

4th September 2025

Manufacturer's Declaration of Compliance

We, INTERmedic, S.A. (Spain), hereby declare that the CO₂ laser SILKLASE™ has the following characteristics:

1. The SILKLASE™ laser system provides **three operating modes** – *Fractional Scanner, Surgical Mode and Derma Mode*. All necessary handpieces and/or other elements required to perform the procedures are included in the system configuration, making it a complete and integrated laser platform.

Each of these operating modes is further differentiated into **Continuous, Pulsed, SuperPulse and FinePulse** sub-modes. The laser operates in fractional mode **only when used together with the fractional scanner; without the scanner, the fractional mode cannot be performed.**

2. The SILKLASE™ laser system includes **integrated treatment programs for skin lesion removal**, such as ablation, cutting, excision, vaporization. These programs consist of pre-configured procedure parameter sets, ensuring optimal treatment outcomes (including power, pulse duration, repetition rate, fractional coverage, and many other settings).

The system allows removal or treatment of a wide range of skin lesions and conditions, including but not limited to:

- Actinic keratosis, actinic cheilitis
- Seborrheic keratosis
- Nevus (moles)
- Fibromas and fibroids
- Syringomas, xanthelasma, millium cysts
- Molluscum contagiosum, warts
- Sebaceous cysts
- Benign non-vascular tumors
- Epitheliomas
- Infectious and inflammatory lesions
- Keloids, scars (including post-acne)
- Wrinkles, stretch marks, dilated pores
- Non-surgical eyelid retraction and rejuvenation procedures.

3. The SILKLASE™ **aiming beam** has an output of ≤ 5 mW, and its intensity is **adjustable** from **0% to 100%**.

Don't hesitate to contact us if you need any additional information.

INTERmedic Arfran S.A.
Mr. Xavier Arcusa
CEO

INTERmedic

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**Rašytinis patvirtinimas / paaiškinimas
Gamintojo atitikties deklaracija**

Rugsėjo 4d, 2025

Mes, **INTERmedic, S.A.** (Ispanija), patvirtiname, kad CO₂ lazeris **SILKLASE™** turi šias savybes:

1. **SILKLASE™ lazerio sistema** turi tris darbo režimus – *frakcinį (naudojant frakcinį skenerį), chirurginį ir derma režimą*. Visi reikalingi antgaliai ir/ar kiti elementai, būtini procedūroms atlikti, yra įtraukti į sistemos komplektaciją, todėl tai yra pilna ir integruota lazerio platforma.

Kiekvienas iš šių darbo režimų papildomai diferencijuojamas į **nuolatinį (Continuous), impulsinį (Pulsed), SuperPulse ir FinePulse** potipius. Lazeris frakciniu režimu veikia **tik naudojant frakcinį skenerį; be skenerio frakcinis režimas negali būti atliekamas**.

2. **SILKLASE™ lazerio sistema** turi **integruotas gydymo programas, naudojamas odos darinių šalinimui**, tokias kaip abliacija, pjovimas, ekscizija, vaporizacija.

Šios programos yra sudarytos iš anksto sukonfigūruotų procedūrų nustatymų rinkinių, užtikrinančių optimalų gydymo rezultatą (įskaitant galią, impulso trukmę, pasikartojimo dažnį, frakcinį padengimą ir daugelį kitų parametrų).

Sistema leidžia šalinti ar gydyti platų spektrą odos darinių ir būklių, įskaitant, bet neapsiribojant:

- Aktininė keratozė, aktininis heilitas
- Seborėjinė keratozė
- Neviai (apgamai)
- Fibromos ir fibroidai
- Syringomos, ksantelazmos, miliumai
- Moliuskai, karpos
- Riebalinės cistos
- Gerybiniai ne kraujagysliniai navikai
- Epitelomos
- Infekciniai ir uždegiminiai pažeidimai
- Keloidai, randai (įskaitant po aknės)
- Raukšlės, strijos, išsiplėtusios poros
- Nechirurginis vokų patempimas ir atjauninimo procedūros.

3. **SILKLASE™ taikiklio spindulys** turi mažiau nei **5 mW galią**, o jo intensyvumas reguliuojamas nuo **0 % iki 100 %**.

Intermedic S.A.
Misteris Xavier Arcusa
Generalinis Direktorius

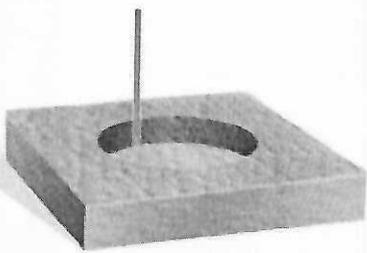
CO2 laser multidisciplinary platform

Optimal for day to day in **consultation** or **operating room**

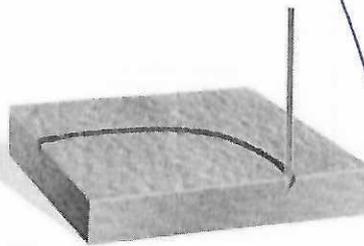
A unique tool with
maximum versatility

- Aesthetic lesions
- Warts
- Actinic keratosis
- Seborrheic keratosis
- Xanthelasma
- Molluscum

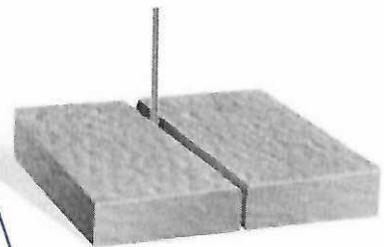
6p.



ABLATION
Abliacija/koaguliacija



CUTTING
pjovimas



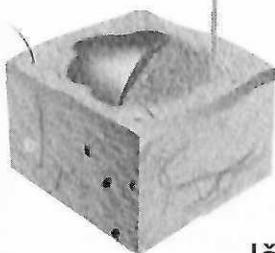
EXCISION
Ekscizija

...and absolute precision

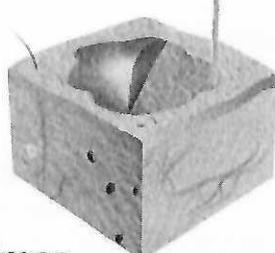
- Precise tissue vaporisation
- Highly predictable depth of effect
- Exquisite thermal control



Superficial
FINEPULSE



Deep
SUPERPULSE



Išgarinimas
VAPORIZATION

Heat delivery to tissue and depth of penetration can be controlled to ensure maximum efficacy and best clinical results, while limiting side effects and recovery time. Thanks to the FinePulse emissions in fractional mode and the random scanner system, the thermal effect can be controlled to the nearest micron.

5p.
Frakcinis
mezizime

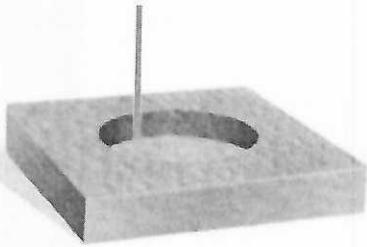
4.
Dermatology

Optimum for day-to-day work in the consulting room or operating theatre

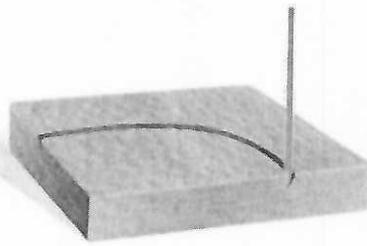
2.

A unique tool with maximum versatility...

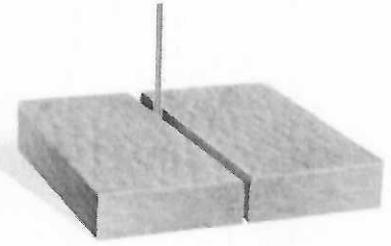
- 3.
- Aesthetic injuries
 - Warts
 - Actinic keratosis
 - Seborrheic keratosis
 - Xanthelasma
 - Molluscs
- 4.



ABLATION



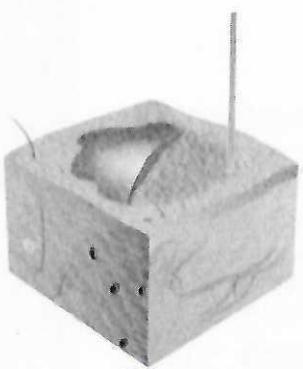
CUTTING



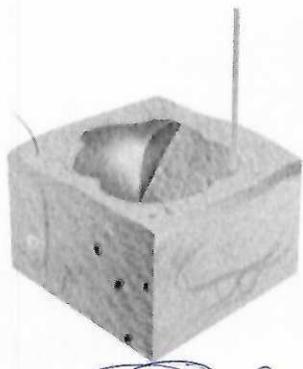
EXCISION

...and absolute precision

- 7.
- Precise tissue vaporisation
 - Highly predictable depth of action
 - Excellent thermal control
- 6.



8. Superficial FINEPULSE



9. Deep SUPERPULSE

VAPORISATION

10.
Heat delivery to the tissue and penetration depth can be controlled to ensure maximum effectiveness 12. and the best clinical outcomes, 14. while reducing 15. side effects and recovery time. Thanks to its 16. FinePulse emissions in fractional mode and random scanner system, the thermal effect can be controlled with micron precision.

14.



VII UNIT PARTS

EQUIPMENT LIST

Following lists enumerate standard, optional and spare pieces of the system:

STANDARD ACCESORIES

Following parts are included in the System: 5p.

- CO2 Laser equipment.
- Power supply cable.
- 3 protector goggles. 7. Apsauginiai akiniai 3 vnt.
- 1 corneal protector.
- Foot-switch.
- Fractional scanner. *Sudėtine lazerio dalis*
- Support for scanner.
- Set of hand-pieces for CO2 laser surgery, FINE CUT and HAEMOSTATIC CUT (focal F-50 and F-100).
- Articulated arm.
- Security key.
- External power meter, optional depending on model.
- User's manual.
- Clinical workbook. 6p.

MULTISCAN STRAIGHT HAND PIECES AND ACCESSORIES

- MultiScan.
- Support for scanner.

DERMATOLOGY ACCESSORIES

Dermatology set. Supplied total or partial depends on the model:

- Set of cones with integrated lenses for scanner fractional (spot 500 μ m and 190 μ m).
- Pin backstop.
- Circular backstop.



without the need to press the foot-switch again with a selectable pause time (from 1 to 5 seconds). Frequency runs between 1 and 100Hz.

- **Aiming Beam (%)**. Adjust aiming beam intensity from 0 to 100%.
- **NO AIMING BEAM WHEN FIRING**. This button is on the right side of the screen. Its function is to turn off the guide when the laser is firing.

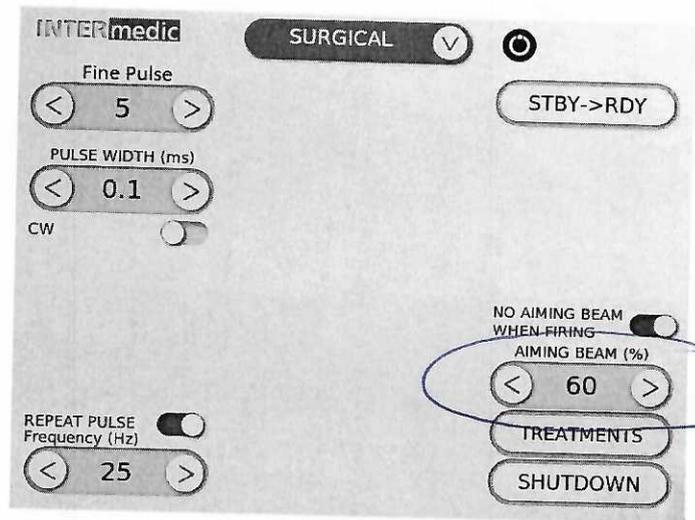


Figure 39: *Surgical Fine Pulse Mode.*

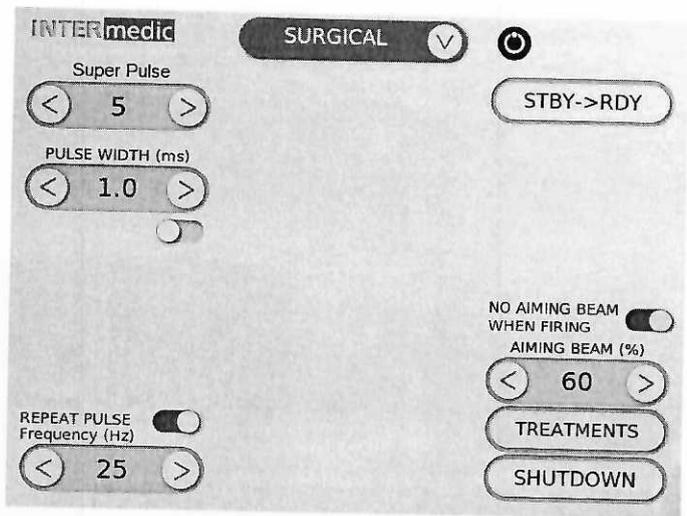


Figure 40: *Surgical Super Pulse Mode.*



DERMA MODE

SYSTEM CONTROL

- **Power (W).** Laser beam power selection for pulses longer than 2.5ms. From 5 to 20W in steps of 1W.
- **Pulse width (ms).** Three thresholds:
 - FINE PULSE [from 0.1ms to 0.9ms]. In this pulse width range there are 5 selectable power levels. From 5 (maximum level) to 1 (minimum level (30% of maximum power level, value 5)). See figure 45. maintain a predefined specified relationship.
 - SUPER PULSE [from 1.0ms to 2.4ms]. In this pulse width range there are 5 selectable power levels. From 5 (maximum level) to 1 (minimum level (30% of maximum power level, value 5)). See figure 46. Pulse duration and power maintain a predefined specified relationship.
 - PULSE
 - * For spot 500 [from 2.5ms to 6ms]. Power selection between 5 to 20W, pressing the arrows near the option square (figure 47).
 - * For spot 190 [from 2.5ms to 10ms]. Power selection between 5 to 20W
- **Energy Density.** This panel shows the calculated value of applied energy over the target zone. It varies depending on the selected energy options.
- **Stacking Repeats.** Selection number of pulse repetitions (until 5). The unit will emit some consecutive pulses of the selected duration. Note: 1 repetition is equal to 2 emissions; 5 repetitions are equal to 6 emissions.
- **Repeat Scanner.** This option enables the selected pulse to be repeated without the need to press the foot-switch again with a selectable pause time (from 1 to 3 seconds).
- **Aiming Beam (%).** Adjust aiming beam intensity from 0 to 100%.
- **NO AIMING BEAM WHEN FIRING.** This button is on the right side of the screen. Its function is to turn off the guide when the laser is firing.

Remember prefixed parameters appear on the screen in soften lines.

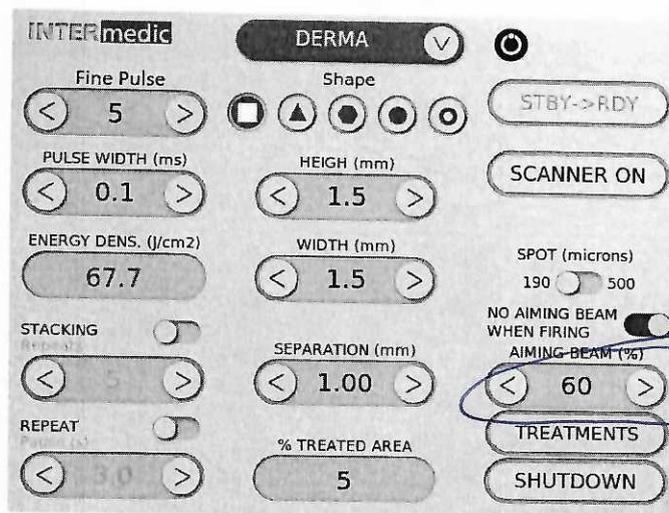


Figure 45: Derma Fine Pulse Mode.