

New Features and Enhanced Capabilities of The GentleMax Pro® Plus System for Laser Hair Removal

Konika Patel Schallen, MD; Meghan Murphy BSN, RN; Nicolle Dest MSN, RN; Raylene Piretti, LE; Jackie Mak, RN

Introduction

Laser hair removal is well recognized as a leading and well-tolerated treatment option for removal of undesired hair, with a favorable safety profile and long-lasting clinical results. It works by the principle of selective photothermolysis¹, whereby light at a particular wavelength can selectively target a discrete chromophore within the skin (hemoglobin, water, melanin), while sparing the surrounding tissue. In the case of hair removal, the target chromophore is melanin localized in the hair shaft, follicular epithelium, and hair matrix. As light is absorbed by melanin, it is converted into heat (thermal energy) that selectively damages the follicle and prevents hair regrowth. To ensure optimal destruction of the hair follicle unit, without collateral damage to the surrounding skin, the choice of a laser system at appropriate wavelength and settings is crucial.

Hair removal treatment efficacy and patient comfort are primarily determined by selecting the most appropriate treatment parameters, including the laser wavelength, pulse duration, spot size, fluence, and epidermal cooling, as well as by considering the patient's individual characteristics, such as skin color, hair color, hair thickness, and the treated site. Generally, hair removal lasers have wavelengths within the red or near infrared spectrum (600 - 1200 nm)², as within this range, melanin has higher absorption coefficients than other competing chromophores (water and hemoglobin) in the skin³, and the light has enough dermal penetration capacity to impact the target.⁴ Successful treatment relies on delivering enough energy to destroy only the hair follicle structure (housing the bulb and bulge) without damaging the surrounding tissue or outer epidermal layer, which also contains melanin, although with a substantially lower proportion.⁵

In recent years, there has been a real surge of interest in dual-wavelength lasers for hair removal, specifically, the 755 nm and 1064 nm wavelengths for the treatment of different Fitzpatrick Skin Types. Longer wavelengths penetrate more deeply in the dermis but are less absorbed by melanin.

In terms of efficacy, the shorter wavelength 755 nm laser is generally regarded as more effective because of melanin's higher absorption value, which decreases with increasing wavelength. However, the longer wavelength 1064 nm laser is considered ideal for treating patients with darker skin types (Fitzpatrick Skin Types IV-VI)^{6, 7} and increased epidermal melanin content⁸, due to its reduced scattering and deeper penetration. During treatment, the laser fluence (laser energy per unit area, measured in J/cm²) should be carefully adjusted to cause thermal damage to the hair follicle unit only, while avoiding collateral tissue damage. In many cases, epidermal cooling is most likely necessary to protect the epidermis from excess heat, adversely affecting the skin. Cooling increases treatment safety, patient comfort⁹ and treatment efficacy¹⁰ since it allows for higher energy delivery, while avoiding thermal injury to the epidermis.

Laser spot size is another important parameter that can be crucial for successful treatment. Laser light delivered with a larger spot size penetrates deeper into the tissue due to decreased scattering within the skin. This enables a more effective energy delivery.^{11,12} Taking into consideration that hair follicle depth can reach up to 7 mm within the tissue³, hair removal treatment often requires laser spot sizes greater than 15 mm. In addition, patients frequently request treatment of large body sites, such as the legs and back. Therefore, for practical purposes, a large spot size and fast repetition rate (rate of the pulses delivered in hertz (Hz)) are essential for efficient and quick coverage of large surfaces.¹³

Laser pulse duration (pulse width) is the time measured across a pulse, and it is commonly adjusted according to hair coarseness and intrinsic structure. Shorter pulse widths allow faster energy delivery into the tissue. Smaller hair follicle structures have lower capacity to retain the laser induced thermal heat and, therefore, respond better to shorter pulse durations, while large volume targets require longer pulse widths to ensure complete energy absorption and irreversible destruction. Based on the theory of selective photothermolysis, the optimal pulse duration ranges from 0.4 ms for 30 µm diameter fine hair, to 2.4 ms for 70 µm diameter

medium coarse hair, to 6.9 ms for 120 µm diameter coarse hair.¹ Therefore, lasers with millisecond pulse-width ranges tend to be best for hair removal procedures.

Candela's GentleMax Pro® Plus System is the new generation of Candela GentleMax Family of Laser Systems. The system is a dual laser platform in one device (Alexandrite and Nd:YAG), which produces laser light outputs of 755 nm and 1064 nm, respectively. The GentleMax Pro Plus System incorporates the following new features and capabilities vs the prior generation device, specifically: A range of **spot sizes up to 26 mm; faster repetition rate (2.5 and 3.0 Hz available with selected spot sizes and fluences for hair removal treatment)**; updated software and hardware to allow for **increased deliverable fluences** and pulse durations from 0.25 – 100 ms with a new **2-millisecond pulse duration** for improved treatment efficacy.¹⁴

To ensure the maintenance of a lower temperature at the epidermal level while reaching the required higher temperature at the target level, the GentleMax Pro Plus incorporates two different epidermal cooling methods that can be separately integrated with the system for various needs: The cryogen based Dynamic Cooling Device™ (DCD) or the optional Air Compatible Cooling (ACC) delivery system. The DCD coordinates the cryogen spray and laser pulse in accordance with operator specifications. It can deliver the cryogen spray before or after the laser pulse. As the cryogen spray evaporates, the heat is reduced from the treated area, and the temperature decreases at the epidermal levels. The user can set the cryogen spray duration and spray delay time according to the need, and the device will perform automatically during treatment. This decreases the risk of human error and ensures a uniform and consistent cooling with each pulse and every treatment. The optional ACC delivery system is an alternative cooling method that provides epidermal cooling but is not electronically controlled. The practitioner has the ability to choose how much chilled air is delivered and the time it is delivered to the tissue. When needed, a compatible air-cooling system can be attached via a clip for continuous delivery of chilled air onto the tissue prior to, during, and following the laser pulse.

The enhanced features in the new GentleMax Pro Plus System allow practitioners to precisely customize laser hair removal treatments across a wide range of hair and skin types, including dark skin. The system's wide variety of spot sizes, and its ability to deliver higher energies, directly affects treatment performance. While the small spot sizes allow treatment of confined and small areas precisely, the new larger spot sizes are ideal for treating large areas and deeper follicles efficiently. The new 2.5 and 3 Hz repetition rates increase the speed at which pulses are fired to treat large

areas more quickly. The additional 2-millisecond pulse width provides a new efficient tool for treating fine or resistant hair.

The GentleMax Pro Plus laser system is a highly versatile platform designed for the reduction of unwanted hair, as well as a wide range of dermatological indications, such as vascular lesions, benign pigmented lesions, wrinkles, and temporary increase of clear nail in patients with onychomycosis*.

As part of an ongoing IRB-approved clinical study**, optimal treatment parameters are being evaluated for treating various clinical indications with the GentleMax Pro Plus laser system. This clinical bulletin describes preliminary data obtained with the new GentleMax Pro Plus device and will outlay the new features and enhanced capabilities for laser hair removal treatments.

The GentleMax Pro Plus large spot delivery system with spot sizes up to 26 mm

The GentleMax Pro Plus laser system can deliver laser light with a wide range of **spot sizes up to 26 mm**, offering an ideal system for covering both large and small areas. Larger spot sizes deliver energy more efficiently into tissue due to the decreased incidence of energy scatter, leading to a deeper depth of penetration. Hence, the new 26 mm spot size offers faster and more efficient treatment.

Methods

A study was performed with the one side of the body being treated with the 26 mm spot size and the contralateral side treated with the 18 mm spot size. Treatment parameters were selected based on the patient's individual characteristics to reach treatment endpoint of perifollicular erythema and edema. Treatment time was recorded and defined as the time from "Ready Mode" to "Standby". Following each treatment session, subjects were asked to rate their discomfort level during the treatment, using a 0-10 scale (0=no pain; 10=worst pain).

Results

Fifteen patients (13 females and 2 males; Fitzpatrick Skin Types II-V; 6 Caucasians, 5 Asian, 4 Other: 1 Eastern European, 1 South Asian, 1 White and Armenian/Mediterranean, 1 Mediterranean and Middle Eastern) with mean age 36±9 years were treated on 21 areas once, using the 18 mm spot size on one side and 26 mm on the contralateral side (a total of 42 contralateral areas). Treatment regions included neck (n=2), chin (n=1), back (n=1), arms (n=1),

axillae (n=9), full leg (n=1), and lower and upper legs (n=4 and n=2, respectively). Treatments were conducted using a single pass with parameters according to patient’s Fitzpatrick Skin Type (FST), (Table 1). Clinical endpoints included subject sensation of a hot rubber band “snap”, as well as perifollicular erythema and edema.

FST	Wavelength (nm)	Spot Size (mm)	Fluence Range (J/cm²)	Pulse Duration (ms)	Repetition Rate (Hz)
II	755	18	10-16	3	1-2.5
	755	26	10-12.5	3	1-1.5
III	755	18	14-16	3	1-2
	755	26	11-12.5	3	1-2
IV	1064	18	14-28	3, 10	1.5-2.5
	1064	26	10-17	3, 10	1.5-2
V	1064	18	16-20	10	2-2.5
	1064	26	7-17	10	1.5-2

Table 1. Treatment parameters (according to skin type).

The 26 mm spot size was more effective and enabled the practitioner to use lower fluences (Table 1) and to apply less pulses during each treatment compared with the 18 mm spot size (Figure 1). The average fluence used for each treatment was reduced from 17.24±3.9 (J/cm²) with the 18 mm spot size to 13±3.4 (J/cm²) with the 26 mm spot size, a reduction of 25%.

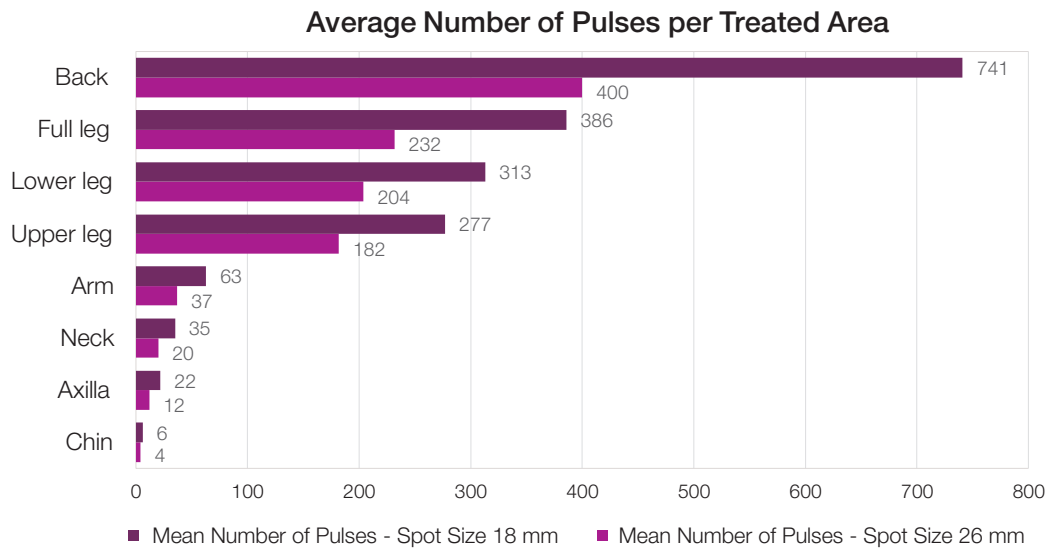


Figure 1. Average number of pulses per treated area.

The average number of pulses per treatment was reduced from 155.5±202.5 pulses with the 18 mm spot size to 95.2±120.8 pulses with the large spot size of 26 mm, a reduction of 39% (range of 21-66%) of pulses on average. Accordingly, the time of treatment with the 26 mm spot size was shorter compared with the 18 mm spot size (Figure 2).

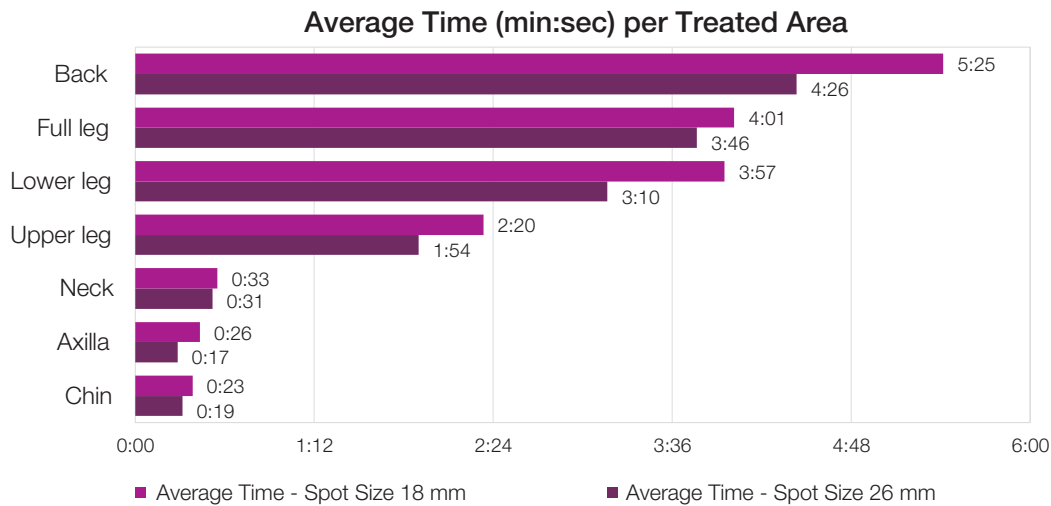


Figure 2. Average time of treatment per treated area.

The average treatment time reduced from 1:50.1 minutes (110.1 ± 131.8 seconds) with spot size of 18 mm to average of 1:25.5 minutes (85.5 ± 106.1 seconds) with spot size of 26 mm, resulting in an average of 22% (range of 1-47%) decrease in treatment time.

Patients tolerated the treatment well, and anesthesia was not needed for patient comfort. Average pain score associated with treatment was very similar for the different spot sizes, with 4.0 ± 2.0 for the 26 mm and 4.2 ± 2.5 for the 18 mm spot size, but treatment time was shorter with the 26 mm spot size. Treatment response was mostly mild erythema. No adverse events were recorded. Treatment efficacy after one treatment is shown in Figures 3 and 4.



Figure 3. A 24-year-old Asian female (Fitzpatrick Skin Type IV) received treatment to the axillae with the GentleMax Pro Plus: Evidence of increased efficacy of the large spot (26 mm) vs. medium spot (18 mm) was noticed. Treatment parameters:

Area	Wavelength (nm)	Cooling Type	Cooling Setting	Spot Size (mm)	Fluence (J/cm ²)	Pulse Duration (ms)	Repetition Rate (Hz)	Treatment Time (sec)	Number of Pulses
Left Axilla	1064	ACC	4	18	20	10	2	N/A	18
Right Axilla	1064	ACC	4	26	14	10	2	N/A	12

**GentleMax Pro® Plus Laser Hair Removal Spot Size of 18 mm vs. 26 mm
Treatment Endpoint Immediately After Treatment**



Figure 4. A forty-year-old Caucasian female (Fitzpatrick Skin Type III) received treatment to the axillae with the GentleMax Pro Plus 755 nm Alexandrite laser: Strong clinical endpoint is evident with the 26 mm spot size. Treatment parameters:

Area	Wavelength (nm)	Cooling Type	Cooling Setting	Spot Size (mm)	Fluence (J/cm ²)	Pulse Duration (ms)	Repetition Rate (Hz)	Treatment Time (sec)	Number of Pulses
Left Axilla	755	DCD	40/30/0	18	14	3	2	28.99	24
Right Axilla	755	DCD	40/30/0	26	12	3	1.5	22.67	19

The GentleMax Pro Plus delivery of short pulse duration for the treatment of fine hair

Laser hair removal techniques may have longer-lasting results on thick hair but can be more challenging on fine hair (hair shaft diameter $< 50 \mu\text{m}$ ¹⁵). The GentleMax Pro Plus system offers a wide range of pulse durations from 0.25 – 100 ms with a **new 2 ms pulse duration for laser hair removal**.¹⁴ Figures 5 and 6 show how treating a thinner hair shaft (fine / resistant hair) with a short pulse duration results in visible hair reduction.

GentleMax Pro® Plus Laser Hair Removal Pulse Width of 2 ms



Figure 5. A 25-year-old Caucasian female (Fitzpatrick Skin Type II) with fine hair (diameter of $40 \mu\text{m}$) on her left arm underwent one treatment using a single pass with the 755 nm Alexandrite laser (18 mm spot size) DCD handpiece. Treatment parameters:

Wavelength (nm)	Cooling Type	Cooling Setting	Spot Size (mm)	Fluence (J/cm ²)	Pulse Duration (ms)	Repetition Rate (Hz)	Number of Pulses
755	DCD	40/20/0	18	14	2	2	111

GentleMax Pro® Plus Laser Hair Removal Pulse Width of 2 ms



Figure 6. A 28-year-old Asian female (Fitzpatrick Skin Type IV) with fine hair on her upper lip received three treatments with 755 nm Alexandrite laser. Her left upper lip was treated with 2 ms pulse duration (each treatment done with 1 pass). Treatment parameters:

Tx	Wavelength (nm)	Cooling Type	Cooling Setting	Spot Size (mm)	Fluence (J/cm ²)	Pulse Duration (ms)	Repetition Rate (Hz)	Number of Pulses
1	755	DCD	40/20/0	12	10	2	1	5
2	755	DCD	40/20/0	12	12	2	1	6
3	755	DCD	40/20/0	12	14	2	1	5

GentleMax Pro® Plus Laser Hair Removal Pulse Width of 3 ms vs. 0.5 ms

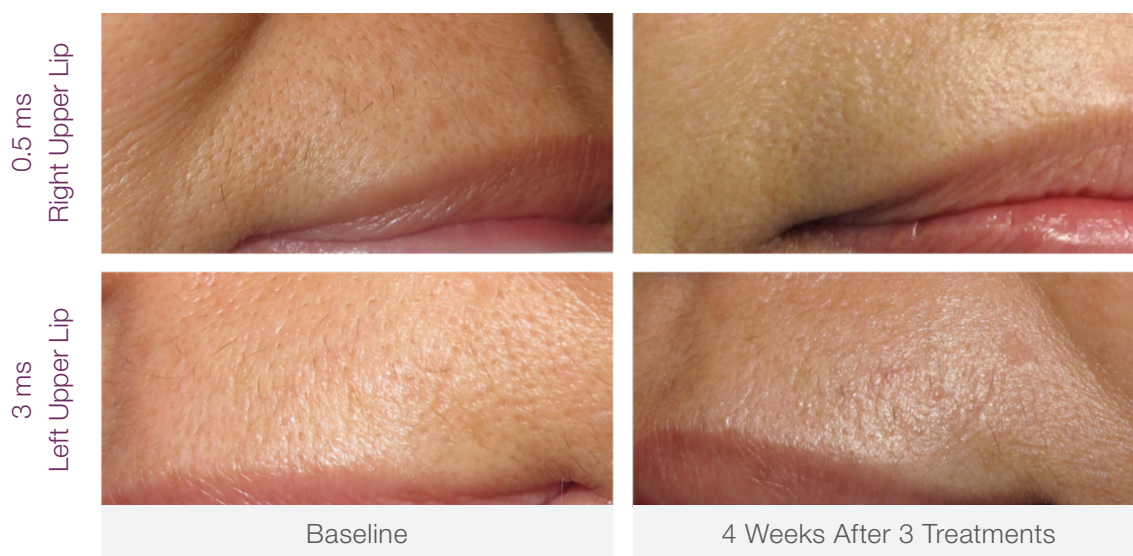


Figure 7. A 53-year-old Asian female (Fitzpatrick Skin Type IV) with fine hair (diameter of 40 μ m) on her upper lip received three treatments with the 1064 nm Nd:YAG laser. The right upper lip was treated with the short pulse duration of 0.5 ms while her left upper lip was treated with 3 ms pulse duration (each treatment done with 1 pass). Superior outcome was obtained on the right upper lip, treated with the short pulse duration (0.5 ms), with 50% reduction in hair count, while the left upper lip did not show improvement.

Treatment parameters:

Upper Lip Side	Tx	Wavelength (nm)	Cooling Type	Cooling Setting	Spot Size (mm)	Fluence (J/cm ²)	Pulse Duration (ms)	Repetition Rate (Hz)	Number of Pulses
Right	1	1064	ACC	6	8	22	0.5	1	10
Right	2	1064	ACC	6	6	25	0.5	1	22
Right	3	1064	ACC	5	6	28	0.5	1	34
Left	1	1064	DCD	30/20/0	8	30	3	1	13
Left	2	1064	DCD	30/20/0	8	35	3	1	35
Left	3	1064	DCD	30/20/0	8	30	3	1	20

The GentleMax Pro Plus new 2.5 and 3 Hz repetition rates for laser hair removal

The GentleMax Pro Plus incorporates a wide range of repetition rates (0.5-10 Hz), for effective fluence to be delivered with improved patient comfort. The varied rates of pulse technology afford maximum control when treating large and smaller surface areas. The new GentleMax Pro Plus system incorporates **new 2.5 and 3 Hz repetition rates** to allow the practitioner a high coverage rate especially for large surfaces.

GentleMax Pro® Plus Laser Hair Removal Repetition Rate of 3 Hz



Figure 8. A 45-year-old Caucasian female (Fitzpatrick Skin Type IV) received two treatments on her right lower leg with the 1064 nm Nd:YAG laser (12 mm spot size) ACC handpiece, using a single pass and repetition rate of 3 Hz. Treatment parameters:

Tx	Wavelength (nm)	Cooling Type	Cooling Setting	Spot Size (mm)	Fluence (J/cm ²)	Pulse Duration (ms)	Repetition Rate (Hz)	Number of Pulses
1	1064	ACC	6	12	40	3	3	321
2	1064	ACC	6	12	42	3	3	239

Summary

The GentleMax Pro Plus dual laser platform is built on the legacy of its renowned predecessor, GentleMax Pro, and has taken laser hair removal to the next level. The system offers a wide range of hair removal treatment options to customize the treatment for all skin types.

The GentleMax Pro Plus system provides a rapid coverage rate, with **higher energies**, larger spot sizes **up to 26 mm and increased repetition rate**, providing enhanced capability to treat large areas more efficiently. The addition of the **2 ms pulse width** extends the capabilities of the prior generation platform in allowing for the treatment of fine, residual hair.

The GentleMax Pro Plus platform is far beyond just a laser hair removal device and can treat a wide range of other dermatological indications including vascular lesions, benign pigmented lesions, wrinkles, and temporary increase of clear nail in patients with onychomycosis.¹⁶

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* GentleMax Pro Plus 510(k) clearance [K201111], May 2020

** IRB-approved study protocol GMP19002: Clinical Evaluation to Assess the Safety and Efficacy of GentleMax Pro / GentleMax Pro Plus

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