of Appearance Medicine and the distributors of Syneron ELOS machines, and place a copy on the Health and Disability Commissioner website www.hdc.org.nz, for educational purposes.

Yours sincerely

Rae Lamb
Deputy Health and Disability Commissioner

Appendix 1



Syneron

Pitanga Advanced™ SR – Skin Renewal

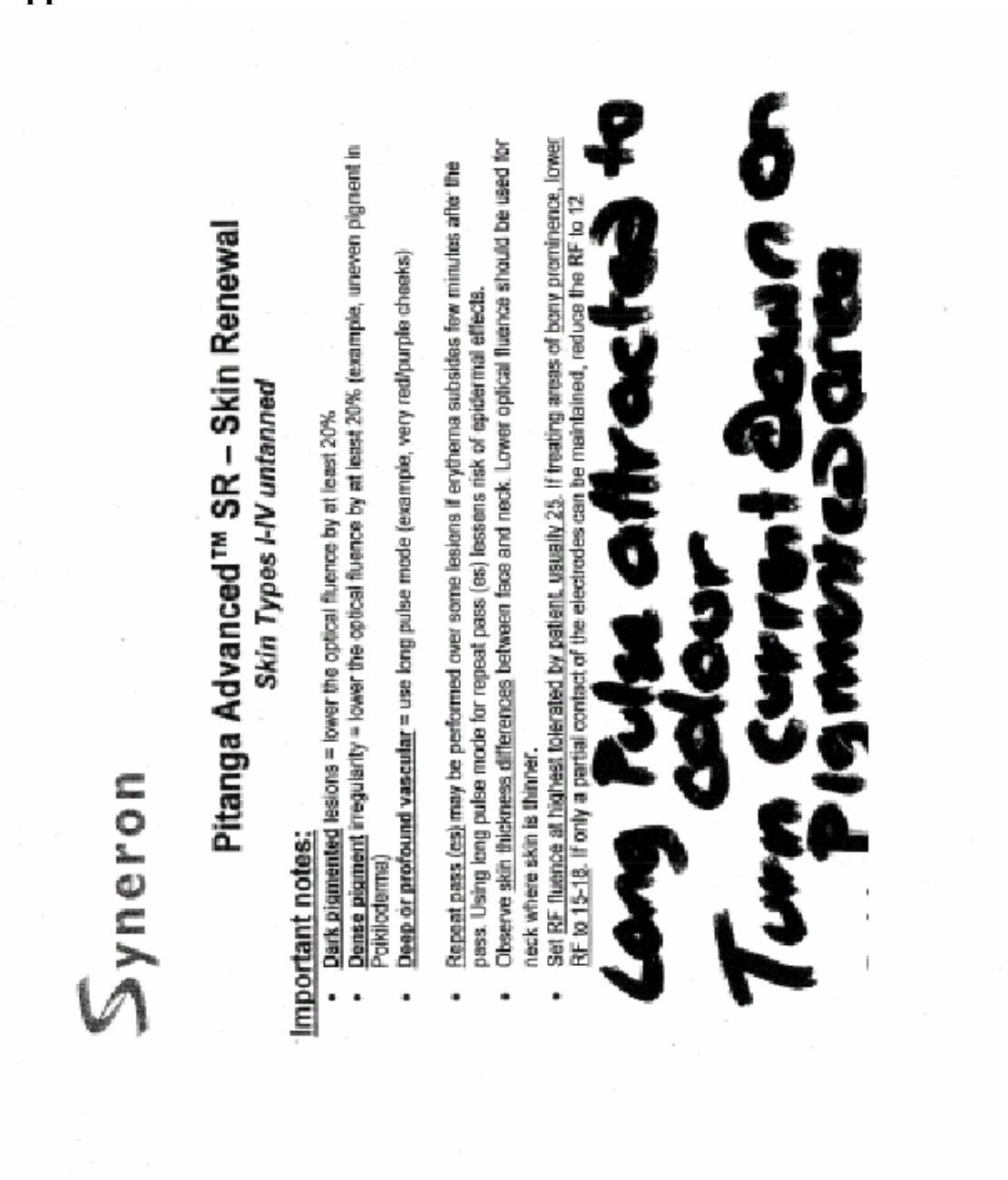
Skin Types I-IV untanned

For combination mild-moderate vascular and/or pigmented lesions					
Skin tone	**Skin Type**	**Optical (J/cm²)**	**RF (J/cm³)**	**Pulse type**	**ISL%**
White, untanned (not able to tan)	I-II	22 and up	18-25	Short	30
White, untanned (has potential to tan)	III	20 and up	18-25	Short	30
Olive/Yellow, untanned (light Asian, Hispanic)	IV	18 and up	18-25	Short	30

RF always at 25 unless over bone then ↓ 18

Names have been removed to protect privacy. Identifying letters are assigned in alphabetical order and bear no relationship to the person's actual name.

Appendix 2



Syneron

Pitanga Advanced™ SR – Skin Renewal

Skin Types I-IV untanned

Important notes:

- Dark pigmented lesions = lower the optical fluence by at least 20%
- Dense pigment irregularity = lower the optical fluence by at least 20% (example, uneven pigment in Poikiloderma)
- Deep or profound vascular = use long pulse mode (example, very red/purple cheeks)

- Repeat pass (ds) may be performed over some lesions if erythema subsides few minutes after the pass. Using long pulse mode for repeat pass (ds) lessens risk of epidermal effects.
- Observe skin thickness differences between face and neck. Lower optical fluence should be used for neck where skin is thinner.
- Set RF fluence at highest tolerated by patient, usually 25. If treating areas of bony prominence, lower RF to 15-18. If only a partial contact of the electrodes can be maintained, reduce the RF to 12

Long Pulse effective to
colour
Turn current down on
Pigmented areas

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