V^2LR (Vulvo Vaginal Laser Reshaping)

SmartXide Touch

The New Era of Vaginal Rejuvenation

Advanced CO\textsubscript{2} Laser System.

- Genitourinary Syndrome of Menopause
- Vaginal Laxity
- Stress Urinary Incontinence
- Vulvar Lichen Sclerosus
- Vestibulodynia
- Postpartum Perineal Trauma
- Genital Functional and Cosmetic Laser Surgery

All it takes is a touch
MonaLisa Touch® is the best-known and most widespread laser procedure designed to treat vulvovaginal conditions. Issues related to gynaecological health are commonly seen in millions of postmenopausal women, breast cancer survivors and hysterectomized women. MonaLisa Touch® provides a unique solution for all women experiencing post-menopausal symptoms, without any of the adverse side effects caused by drug-based therapies.

“I feel that the MonaLisa Touch® procedure is a game changing technology. It is truly remarkable that such a simple minimally invasive office procedure can be so effective in treating a variety of skin conditions of the vagina and vulva. The success we have seen with this therapy has far exceeded our expectations, with almost all women noting significant improvement or even a complete cure of their condition.”

Mickey Karram, MD
Director of Fellowship Program on Female Pelvic Medicine & Reconstructive Surgery,
The Christ Hospital, Cincinnati - OH (USA)

“MonaLisa Touch® is certainly the procedure that has the best evidence in medical literature, showing how safe and how good it is. Other lasers still have to produce that evidence and each single laser is completely different from the other, so we cannot actually say that all CO₂ lasers produce the same effects with the same safety.”

Stefano Salvatore, MD
Head of the Urogynaecology Department,
San Raffaele Hospital and Vita Salute University, Milan - Italy

“I found that MonaLisa Touch® has a beneficial effect on the vaginal microenvironment in women with symptoms of GSM. This laser therapy restores the vaginal equilibrium to a healthier status, as would normally be expected if estrogen levels were sufficient. The more acidic pH of vaginal fluid, achieved after SmartXide Touch therapy, could protect postmenopausal women from vaginal infections, inflammation and possibly from UTIs.”

Stavros Athanasiou, MD, MRCOG
Associate Professor of Urogynaecology
Urogynaecology Unit, 1st Dept. of Obstetrics and Gynaecology, “Alexandra” Hospital
National and Kapodistrian University of Athens, Athens - Greece

“My studies demonstrated that the uniquely delivered DEKA CO₂ laser is capable of treating lichen sclerosus effectively. MonaLisa Touch® procedure represents a significant divergence from steroid- and corticosteroid-bulwark dependence and their expected serious side effects.”

Michael S. Baggish, MD, FACS, FACOG
St. Helena Hospital, St. Helena - CA (USA)
Dept. of Obstetrics and Gynecology, University of California, San Francisco - CA (USA)
SmartXide Touch, with V^2LR configuration, offers the latest breakthrough laser treatment for the MonaLisa Touch® procedure and cosmetic/functional female genital surgery. To perform these innovative procedures, DEKA has designed a new radiofrequency CO_2 laser, featuring proprietary PSD® (Pulse Shape Design) technology. This generates the only pulse specifically developed for treating genital mucosa: D-Pulse or DEKAPulse.

Why choose MonaLisa Touch®:

- **Effective.** The sole procedure demonstrated by clinical, histological and ultrastructural studies published in the international peer-reviewed literature.
- **Simple.** In-office non-surgical procedure, 5-minute treatments; the ergonomic scanner and probes make it easy to perform.
- **Safe.** Virtually side effect-free. Minimally invasive. Thousands of women successfully treated since 2009.
- **Painless.** Requiring no anaesthesia inside the vagina. Very short downtime.
- **Immediate.** Symptom relief after just 1 treatment, even greater improvement after treatments 2 and 3.
- **Non-hormonal therapy.** Suitable for patients who cannot, or prefer not to receive oestrogen therapy.
- **Cheaper** than alternatives involving tablets or creams that need to be taken/applied every day for months and that only focus on symptoms rather than address the causes.

PLUS

2009  
DeKA was the first company to apply DOT Therapy to vulvovaginal treatments.

2012  
In conjunction with Italian centres of excellence, DEKA presented amazing clinical and histological results achieved with the revolutionary MonaLisa Touch® treatment.

PSD® Technology  
The exclusive Pulse Shape Design technology assures maximum pulse shape flexibility: S-Pulse, D-Pulse, H-Pulse, U-Pulse and CW mode make SmartXide Touch the most effective and versatile laser system.

D-Pulse  
The exclusive pulse shape specifically developed for treating vaginal mucosa.

Peer-reviewed studies  
Clinical assessments of MonaLisa Touch® have been published worldwide in the peer-reviewed literature. In just two and a half years, over 20 international publications have confirmed the great efficacy and safety of this outstanding procedure.

HiScan V^2LR  
DEKA’s exclusive scanning system, specifically designed for V^2LR. Different probes are available for specific treatments and conditions.

Multimedia & Database  
Integrated photos, video tutorial and protocols developed for V^2LR, Gynaecology as well as various fields of medical applications.
Menopause, whether natural or induced, determines a range of changes caused by lower levels of circulating oestrogen in a woman’s body. Genitourinary syndrome of menopause (GSM), previously known as vulvovaginal atrophy (VVA), affects quality of life and sexual function in up to 50% of postmenopausal women.

GSM is characterized by atrophy of vaginal and vulvar tissues. Common manifestations include reduced lubrication and symptoms of itching, burning, dryness, irritation, dysuria and dyspareunia. The vagina is less nourished and increasingly prone to trauma, tearing, bleeding and pain as the mucosa thins and becomes more fragile. The prevalence of urogenital infection may also rise as vaginal secretions become more alkaline, altering the character of the vaginal flora.

The most recent consensus statement includes GSM as a cause of vulval pain (vulvodynia). Finally, vulvar lichen sclerosus also commonly affects postmenopausal women.
Since its introduction, MonaLisa Touch® has given a new boost to the development of genital mucosa treatments. The international peer-reviewed literature confirmed that it is feasible, safe, and effective for the treatment of GSM symptoms, improving patient’s sexual health and quality of life. Perino et al. (Eur Rev Med Pharmacol Sci 2016) and Gonzalez et al. (Int Urogynecol J 2017) underline the efficacy of this new approach not only on VVA but also for related stress urinary incontinence management. Stimulation of vaginal tissues using the D-Pulse CO₂ laser restores urinary continence, with a dramatic improvement in quality of life, at both physical and psychological level.

Women suffering from hormone-dependent cancers are affected by therapy-induced menopause symptoms, such as VVA. Pieralli et al. (Arch Gynecol Obstet 2016) and Pagano et al. (Menopause 2016) focused their attention on these patients, in whom hormone-replacement therapy is strongly contraindicated. Their results show that MonaLisa Touch® is safe, well-tolerated and effective.

Murrina et al. (J Sex Med 2016) evaluated the effectiveness and safety of the DEKA CO₂ laser for the vulvar vestibule in the management of patients presenting idiopathic vulvar pain (vestibulodynia). They reported a statistically significant improvement in more than 67% of patients.

Dr M.S. Baggish (J Gynecol Surg 2016) investigated MonaLisa Touch® for the treatment of vulvar lichen sclerosus. Again, results were extremely positive and provided indisputable evidence of amelioration in symptoms such as pruritus.

The Missing Solution to Postpartum Sexual Problems

Many women experience postpartum sexual pain due to lactational atrophic vaginitis or following perineal trauma. These life-altering conditions can lead to both physical and psychological problems. Early, sensitive management is crucial in preventing long-term complications. MonaLisa Touch® helps solve these situations delicately and safely. The treatment acts gently, improving the functionality of the treated area and restoring proper trophic balance to the mucous membranes.

Non-Surgical Tightening for Vaginal Laxity

Stretching of the vagina and introitus can occur from vaginal delivery or may be part of the natural ageing process. Vaginal laxity is a bothersome condition that may impact sexual function. MonaLisa Touch® acts on the vaginal mucosa, improving its elasticity (Sokol et al., Menopause 2016; Sokol et al., Menopause 2017) and pelvic floor support (van Raatle et al., IUGA Meeting 2016). The SmartXideTouch laser acts directly on the mucosal walls, tightening, reshaping, toning and stimulating tissue and regenerating collagen.

Distribution of dilator size data shown as percentages of women able to accept an XS, S, M, or L vaginal dilator at each of four time points: before treatments 1, 2, and 3 as well as 3-month follow up (Sokol et al., Menopause 2016). At 1-year time point 73.3% of women were comfortable with a dilatator size larger than that one accepted at 3-month follow up; 21% were comfortable with the same dilator size (Sokol et al., Menopause 2017).

Decrease in the mean vaginal pH levels and increase in the growth of lactobacilli at baseline and after subsequent treatments (Athanasiou et al., Climacteric 2016).

Distribution of H&E vaginal mucosa histological image. The D-Pulse produces a superficial vaporization on the epithelium forming a layer of denatured collagen. Below this layer, laser stimulation produces a controlled temperature gradient which activates HSP47, a protein specific for synthesising new collagen fibroblasts.

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Vaginal mucosa and skin differ significantly in epithelium structure. The outer skin layer has plenty of keratin and little water, while mucosal epithelium is nonkeratinized, containing water and glycogen. Due to their different levels of hydration, the CO$_2$ laser (highly absorbed by water) has different effects on skin and on mucosa. It follows that in order to stimulate these two tissues in depth, two different barriers have to be overcome. Therefore, a laser conceived for skin rejuvenation does not have the same efficacy on mucosa. This led DEKA to develop a special pulse shape, known as the D-Pulse or DEKA-Pulse, designed specifically for the vaginal mucosa.

The D-Pulse consists of:

- an initial portion with constant high-peak power for rapid painless superficial removal of atrophic epithelial mucosa;
- a second variable portion, with lower peak power and longer emission times, that allows the laser energy to penetrate into the mucosa and stimulate it properly in depth.

The result is the right CO$_2$ laser penetration beyond the epithelium, and into the connective tissue, activating mucosa regeneration without any risk to surrounding tissues and organs. This is the only way to achieve the structural improvements needed to restore nourishment and full functionality to the supporting structures of the vaginal walls.

Only the combined use of D-Pulse and fractional DOT Therapy guarantees durable results like no other!

Reduction labiaplasty, surgical vaginal reshaping or clitoral unhooding performed with SmartXide Touch offers better results and safer procedures than a scalpel. In fact, laser treatment coagulates, minimizes scarring and swelling, reduces patient post-op discomfort and increases mucosal firmness and elasticity, stimulating collagen production.

MonaLisa Touch requires the Hi-Scan V$^2$LR scanner system to deliver fractionated laser energy to the vaginal mucosa. A wide range of autoclavable probes are available to perform the procedure, depending on the patient’s specific needs.
Colposcopic images of vaginal mucosa: (A) atrophic thin epithelium with petechiae, lack of vaginal rugae and mucus; (B) the same patient 30 days after 1 MonaLisa Touch® treatment. The mucosa aspect is typical of a premenopausal healthy epithelium with natural pink colour, no petechiae, evidence of vaginal rugae and mucous lubrication. [Courtesy of M.G. Fallani M.D.; A. Pieralli M.D.; Prof. S. Guaschino, M.D.; Prof. C. Penna, M.D. Careggi University Hospital. Florence, Italy]

Left labia minora hypertrophy. (A) Asymetrical condition before laser labiaplasty. (B) Picture showing post-op 10 days after the surgery. [Courtesy of P. González Isaza, M.D. - Pereira, Colombia]

The graphs show the improvement (%) in the main symptoms of vaginal atrophy (A) and urinary incontinence (B) after 3 MonaLisa Touch® sessions. The study was carried out at the San Raffaele Hospital Department of Gynaecology on patients with GSM symptoms. [Courtesy of S. Salvatore, M.D. - IRCCS San Raffaele Hospital, Milan, Italy]

For detailed literature references, please ask for the “MonaLisa Touch® International Scientific Community Recognition” booklet.

For more in-depth information on the MonaLisa Touch® procedure, please ask for the dossier “MonaLisa Touch®. The Game Changing Laser Therapy for Vulvovaginal Health” and visit the website at www.monalisatouch.com.
## TECHNICAL DATA

<table>
<thead>
<tr>
<th>Smartxide Touch - Suggested Configurations in VLR</th>
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</thead>
<tbody>
<tr>
<td><strong>Laser Type</strong></td>
<td>CO₂ RF - PSD®</td>
</tr>
<tr>
<td><strong>Wavelength</strong></td>
<td>10.6 µm</td>
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<tr>
<td><strong>Emission Beam</strong></td>
<td>TEM₀₀</td>
</tr>
<tr>
<td><strong>Emission Modes</strong></td>
<td>CW - SP - DP - HP - UP</td>
</tr>
<tr>
<td><strong>CW Power</strong></td>
<td>From 0.5 to 60 W</td>
</tr>
<tr>
<td><strong>SP Power</strong></td>
<td>From 0.1 to 15 W</td>
</tr>
<tr>
<td><strong>DP Power</strong></td>
<td>From 0.2 to 15 W</td>
</tr>
<tr>
<td><strong>HP Power</strong></td>
<td>From 0.1 to 8 W</td>
</tr>
<tr>
<td><strong>UP Power</strong></td>
<td>From 0.5 to 60 W</td>
</tr>
<tr>
<td><strong>Emission Time</strong></td>
<td>From 0.01 to 0.9 s</td>
</tr>
<tr>
<td><strong>Delay Emission Time</strong></td>
<td>From 0.1 to 5 s</td>
</tr>
<tr>
<td><strong>Beam Delivery</strong></td>
<td>7 Mirrors articulated arm</td>
</tr>
<tr>
<td><strong>Aiming Beam</strong></td>
<td>Laser diode @ 635 nm - 4 mW - Adjustable intensity from 1% to 100%. Diode Off While Lasing (DOWL).</td>
</tr>
<tr>
<td><strong>Internal Database</strong></td>
<td>About 150 factory stored protocols, upgradable by USB. Possibility of storing unlimited number of custom user’s protocols.</td>
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<tr>
<td><strong>Control Panel</strong></td>
<td>Wide LCD Colour Touch Screen (8.4”)</td>
</tr>
<tr>
<td>**Accessories ***</td>
<td>HiScan V/LR Scanner System. Wide range of surgical handpieces.</td>
</tr>
<tr>
<td><strong>Electrical Requirements</strong></td>
<td>From 100 to 230 Vac (automatic selection). 1,200 VA - 50/60 Hz.</td>
</tr>
<tr>
<td><strong>Dimensions</strong> ** and Weight**</td>
<td>118 (H) x 42 (W) x 54 (D) cm - 62 kg</td>
</tr>
</tbody>
</table>

### HiScan V/LR Scanner System

| Max Scanning Area | Square 8 x 8 mm (for single-angle and vulvar probes) |
| Dwell Time | From 100 to 2,000 µs |
| DOT Spacing | From 0 to 2,000 µm |
| **SmartStack Level** | From 1 to 5 |
| **Scanning Methods** | Normal, Interlaced, SmartTrack. |
| **Emission Modes** | SP - DP - HP |
| **Accessories** | Vaginal Probes: 360° full-angle, 90° single-angle “closed” (optional), 90° single-angle “open” (optional). Vulvar Probe. |

* In this catalogue only the technical features of the V/LR (Vulvo-Vaginal Laser Reshaping) applications are listed.

** Height with folded articulated arm

### CAUTION

Visible and invisible laser radiation. Avoid eye or skin exposure to direct or scattered radiation. Class 4 laser product.

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**DEKA The Code of Excellence**

A spin-off of the El.En. Group, DEKA is a world-class leader in the design and manufacture of lasers and light sources for applications in the medical field. DEKA markets its devices in more than 80 countries throughout an extensive network of international distributors as well as direct offices in Italy, France, Germany, Japan and USA. Excellence is the hallmark of DEKA’s experience and recognition garnered in the sphere of R&D in over thirty years of activity. Quality, innovation and technological excellence place DEKA and its products in a unique and distinguished position in the global arena. DEKA manufactures laser devices in compliance with the specifications of Directive 90/42/EEC and its quality assurance system is in accordance with the ISO 9001 and ISO 13485 standards.

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**DEKA The Code of Excellence**

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