SMARTXIDE² V²LR

V²LR (Vulvo-Vaginal Laser Reshaping)

SMARTXIDE²

MonaLisa Touch™

The New Era of Vaginal Rejuvenation

Treatment of Atrophy and Laxity of the Vaginal Mucosa and Urinary Incontinence to Them Related

Female Genital Functional and Cosmetic Laser Surgery

DEKA Intelligent Technologies:
Experts from the Start

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The Code of Excellence

SMARTXIDE² V²LR

A REVOLUTIONARY NEW APPROACH TO FEMALE SEXUALITY

Like all the other organs in our bodies, the female genitals are not immune to the effects of time, especially during menopause. The genital tract is particularly affected by declining oestrogen production. Almost 50% of postmenopausal women complain about the typical symptoms of genital atrophy interfering heavily with their sexual experience and quality of life. Increasingly, relatively young and socially active women turn to specialists for treating this condition. DEKA has developed a breakthrough procedure for treating age-related vulvo-vaginal problems. **SmartXide²**, the innovative CO_2 laser system specifically produced for V²LR (*Vulvo-Vaginal Laser Reshaping*), deals with the new field of medicine for vulvo-vaginal reshaping. A solution for all women without the adverse side effects of drug therapies.

*"The demand for functional and/or cosmetic female genital organ treatment is constantly increasing. Natural ageing can significantly affect the vaginal tract, causing serious physiological and psychological problems for women, especially due to the vaginal atrophy. By using the treatment called **MonaLisa Touch™**, we consider **SmartXide² V²LR** a versatile and irreplaceable instrument for vaginal mucosa regeneration and outpatient genital surgery. I have found the workstation to be particularly effective, consistently ensuring excellent results and maximum comfort for my patients. With **SmartXide² V²LR** we have experienced amazing improvements on atrophic mucosa as early as a month after a single treatment, and results that are immediately noticeable in the surgical correction of vulvar dysmorphism."*

Stefano Salvatore, M.D.
Head of the Urogynaecology Unit
IRCCS San Raffaele Hospital, Milan - Italy

*"Histological studies conducted on women suffering from vaginal atrophic conditions, have shown that the **MonaLisa Touch™** treatment with **SmartXide² V²LR** restores the mucosa to a pre-menopausal condition, as would occur after an oestrogen hormone replacement treatment. This particular laser system stimulates the epithelial surface and the connective tissue, through a physical medium rather than using drugs, basically making the vaginal mucosa younger."*

Prof. Alberto Calligaro
Professor of Histology and Embryology
University of Pavia - Italy

V²LR (Vulvo-Vaginal Laser Reshaping)

SMARTXIDE² V²LR

V²LR CONFIGURATION OF SMARTXIDE²: A MINIMALLY INVASIVE TECHNOLOGY THAT ENHANCES QUALITY OF LIFE

The **SmartXide²** system, with V²LR configuration, offers the latest breakthrough laser treatment for vulvo-vaginal problems (***MonaLisa Touch™***) and cosmetic/functional female genital surgery. Safe and minimally invasive, these procedures are the new alternative to:

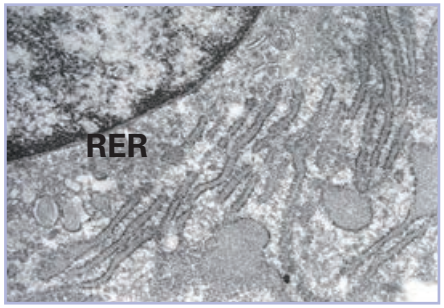
- pharmacological therapy for post-menopause atrophy of genital mucosa, using the ***MonaLisa Touch™*** treatment;
- surgical treatment of vaginal laxity;
- annoying or invasive treatments of urinary incontinence;
- traditional plastic surgery for the correction of vulvo-vaginal morphological alterations due to hereditary factors, pregnancy or natural ageing.

To perform these innovative procedures, DEKA has designed a new radiofrequency CO_2 laser, with the exclusive ***PSD®*** (*Pulse Shape Design*) technology that generates pulses specifically developed for V²LR applications (***D-Pulse*** or ***DEKA-Pulse***), together with DEKA's proprietary *HiScan V²LR* scanning system.

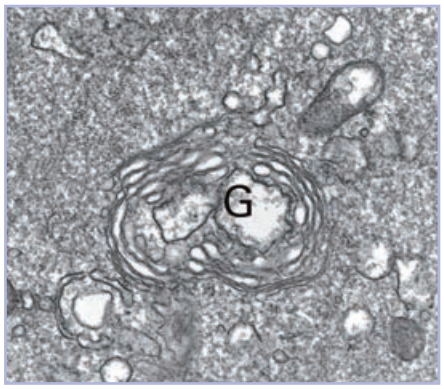
2009	DEKA is the first to introduce the V²LR procedure, applying *DOT Therapy* to vulvo-vaginal treatments.
2012	DEKA, in collaboration with important Italian centres of excellence, presents amazing clinical and histological results achieved with the revolutionary ***MonaLisa Touch™*** vaginal treatment.
PSD® Technology	The first radiofrequency CO_2 laser system with the exclusive **Pulse Shape Design** technology that enables the maximum flexibility of the pulse shape: S-pulse, D-pulse, H-pulse, U-pulse and the CW mode, and greatly expands the surgical capabilities of the SmartXide² making it an effective, versatile and powerful laser system.
D-Pulse	The exclusive pulse shape specifically developed for treating vaginal mucosa.
HiScan V²LR	DEKA's new and exclusive scanning system, specifically designed for V²LR.
Database	Integrated protocols developed for V²LR, Gynaecology as well as various fields of medical applications (Dermatology, Cosmetic Surgery, ENT and Dentistry).
Multimedia Features	Integrated photos and video tutorial.

	sexual maturity	pregnancy	post menopause
Oestrogens	++	+++	-
Epithelium of mucosa			
Glycogen	+	++	-
pH	3,5 - 5	3 - 4,5	6 - 8
Microorganisms population	lactobacilli		mixed

Vaginal environment at different ages and physiological conditions.



Electron microscope image of the inside of a fibroblast in the vaginal mucosa stimulated with SmartXide² V²LR laser. The Rough Endoplasmic Reticulum (***RER***) can be seen, well-developed with many ribosomes attached to the membranes of flattened cisternae. Some of these cisternae develop vesicles in the terminal part, in which filamentous structures can be observed.



Electron microscope image of the inside of a fibroblast in the vaginal mucosa stimulated with SmartXide² V²LR laser. The Golgi apparatus (***G***) is also well developed. Vesicles can be observed which, we can suppose, contain the components that will form the ground matrix.

VAGINAL ATROPHY: CHANGES THAT AFFECT QUALITY OF LIFE

Menopause, whether natural or induced, determines a range of changes, involving virtually all organs and systems of a woman's body. The end of oestrogen production by the ovaries is linked to the onset of disorders resulting from the vulvo-vaginal atrophy such as dryness, dyspareunia, vaginal irritation with itching and burning.

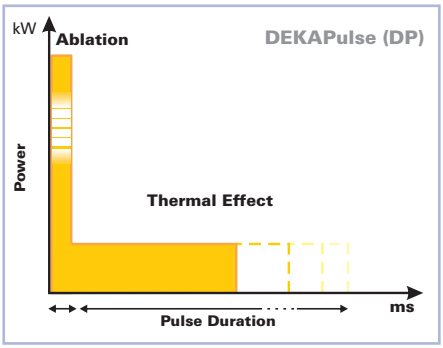
Vaginal atrophy becomes clinically apparent a few years after the onset of menopause. Studies show that the changes and symptoms are present in 50% of post-menopausal women, determining adverse effects on their overall well-being and, in many cases, their sexual life.

During menopause, the fibroblasts sited in the vaginal mucosa, reduce their own activity and cannot produce the proper amount of collagen and molecules required to maintain an adequate ground matrix structure that is necessary to preserve a correct connective tissue hydration. The mucosa becomes dry, less *nourished* and therefore fragile and more prone to infection due to the higher pH, making the environment open to colonization of pathogenic microorganisms.

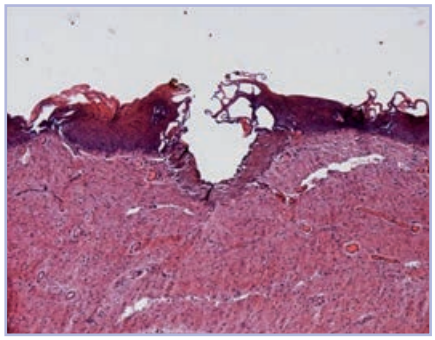
MONALISA TOUCH™: ANOTHER STEP FORWARD FOR WOMEN'S WELL-BEING

MonaLisa Touch™ is simply the application of DEKA CO_2 laser on the vaginal walls by specifically designed probes to be used even in the tightest vaginal channel.
To render this procedure absolutely safe and fast the CO_2 laser is distributed in small spots (called DOTs) separated from each other by healthy tissue.
This particular technique is called fractioned and has been proven to be effective in restoring the atrophic vaginal mucosa by inducing a true rejuvenation. The vagina rolls back the years regaining extramatricial components and fluids, thickness of the connective tissue and epithelium, thus recovering trophism, tonicity, elasticity and firmness as when it was younger. Restabilizing the natural turnover of the epithelial cells the natural conditions for nourishment of lactobacilli is restored; pH goes back to lower levels, reactivating the acid barrier to pathogens.

The laser acts directly on the mucosa of the vaginal walls by stimulating the metabolic activation of the fibroblasts. A detailed histological investigation, carried out in collaboration with the University of Pavia, has allowed to study ultrastructural aspects in depth. The results highlighted that the treatment with SmartXide² V²LR activates the biosynthesis of collagen and the restoration of the proper composition of the extracellular matrix, with collagen fibres, ground substance and adequate water content. The regenerated mucosa restores functionality that it had lost over the years.



D-Pulse: the pulse specifically developed by DEKA for V²LR.



Vaginal mucosal histological preparations stained with haematoxylin and eosin (H&E). Observe the effect produced by a D-Pulse on the mucosa epithelium with vaporization and the formation of a band of collagen denaturing. Below this area, laser stimulation produces a controlled temperature gradient which induces the activation of a specific Heat Shock Protein (HSP47) capable of promoting the synthesis of new collagen fibroblasts.

Vulva appearance immediately after the ***MonaLisa Touch™*** treatment. Observe the DOTs on the mucosa without any reddening or bleeding. *[Courtesy of M. Filippini, M.D. and M. Farinelli, M.D. San Marino State Hospital, San Marino]*

D-PULSE: THE PERFECT PULSE FOR V²LR

DEKA developed the SmartXide² V²LR system for the ***MonaLisa Touch™*** treatment, capable of supplying energy with a specific pulse, derived from dermatological experience, but taking into account the peculiarities of vaginal mucosa: this dedicated pulse shape is called ***D-Pulse*** or DEKA-Pulse.

The *D-Pulse* consists of:

- an initial part with constant, high energy peak power, for rapid superficial removal of the epithelial component of atrophic mucosa characterized by low water content;
- a second variable part, with lower peak power and longer emission times, that allows the laser energy heat to penetrate in the mucosa, stimulating the synthesis of new collagen and of the components of the ground substance of the matrix.

The result is the structural improvements needed to restore the trophism and full functionality of the supporting structures of the vaginal walls.

DOT THERAPY WITH D-PULSE: UNIQUE, SAFE, MINIMALLY INVASIVE, PAINLESS AND EFFECTIVE

In ***MonaLisa Touch™*** treatment the combined use of *DOT Therapy* and *D-Pulse* guarantees effective and durable results and unrivalled advantages:

Safe. DOT Therapy is performed using laser energy not continuously distributed over the vaginal walls, but deployed in small dots of 200 microns. Only a few percent of the vagina tissue is treated by the laser. This is important to achieve the right mechanisms of regeneration without side effects.

Minimally Invasive. The particular structure of D-Pulse allows the right penetration of the CO_2 laser energy in the connective tissue. As shown on the left side margin histology, the penetration is beyond the epithelium for activation of the regeneration, without any risk to all the surrounding tissues and organs.

Painless. The ***MonaLisa Touch™*** treatment is absolutely painless inside the vagina (no anaesthesia) and well tolerated on vulva. The DEKA's proprietary scanning system *HiScan V²LR* assures a very fast treatment of the vaginal tissues. It takes only a few minutes of application to get an important and deep stimulation.

Unique. SmartXide² is the first laser system to be used for reducing vaginal atrophy and laxity. ***MonaLisa Touch™*** is a DEKA trademark.

Effective. ***MonaLisa Touch™*** is the sole procedure demonstrated not only with clinical results, but also by histological and ultrastructural detailed studies. Vaginal tissues are regenerated thanks to the deep stimulation obtained with the unique combination of the specific CO_2 wavelength, D-Pulse structure and the appropriate power emission.

The new full-angle probe emitting the laser energy in a 360 degree angle in one time. Faster and less invasive treatments are now possible even for the more severe atrophies.

Single-angle available probes for HiScan V²LR. Simply changing the probe, the scanner can be easily adapted to all patient's needs.

The simple and intuitive Smartxide² new graphical interface allows quick access to all functions. Its large LCD Touch Screen makes it easy to select the operating parameters.

MONALISA TOUCH™: TOTAL TISSUE REGENERATION

With the introduction of fractional CO_2 laser technology, DEKA V²LR procedure has given a new boost to the development of vaginal mucosa treatments. Thanks to the effective action of the D-Pulse, ***MonaLisa Touch™*** improves and replaces also the most common techniques for treating vaginal relaxation.
The term ***wide vagina*** usually refers to a condition where the diameter of the vagina has increased. This often happens naturally, although traumatic events such as childbirth or the natural ageing process can also contribute. Thanks to DOT Therapy it is possible to treat all cases where relaxation is due to a loss of tone of the mucosa.
When inserted in the vagina, using the special probe of the *HiScan V²LR* scanning system, the laser acts directly on the mucosa of the vaginal walls, reshaping, toning and stimulating tissue and regenerating collagen.
Recent studies show that ***MonaLisa Touch™*** is largely effective also in treating one of the most embarrassing symptoms that seriously affect many women in menopause: **urinary incontinence**. The beneficial stimulation of vaginal tissues, due to the DEKA-pulse CO_2 laser emission, re-establish the proper functionality of urogenital involved structures. This allows restoration of correct *urinary continence*, with a dramatic positive improvement in the quality of life, both physically and psychologically.

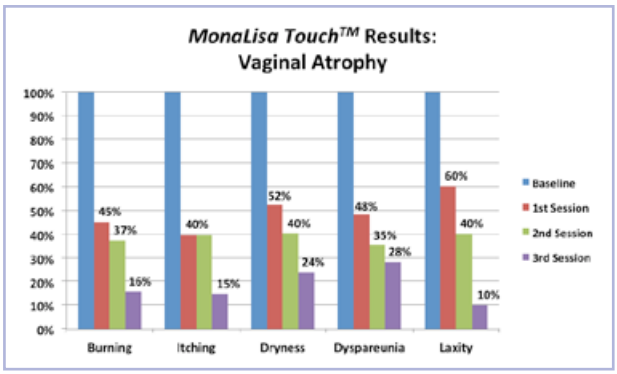
MONALISA TOUCH™: SPECIAL PROBES FOR A SPECIAL PROCEDURE

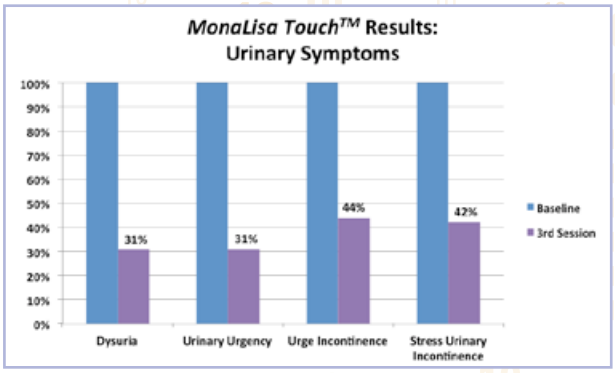
MonaLisa Touch™ requires a special scanner system to deliver the fractioned laser energy on the vaginal mucosa. A wide range of autoclavable probes is available to perform the procedure depending on the specific patient needs:

- full-angle probe, useful even for the most atrophic vaginas. The CO_2 laser DOTs are distributed in a 360° angle frame thanks to the exclusive pyramidal-mirror assembly;
- single-angle probes for urinary incontinence. Choosing among different shapes and sections it is possible to treat all types of vaginal introitus;
- vulvar probe for DOT Therapy of external genitalia.

VULVO-VAGINAL V²LR COSMETIC AND FUNCTIONAL SURGERY: UNMATCHED TECHNIQUE AND PERFORMANCE

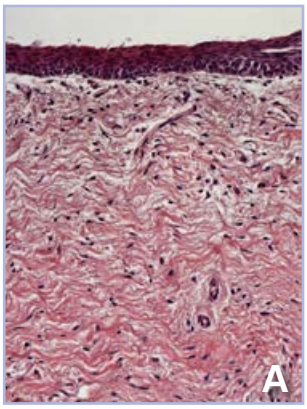
Reduction labiaplasty, vaginal reshaping or clitoral unhooding, performed with ***SmartXide² V²LR*** offers better and safer results than the scalpel. In fact, laser coagulates, minimizes scarring and swelling, reduces the patient's post-op discomfort, and increases the firmness and elasticity of the mucosa while stimulating collagen production.

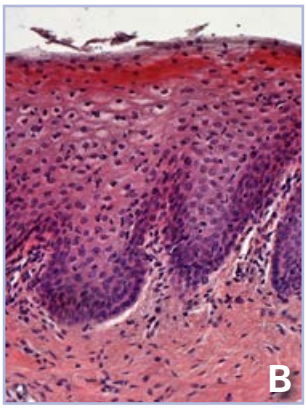




The graphs represent the percentage of reduction for the main symptoms of **vaginal atrophy** and **urinary incontinence** after 3 ***MonaLisa Touch™*** sessions. The study was carried out at the Department of Gynaecology of the San Raffaele Hospital on patients with symptoms of uro-genital atrophy. *[Courtesy of S. Salvatore, M.D. - IRCCS San Raffaele Hospital. Milan, Italy]*

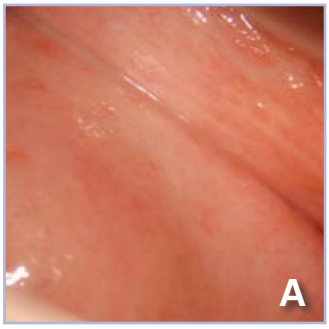
MONALISA TOUCH™: HISTOLOGICAL STUDY

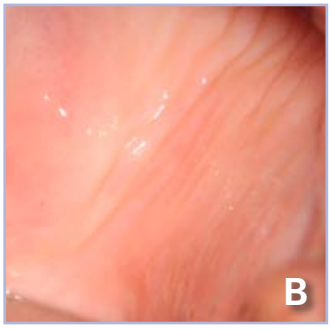




Histological preparation of a section of the vaginal mucosa stained with haematoxylin and eosin (H&E). (**A**): Vaginal mucosa in the basal condition. It is possible to see a thinner epithelium. (**B**): Vaginal mucosa of the same patient 2 months after a session with the ***MonaLisa Touch™*** treatment. The much thicker epithelium and shedding of numerous big cells from the free surface, together with the larger diameter of epithelial cells rich in glycogen, demonstrate the restored metabolic trophism and dynamics of the whole epithelium. *[Courtesy of Prof. A. Calligaro. University of Pavia, Italy]*

CLINICAL CASES





Colposcopic images of vaginal mucosa: (**A**) atrophic thin epithelium with petechiae, lack of vaginal rugae and muco; (**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: MG. Fallani M.D.; A. Pieralli M.D.; Prof. S. Guaschino, M.D.; Prof. C. Penna, M.D. University Hospital of Careggi. Florence, Italy]*

Labia minora hypertrophy. Before laser labioplasty (**A**) and 10 days post-op (**B**) pictures. *[Courtesy of P. González Isaza, M.D. - Pereira, Colombia]*

TECHNICAL DATA

SMARTXIDE² - Suggested Configurations in V²LR

Models*	C40	C60	C80
Laser Type	CO_2 RF - PSD®		
Wavelength	10.6 µm		
Emission Beam	TEM_{00}		
Emission Modes	CW - SP - DP - HP	CW - SP - DP - HP - UP	
CW Power	From 0.5 to 40 W	From 0.5 to 60 W	From 0.5 to 70 W
SP Power	From 0.1 to 12 W	From 0.1 to 15 W	From 0.1 to 15 W
DP Power	From 0.2 to 12 W	From 0.2 to 15 W	From 0.2 to 15 W
HP Power	From 0.1 to 4 W	From 0.1 to 8 W	From 0.1 to 15 W
UP Power	N/A	From 0.5 to 60 W	From 0.5 to 80 W
Emission Time	From 0.01 to 0.9 sec.		
Delay Emission Time	From 0.3 to 5 sec.		
Beam Delivery	7 Mirrors articulated arm with counterweight.		
Aiming Beam	Laser diode @ 635 nm - 4 mW - Adjustable intensity from 2% to 100% - Aiming light OFF or Diode Off While Lasing (DOWL).		
Internal Database	About 150 factory stored protocols, upgradable by USB. Possibility of storing unlimited number of custom user's protocols.		
Control Panel	Wide LCD Colour Touch Screen (10.4")		
Accessories*	HiScan V²LR Scanner System. Wide range of surgical handpieces.		
Electrical Requirements	From 100 to 120 Vac - 50/60 Hz From 220 to 230 Vac - 50 Hz - 1,600 VA		
Dimensions** and Weight	162 (H) x 59 (W) x 56 (D) cm - 95 kg		
	63.8" (H) x 23.2" (W) x 22.0" (D) - 267 lb		

HiScan V²LR Scanner System

Max Scanning Area	8 x 8 mm
Dwell Time	From 100 to 2000 µs
DOT Spacing	From 0 to 2000 µm
SmartStack Level	From 1 to 5
Scanning Shapes	DOT, Line, Square.
Scanning Methods	Normal, Interlaced, SmartTrack.
Emission Modes	SP - DP - HP***

* In this catalogue only the technical features of the V²LR (Vulvo-Vaginal Laser Reshaping) applications are listed. Please refer to the SmartXide² General Catalogue for the complete list of characteristics.
** Height with folded articulated arm.
*** Not available for C40 model.

SmartXIDE²

MonaLisa Touch™

TREATMENT OF ATROPHY AND LAXITY OF THE VAGINAL MUCOSA AND URINARY INCONTINENCE TO THEM RELATED
FEMALE GENITAL FUNCTIONAL AND COSMETIC LASER SURGERY

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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 93/42/EC and its quality assurance system, certified by, is in accordance with the ISO 9001 and ISO 13485 standards.

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