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Фракционный лазер CO2 SMARTXIDE2 V2LR (MONALISATOUCH)

V²LR (VULVO-VAGINAL LASER RESHAPING)

SMARTXIDE²

Atrophic Vaginitis
Vaginal Laxity
Stress Urinary Incontinence
Postpartum Perineal Trauma
Genital Functional and Cosmetic Laser Surgery

The New Era of Vaginal Rejuvenation
Advanced CO₂ Laser System

MonaLisa Touch[®]

SMARTXIDE² V²LR

THE REVOLUTIONARY NEW APPROACH TO WOMEN INTIMATE PARTS

Many disorders related with women's intimate area are often overlooked and ignored because they are perceived as an inevitable consequence of a natural physiological process that occur as a result of childbirth or menopause, for which little or nothing can be done. It is thought that these disorders may have an important impact both physical discomfort (pain, burning, incontinence), and psychological, causing an adverse effect on the relationship with the partner and quality of life in general.

SmartXide² is the new CO₂ laser system specifically designed for V²LR (Vulvo-Vaginal Laser Reshaping) and **MonaLisa Touch[®]**, the breakthrough procedure developed by DEKA known worldwide for treating age-related and postpartum vulvovaginal troubles. A unique solution for women without the adverse side effects of drug therapies.

*"The demand for functional and/or cosmetic female genital organ treatment is constantly increasing. By using the **MonaLisa Touch[®]** treatment, we consider **SmartXide² V²LR** a versatile and irreplaceable instrument for vaginal mucosa regeneration and outpatient genital surgery. I have found the system to be particularly effective, consistently ensuring excellent results and maximum comfort for my patients. With SmartXide² we have experienced amazing improvements on atrophic mucosa as early as a month after a single treatment with immediately noticeable results for surgical correction of vulvar dysmorphism."*

Stefano Salvatore, M.D.

Head of the Urogynaecology department,
San Raffaele Hospital and Vita Salute, Milan - Italy

*"Histological studies conducted on women suffering from atrophic vaginitis, have shown that the **MonaLisa Touch[®]** treatment with **SmartXide² V²LR** restores the mucosa to a pre-menopausal condition, as it would occur after an oestrogen hormone replacement therapy. This particular laser system stimulates epithelial surface and 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

*"Postpartum perineal pain following a spontaneous vaginal delivery, an instrumental delivery or related to the episiotomy is a disabling condition of women after giving birth, especially when lasting over time. For symptom relief we have successfully used the **MonaLisa Touch[®]** method which acts gently on vaginal tissues to restore the correct functionality of the treated area. First created to solve problems related to vaginal atrophy post-menopause, **MonaLisa Touch[®]** is proving also to be extremely useful and effective in other situations."*

Maurizio Filippini, M.D.

Gynaecological Endoscopy Functional Unit of
the Republic of San Marino State Hospital - San Marino

V²LR (VULVO-VAGINAL LASER RESHAPING)

SMARTXIDE² V²LR

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

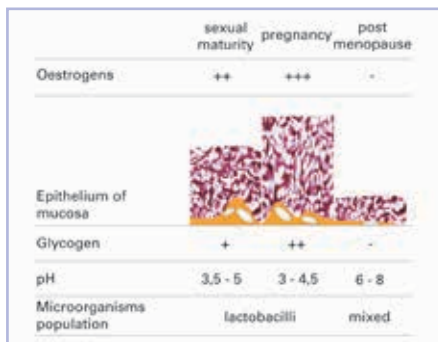
SmartXide², with V²LR configuration, offers the latest breakthrough laser treatment for vulvo-vaginal problems (**MonaLisa Touch[®]**) and cosmetic/functional female genital surgery. These safe and minimally invasive procedures present a new alternative to:

- pharmacological therapy for post-menopause or postpartum atrophy of genital mucosa;
- surgical treatment of vaginal laxity;
- pharmacological analgesic therapy for dyspareunia due to postpartum perineal trauma;
- annoying or invasive treatments for urinary incontinence;
- traditional plastic surgery for correction of vulvo-vaginal morphological alterations due to hereditary factors, pregnancy or natural ageing.

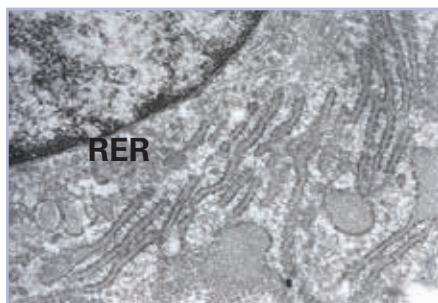
To perform these innovative procedures, DEKA has designed a new radiofrequency CO₂ laser, with the exclusive **PSD[®]** (*Pulse Shape Design*) technology that generates pulses specifically developed for V²LR applications (**D-Pulse** or **DEKA-Pulse**), together with proprietary HiScan V²LR scanning system.



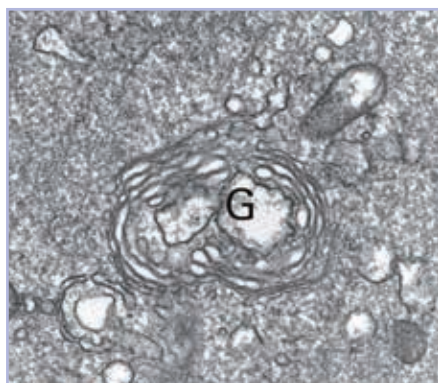
2009	DEKA is the first company to introduce the V ² LR procedure, applying <i>DOT Therapy</i> to vulvo-vaginal treatments.
2012	DEKA, in collaboration with important Italian centres of excellence, presents amazing clinical and histological results achieved with the revolutionary MonaLisa Touch[®] vaginal treatment.
PSD[®] Technology	The first radiofrequency CO ₂ laser system with exclusive Pulse Shape Design technology that enables the maximum flexibility for pulse shape: S-Pulse, D-Pulse, H-Pulse, U-Pulse and CW mode, and greatly expands the surgical capabilities of the SmartXide ² V ² LR making it the most 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 V ² LR. Different probes (intra-vaginal 360° and single-angle probes; vulvar probe) are available for specific treatments and conditions.
Database	Integrated protocols developed for V ² LR, Gynaecology as well as various fields of medical applications (Dermatology, Cosmetic Surgery and Dentistry).
Multimedia Features	Integrated photos and video tutorial.



Vaginal environment at different ages and physiological conditions.



Electron microscope image inside a fibroblast of the vaginal mucosa after a **MonaLisa Touch®** treatment. The Rough Endoplasmic Reticulum (**RER**) can be seen, well-developed with many ribosomes that are 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 inside of a fibroblast in the vaginal mucosa after a **MonaLisa Touch®** treatment. The Golgi apparatus (**G**) is particularly well developed. We can observe vesicles which 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 uro-genital atrophy such as dryness, dyspareunia, vaginal irritation with itching and burning, vaginal laxity, and stress urinary incontinence. Studies show that symptoms caused by the atrophic vaginitis 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 prone to infection due to the higher pH, setting up the environment to colonization of pathogenic microorganisms.

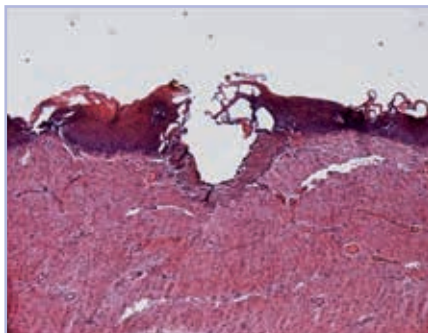
PREVENTION AND CURE WITH **MONALISA TOUCH®**: ANOTHER STEP FORWARD WOMEN'S WELL-BEING

MonaLisa Touch® is the application of unique DEKA CO₂ lasers on the vaginal walls by using specifically designed probes. To render this procedure absolutely safe and fast **SmartXide²** is equipped with an exclusive pulse, called **D-Pulse** or **DEKA-Pulse**, together with a fractional emission mode that have been proven to be effective in restoring the atrophic vaginal mucosa by stopping ageing and inducing a true rejuvenation. A detailed histological investigation carried out by the University of Pavia has demonstrated these ultrastructural aspects in-depth. The laser acts directly on the mucosa by stimulating the metabolic activation of the fibroblasts and the biosynthesis of collagen. The vagina rolls back the years regaining extramatrix components and water, 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. In this way the regenerated mucosa restores its physiological functionality that it had lost over the years.

Not only cure but prevention! Thanks to the treatment **MonaLisa Touch®** it is possible to slow down the aging process, while preserving the functionality of the vaginal mucosa. A simple and safe way for all women who want to regain the intimate part of their femininity.



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



Vaginal mucosal histological preparations stained with haematoxylin and eosin (H&E). The effect produced by a D-Pulse on the epithelium is a superficial vaporization and the formation of a band of denatured collagen. 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.



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

Since the introduction of fractional CO₂ laser technology, DEKA V²LR procedure has given a new boost to the development of genital mucosa treatments.

The Missing Solution to Postpartum Intimate Problems

Postpartum sexuality is an important aspect of women's health. Many women commonly experience postpartum sexual problems such as **Dyspareunia** due to lactational atrophic vaginitis or following perineal trauma. Consequently, painful sexual intercourse is the most common sexual problem for puerperae and represents both a physical and psychological problem for many women and their partners. In these situations, an early and sensitive management is crucial in preventing long-term problems. Today, thanks to the capabilities of **MonaLisa Touch**® to stimulate tissue regeneration, it is now possible to resolve these situations delicately and safely. The treatment acts gently by stimulating collagen production, improving the functionality of the treated area and restoring the proper trophic balance of the mucous membranes.

Non Surgical Tightening for Vaginal Laxity

Stretching of the vagina and introitus can occur from vaginal delivery or to be part of natural ageing process. Vaginal laxity may be a bothersome condition to patients that may impact on "happiness and sexual function". Thanks to the effective action of the D-Pulse, **MonaLisa Touch**® improves and replaces also the most common techniques for treating vaginal relaxation due to a loss of tone of vaginal mucosa. When inserted in the vagina by using the special probe of the **HiScan V²LR** scanning system, the laser acts directly on the mucosa of the walls, tightening, reshaping, toning and stimulating tissue and regenerating collagen.

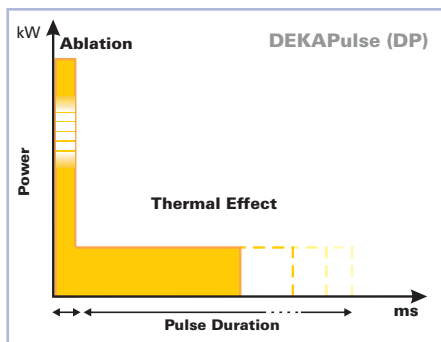
Stress Urinary Incontinence

Recent studies show that **MonaLisa Touch**® is largely effective in treating one of the most embarrassing symptoms that seriously affect many women after childbirth or in menopause: **mild urinary incontinence**. The beneficial stimulation of vaginal tissues, due to the DEKA-pulse CO₂ 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.

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

Reduction labiaplasty, vaginal reshaping or clitoral unhooding performed with **SmartXide²** offers better results and safer procedures than a 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.

**D-PULSE: THE PERFECT PULSE FOR V²LR.
UNIQUE, SAFE, MINIMALLY INVASIVE, PAINLESS AND EFFECTIVE**



D-Pulse: the pulse specifically developed by DEKA for **MonaLisa Touch**[®] and V²LR.

DEKA developed the **SmartXide²** system capable of supplying energy with the dedicated pulse shape called **D-Pulse** or **DEKA-Pulse**, derived from dermatological experience, but taking into account the peculiarities of vaginal mucosa.

The D-Pulse consists of:

- an initial part with constant and high peak power for rapid and painless 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 to penetrate in the mucosa and stimulate it properly in-depth.

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

With **MonaLisa Touch**[®] the combined use of D-Pulse and DEKA fractional emission mode (DOT Therapy) guarantees effective and durable results and unrivalled advantages:

Safe. The DOT therapy laser energy is distributed in small spots (called DOTs) of 200 microns separated from each other by healthy tissue. This is important to achieve the right mechanisms of regeneration without side effects.

Minimally Invasive. The D-Pulse structure allows the right penetration of the CO₂ laser in the connective tissue. 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**[®] procedure is absolutely painless inside the vagina (no anaesthesia) and well tolerated on vulva. The treatment takes only a few minutes of application to get an important and deep stimulation.

Unique. **MonaLisa Touch**[®] is a trademark of DEKA. The first and only laser procedure to be used for reducing vaginal atrophy and laxity.

Effective. **MonaLisa Touch**[®] is the sole procedure demonstrated not only with clinical results, but also by histological and ultrastructural detailed studies.



Vulva appearance immediately after **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]

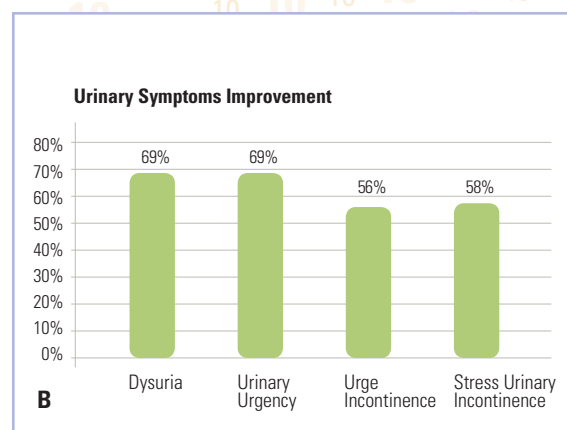
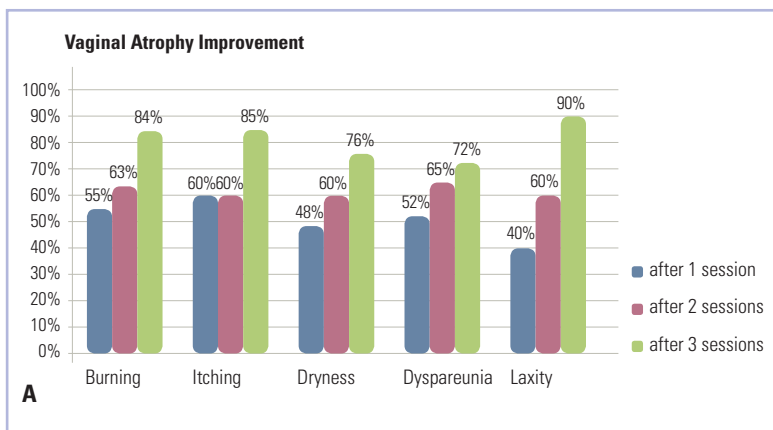


The full range of available probes for HiScan V²LR. Simply changing the probe, the scanner can be easily adapted to all patient's needs.

MONALISA TOUCH[®]: SPECIAL PROBES FOR A SPECIAL PROCEDURE

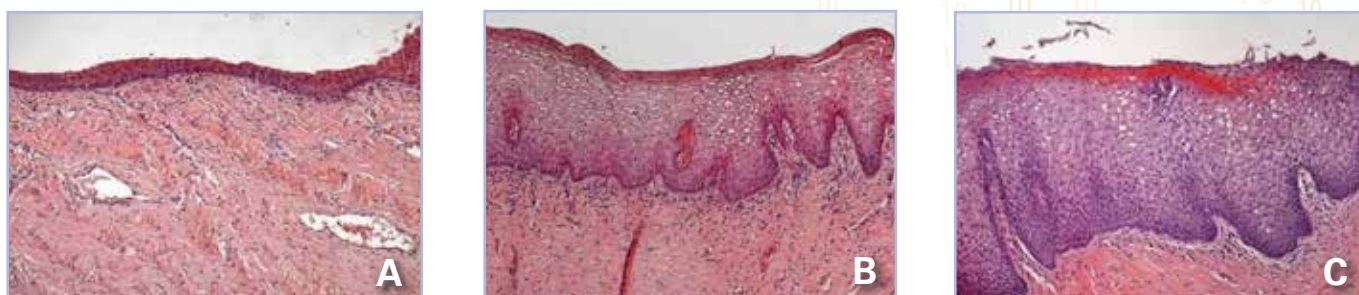
MonaLisa Touch[®] requires a special scanner system to deliver the fractioned laser energy on the vaginal mucosa. A wide range of autoclavable probes is available to perform the procedure depending on the specific patient needs:

- full-angle probe, useful even for the most atrophic vaginas. The CO₂ laser DOTs are distributed in a 360° angle frame thanks to the exclusive pyramidal-mirror assembly;
- single-angle probes for urinary incontinence. In choosing from among different shapes and sections make it suitable for treatment of various introitus of vaginas;
- vulvar probe for DOT Therapy of external genitalia.



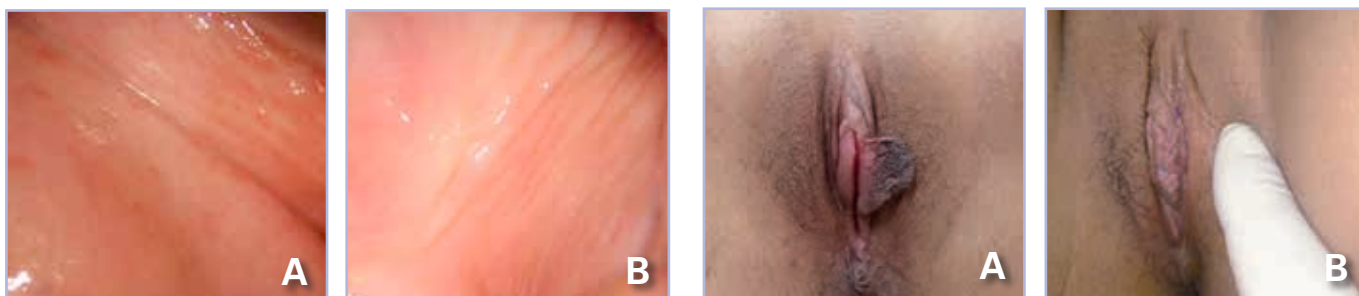
The graphs show the improvement (%) for the main symptoms of vaginal atrophy (A) and urinary incontinence (B) after 3 **MonaLisa Touch**® sessions. The study was carried out at the Department of Gynaecology of the San Raffaele Hospital on patients with symptoms of uro-genital atrophy. [Courtesy of S.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

MONALISA TOUCH®: HISTOLOGICAL STUDY



Histological preparation of vaginal mucosa section stained with haematoxylin and eosin (H&E). (A): Basal condition. The morphology indicates an advanced stage vaginal atrophy with the epithelium formed by few cell layers and no papillae. (B) & (C): The same patient one month after the 1st session (B) and after the 2nd session (C) with **MonaLisa Touch**® treatment. The much thicker epithelium and 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. Careggi University Hospital. Florence, Italy]

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

Scientific Bibliography Selection

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3. Is vaginal fractional CO₂ laser treatment effective in improving overactive bladder symptoms in post-menopausal patients? Preliminary results. A. Perino et al. Eur Rev Med Pharmacol Sci 2016 Jun; 20(12):2491-7.
4. Fractional CO₂ laser for vulvovaginal atrophy (VVA) dyspareunia relief in breast cancer survivors. A. Pieralli et al. Arch Gynecol Obstet 2016 Oct; 294(4):841-6. Epub 2016 May 12.
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6. Sexual function after fractional microablative CO₂ laser in women with vulvovaginal atrophy. S. Salvatore et al. Climacteric 2015 Apr; 18(2):219-25. Epub 2014 Dec 16.
7. Microscopic and ultrastructural modifications of postmenopausal atrophic vaginal mucosa after fractional carbon dioxide laser treatment. N. Zerbinati et al. Lasers Med Sci 2015 Jan; Vol. 30, No. 1:429-36. Epub 2014 Nov 20.
8. A 12-week treatment with fractional CO₂ laser for vulvovaginal atrophy: a pilot study. S. Salvatore et al. Climacteric Aug 2014; Vol. 17, No. 4:363-369. Epub 2014 Jun 5.

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 - 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 s		
Delay Emission Time	From 0.3 to 5 s		
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). About 150 factory stored protocols, upgradable by USB.		
Internal Database	Possibility of storing unlimited number of custom user's protocols.		
Control Panel	Wide LCD Colour Touch Screen (10.4")		
Accessories*	HiScan V ² LR 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	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 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.



This brochure is not intended for the market of USA.

SmartXIDE²
MonaLisa Touch[®]

**ATROPHIC VAGINITIS - VAGINAL LAXITY - STRESS URINARY
INCONTINENCE - POSTPARTUM PERINEAL TRAUMA
GENITAL FUNCTIONAL AND COSMETIC LASER SURGERY**

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