Z Y E

INSTRUCTIONS FOR USE

VYDENCE MEDICAL – Indústria e Comércio Ltda.

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1 PREFACE AND INITIAL CONSIDERATIONS

Congratulations on your ZYE® equipment purchase.

This manual is your guide to the safe, optimized, and correct usage of the equipment. Always keep this manual close to the equipment for your reference.

Initial Considerations:

Before installing or using this device, read the instruction manual closely and follow all directions. Consult this manual as much as necessary.

ZYE® Equipment must be used by trained professionals with the skills necessary for its use. Minimum qualifications vary between countries, and for this reason it is the user's responsibility to research further information on the skills required according to the competent local authorities.

This manual is a document accompanying the product. Partial or complete reproduction of this manual without VYDENCE medical's permission is prohibited.

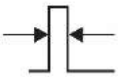
VYDENCE Medical reserves the right to alter and/or modify the equipment and parts of and/or the entirety of this instruction manual without warning.

Do not use this product without fully understanding its characteristics. Non-compliance with this recommendation could put the patient or the user at risk.

Strictly in the U.S.-Warning: Federal American laws restrict the sale of this equipment by or on a physician's orders.

2 SYMBOLISM

	Alternating Current
	Functional Ground
	Protective Ground
	Warning
	Required Action.
	Follow the instructions for use.
	Low priority alarm signal
	Connector for Remote Interlock Device.
	LASER Radiation
	Applied Part type BF (Degree of electrical protection)

	Turned on (with electrical energy)
	Turned off (without electrical energy)
	On (for equipment parts)
	OFF (for equipment parts)
	STOP (emergency stop).
	Equipment Disposal (Guideline 2002/96/EC)
	Connector to footswitch pedal
	Energy
	Pulse Width
	Pulse Repetition Frequency (rate)
	Keep dry

	Indicates transport position
	Maximum Stacking Stacking of this product is prohibited
	Moisture limits
	Temperature limits
	Fragile, handle with care.
	Keep away from the sun
	Do not lift the packaging toward that side
	High Intensity Light Source
	Electrical hazard symbol

3 TERMS, UNITS AND ABBREVIATIONS

Term	Definition
AC	Alternating current
Hz	Unit of frequency, Hertz
m	Unit of distance, meters
mm	Unit of distance, millimeters
cm	Unit of length, centimeter
µm	Unit of length, micrometer
nm	Unit of wavelength, nanometer
°C	Unit of temperature, degrees Celsius
s	Unit of time, seconds
ms	Unit of time, milliseconds
µs	Unit of time, microseconds
J	Unit of energy, Joules
J/cm²	Unit of energy density, Joules per centimeter squared
LED	Light-Emitting Diode
V.A.	Unit of apparent electrical power Volt Amperes.
NOHD	Nominal Ocular Hazard Distance
λ	Symbol of wavelength

4 PRESENTATION

Summary of the Application Specifications

Developed specially to attend to the practical needs and specific demands of physicians and patients, ZYE® joins the greatest parts of multiplatform technology for LASER and light systems. Incorporating the most recent advances in electronic optics, ZYE® is the newest and most efficient high technology treatment option, offering several therapeutic uses, improving safety and clinical efficiency in the same equipment.

ZYE® is sharing the latest LASER and light-based technology in the dermatology, vascular surgery, and gynecological fields, bringing the most versatility to the physician in the face of a growing demand in clinical practices. Inspired by the precepts and ideas of the most advanced multiplatform devices in the world, ZYE® is a highly versatile system with expansive electronic architecture and an advanced graphic interface.

The following is a presentation of the platform operating principles, with citations for the applicators referred to in each principle.

PRINCIPLES OF OPERATION

NON-LASER EMISSION SYSTEMS

IPL-SQ™: INTENSE PULSED LIGHT SYSTEM

The INTENSE PULSED LIGHT is a technology devoted to clinical treatments and cosmetics, with differential in the multidisciplinary of use indications and specificity of action in various chromophores (melanin, water, hemoglobin and methemoglobin, etc.) and depth of tissue. With a single applicator, it is possible to offer a wide range of therapeutic options that encompasses more than 30 signs, in accordance with the cut filter and spectrum chosen.

The basis of the system of INTENSE PULSED LIGHT uses a broad-spectrum high intensity discharge (HID) lamp emission (~400-1200 nm), driven through a micro controlled system that combines time and electric current. The structure of the internal cooling of the lamp, performed by the movement of water, also acts on the sapphire, which delivers the optical power and is in contact with the patient's skin.

Thus, the IPL-Sq™ APPLICATOR can be considered one of the most advanced systems of INTENSE PULSED LIGHT AVAILABLE ON THE MARKET:

Energy Optimization of pulse with square discharge (Square-Wave™ Pulse, IPL-Sq™): acting differently among the traditional IPL appliances (where the discharge energy is free and, consequently, the energy delivered at the beginning of the time of pulse is greater than the one delivered at the end). The Square-Wave™ Pulse (IPL-Sq™) technology promotes a micro processed and controlled energy delivery, which is released in a uniform manner throughout the pulse. This shooting mode: 1. prevents the formation of critical risky areas that, in practice, can cause unwanted effects; 2. ensure the emission of energy with constant and uniform spectrum throughout the pulse, generating better therapeutic results; and 3. provides much more safety and effectiveness for the procedure.

Sapphire spot, with intense cooling - Contact-Cooling™: The benefits of cooling the spots (applied part in contact with the patient's skin) in systems of laser and light are a consensus fully adopted among users of these Medical devices.

Through the intense cooling of the spot, the procedure becomes much safer and more effective, since, in addition to promoting a high degree of comfort for the patient, also protects the epidermis of the region during the shooting. ZYE® also provides the control of cooling up to five (5) levels of intensity.

A high rate of recurrence: the speed of repetition between pulses in the systems of laser and light is crucial to achieve the speed of the procedure. Within this concept, ZYE® has a power source especially designed to obtain high repetition rates.

Wide application area or spot size: when working on a wide application area (12 x 40 mm), ZYE® promotes greater speed, agility and cost savings in the procedures, since it is necessary less shots for the effective treatment of a region. Besides these advantages and benefits, the clinical literature states that large areas of application are more beneficial in the procedures, thus reducing, to some extent, the processes of scattering of light in the tissue and promoting greater penetration.

Cutting Filters with slice system/plugin: ZYE® also has an intelligent system of replacement of the cutting filters. Different from most devices available on the market, in which to change the filter you must also replace the entire application module, ZYE® uses a quick and easy replacement system (plug-in), at any time, without the need to turn off or restart the appliance.

Spots specially developed for localized lesions VascuSpots™: in addition to the spot size with 12 x 40 mm, ZYE® has spots as available fittings with dimensions of 12 x 12 mm and 8 mm, which allow for greater ease and precision for vascular treatments of localized regions, such as the nasal wing and back of the hands.

INTENSEIR®: HIGH POWERED INFRARED LIGHT

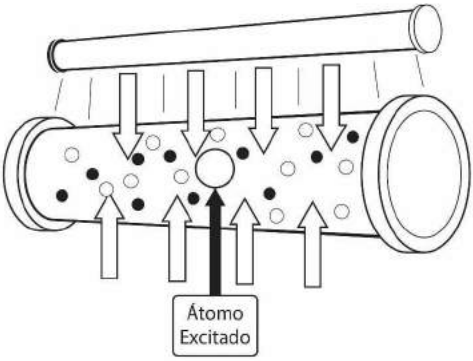
The APPLICATOR IntenseIR® has skin tightening as its main indication through the use of infrared light of high power, through the conversion of light energy into heat, reaching the subcutaneous tissue and inducing the neocolagenesis. The cutting filters, specially developed for absorption and reflection, combined with the use of a halogen bulb and the cooling system of sapphire, before and after the discharge of energy (pre/post-cooling), intenseIR™ offers a widely effective treatment.

It offers applications with different techniques - static and in-motion - intenseIR™ combines two different methods of treatment in a single applicator.

LASER ENERGY PUMPING SYSTEMS

The LASER system specifically designed for ZYE® LASER has a broad-spectrum xenon lamp as its base which, during the light emission, excites the active medium responsible for LASER beam emission. Depending on the wavelength, a different type of crystal (active medium) and dopant are used. The xenon lamp is activated with emission control that guarantees the perfect timing between the shot and the electrical current transmission, offering stability, safety, and system reliability.

Therefore, the LASER beam emission happens during a shot of a specific wave determined by light-stimulated emissions that are reflected in partiality or totality in mirrors of the optic cavity while the energy emitted keeps itself directly correlated to the energy emitted by the xenon lamp.



Example of the optic cavity: 1. Xenon lamp; 2. crystal or active medium directly responsible for the LASER beam generation in the specified wavelength;

The LASER beam emitted by the crystal crosses through a very specific optical set, allocated in each applicator that also determines the final geometry (a collimated

or fractionated beam, and the diameter of the output for each application. The optic set is refrigerated in water.

FRACTIONAL LASER SYSTEMS

The fractional photothermolysis is, in fact, one of the most recent improvements in terms of LASER technology used for the purposes of skin resurfacing. The principle of operation is based on the formation of microscopic treatment zones (called MTZ) through the division of collimated LASER BEAM in multi spot delivery points simultaneously. The formation of the MTZ, produced by lenses specially designed for the better use of the beam and energy emitted, allows for a high fluency flow to be concentrated in a single spot, promoting the induction of the heat while preserving the adjacent and non-treated regions in order to promote the regeneration of the tissue.

LONGPULSE® SYSTEM: ND:YAG LASER AT 1064 NM

The effectiveness of the Nd:YAG laser 1,064nm LongPulse™ in vascular treatments is a consensus adopted long ago by the clinical and scientific literature - a technology known for its broad ability to treat deep and superficial lesions in a completely non-invasive manner and with little or no discomfort or downtime. The high penetration of the laser beam in the tissue and its absorption by the hemoglobin result in uniform distribution and constant energy, which ensures the reach of treatment even in more profound vessels. The longer pulse widths of LongPulse™ result in heating extended chromophore-target, increasing the internal temperature of the vessels and the consequent closure of the same. The LASER LongPulse™ penetrates the tissue, where it is absorbed by hemoglobin. The heat generated by the absorption of energy heats the hemoglobin, resulting in coagulation and subsequent constriction of the vessel. The treated vessel degenerates, disappearing from the surface of the skin. The elimination of the residual material is performed through the process of phagocytosis.

ACROMA® SYSTEM: ND: YAG LASER Q-SWITCHED AT 1064-532 NM

ACROMA-QS™ brings a new therapeutic option for the safe and effective treatment of vascular lesions, removal of pigments, tattoos and melasma. This technology is widely used in dermatology.

ACROMA-QS™ combines the technology of the latest generation of Q-switched LASERs and offers a platform for differentiated treatments, with wavelengths at 1064/532 nm, providing the physicians and patients with the ideal combination of

instantaneous power and short pulse duration (20 ns), causing the chromophore-target to be fragmented by the photomechanical effect from the shock wave, derived from the sudden energy delivery

PRODEEP®: FRACTIONAL LASER SYSTEM ND: YAP IN 1340 NM

The Nd: YAP ProDeep® LASER reaches the subdermal layers and stimulates collagen, acting directly on the relative indications for non-ablative fractionated LASER treatment.

The most effective LASER tissue penetration, compared to other equipment on the market, assures treatments with deeper action. The relation between the density of the energy applied and the ProDeep® technology increases the LASER work on collagen, providing a new look and feel of firm and well-defined skin.

GOSMOOTH®: LASER SYSTEM ER: GLASS IN 1540 NM

• Specially designed to meet an increasingly demanding market for high technology therapeutic indications of and with applications that are safe and effective to treat the most diverse conditions related to the photoaging of tissue, the GoSmooth™ APPLICATOR brings a distinctive concept and a new option for the treatment of wrinkles, scars, skin irregularities, striae and melasma.

DUALMODE®: FRACTIONAL LASER SYSTEM ER: YAG IN 2940 NM

The LASER DualMode® works at a 2940 nm wavelength for localized tissue ablation-in a fractionated or collimated way- and the exclusive system of coagulative combined pulses (DualMode® system with double shot) depending on the time of the pulse choses (300 and 500 µs for purely ablative pulses and 1 to 5 ms for coagulative combined pulses.) This technology allows the applicator to provide a deeper and more effective rejuvenation treatment with tissue vaporization and a greater residual thermal zone formation using coagulative pulsing and inducing neocolagenesis.

INTERNAL CAVITY LASERS

ZYE ALEX®: ALEXANDRITA 755 NM

ZYE ALEX® presents the newest innovation in versatility and system technology, with an expandable platform bringing an exclusive offer of Alexandrite 755 NM LASER cavity, offering physicians the gold standard in wavelength for progressive removal and hair definition, in addition to supporting treatment of pigmentary and vascular lesions.

ZYE YAG®: ND: YAG 1064 NM

ZYE YAG® presents the newest innovation in versatility and system technology, with an expandable platform that brings an exclusive offer of the LASER cavity Nd: YAG in 1064 nm, offering physicians the gold standard in wavelength treatment of various vascular lesions (face and lower limbs), rejuvenation, and LASER toning for all photo types and conditions of tanning, progressive hair removal, and suggestions for onychomycosis and the newest INTENSE mode for localized fat and skin tightening on the body and neck.

INDICATIONS FOR USE

IPL-SQ™: INTENSE PULSED LIGHT

- The IPL-Sq (390 nm) is indicated for the treatment of of leukoderma, including vitiligo (acquired leukoderma). The treatment of psoriasis, atopic dermatitis (eczema), and seborrheic dermatitis. The treatment of inflammatory acne (acne vulgaris).
- The IPL-Sq (400 nm) is indicated for the treatment of moderate inflammatory acne vulgaris; for the treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles); for the treatment of benign cutaneous lesions including, scars and striae; for the treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, Poikiloderma of Civatte, leg veins and venous malformations. Use on all skin types (Fitzpatrick I-VI).
- The IPL-Sq (515 nm) is indicated for the treatment of moderate inflammatory acne (acne vulgaris); for the treatment of benign pigmented epidermal and cutaneous lesions including scars, striae, dyschromia, hyperpigmentation, melasma, ephelides (freckles), lentigines, nevi, melasma, and cafè-aulait macules; for the treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations; for the removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair growth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime. Use on Fitzpatrick skin types I-V.

- The IPL-Sq™ (540 nm) is intended for use in the treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, and cafe-au-lait macules; for the treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations; for the treatment of cutaneous lesions including scars and striae; for the removal of unwanted hair to effect stable long-term or permanent hair reduction. Permanent reduction in hair growth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime. Use on all skin types (Fitzpatrick I-VI).
- The IPL-Sq™ (580 nm) is intended for use in the treatment of moderate inflammatory acne vulgaris; for the treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma and ephelides (freckles); for the treatment of face and body vascular and pigmented lesions; for the treatment of cutaneous lesions, including scars and striae; for the treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations; for the removal of unwanted hair to effect stable long-term or permanent hair reduction. . Permanent reduction in hair growth is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6,9 and 12 months after the completion of a treatment regime. Use on all skin types (Fitzpatrick I-VI).
- The IPL-Sq™ (640 nm) is indicated for the treatment of mild to moderate inflammatory and pustular inflammatory acne vulgaris; for the treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and cafe-au-lait; for the treatment of cutaneous lesions including scars and striae; for the treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations; for the removal of unwanted hair, for stable long term or permanent hair reduction (permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen). Use on all skin types (Fitzpatrick I-VI), including tanned skin.
- The IPL-Sq™ (695 nm) is indicated for the removal of unwanted hair, for stable long term or permanent hair reduction (permanent hair reduction is defined

as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regimen). Use on all skin types (Fitzpatrick I-VI), including tanned skin.

INTENSEIR•: HIGH POWERED INFRARED LIGHT

- The IntenseIR® applicator is indicated for the subdermal heating for the stimulation of collagen for the treatment of sagging and skin tightening of the tissue, with therapeutic indication for face and body.

LONGPULSE•: LASER SYSTEM ND: YAG EM 1064 NM

The LongPulse™ Nd: YAG 1064 nm laser is intended for removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime; for the treatment of pseudofolliculitis barbae (PFB); for the treatment of benign vascular lesions: Port wine stains; Hemangiomas; Warts; Superficial and deep telangiectasias (venulectasias); Reticular veins (0.1-4.0 mm dia.) of the leg; Rosacea; Venus lake; Leg veins; Spider veins; Poikiloderma of Civatte; Angiomas; for the treatment of benign pigmented lesions: Lentigos (age spots); Solar lentigos (sun spots); Cafè-au-lait macules; Seborrheic keratoses; Nevi and nevus of Ota; verrucae, skin tags, keratoses; for the treatment of benign cutaneous lesions: warts, scars, striae; for the treatment of pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments; the non-ablative treatment of facial wrinkles: periocular wrinkles, perioral wrinkles, laser skin resurfacing procedures for the treatment of acne scars, wrinkles, reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

- The applicator Nd: YAG 1.064 nm LongPulse is indicated for podiatry in periungual and subungual warts, plantar warts, neuromas; for treatment of onychomycosis.

ACROMA•: LASER SYSTEM ND: YAG Q-SWITCHED IN 1064-532 NM

- The ACROMA-QS™ 1064 nm is indicated for treatment of benign vascular lesions: port wine stains; hemangiomas; warts; superficial telangiectasias (venulectasias); rosacea; Poikiloderma of Civatte; angiomas; benign cutaneous lesions: warts; scars; striae; benign pigmented lesions: lentigos (age spots); solar lentigos (sun spots); cafe-au-lait macules; seborrheic keratoses; nevi and Nevus of Ota; chloasma; verrucae; skin tags; keratoses; the removal of black, blue or green tattoos (significant reduction in the intensity of black and/or blue/black tattoos); plaques; pigmented benign lesions to reduce lesions' size for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments; the non-ablative treatment of facial wrinkles, including periocular wrinkles; perioral wrinkles; laser skin resurfacing procedures for the treatment of acne scars; wrinkles; reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.
- The ACROMA-QS™ 532 nm is indicated for tattoo removal: light blue, yellow, red; green; vascular lesions: Hemangiomas (port wine stains/birthmarks, cavernous, cherry, spider, hemangiomas); angiomas (cherry, spider); telangiectasias; spider nevi; benign pigmented lesions: cafe-au-lait macules; lentigines (senile and solar); freckles (ephelides); nevi; nevus spillus; Nevus of Ota; Becker's Nevi; other benign pigmented cutaneous lesions: verrucae; skin tags; keratoses; plaques.

PRODEEP•: FRACTIONAL LASER SYSTEM ND: YAP EM 1340 NM

- The non-ablative 1340 nm ProDeep™ Nd: YAP laser applicator is intended for use in the coagulation of soft tissue, skin resurfacing procedures as well as the treatment of fine lines and wrinkles, melasma, striae, acne scars and surgical scars.

GOSMOOTH•: SISTEMA LASER ER: GLASS EM 1540 NM

- The non-ablative 1540 nm GoSmooth™ Er: Glass laser applicator is intended for use in the coagulation of soft tissue, skin resurfacing procedures as well as the treatment of fine lines and wrinkles, melasma, striae, acne scars and surgical scars.

DUALMODE•: FRACTIONAL LASER SYSTEM ER: YAG EM 2940 NM

The DualMode Er: YAG 2940 nm applicator is indicated for the ablation of tissue (skin, cutaneous and subcutaneous tissue, soft tissue and mucosa including oral and intravaginal mucous).

- DERMATOLOGY AND PLASTIC SURGERY: fractional resurfacing; wrinkle treatment; epidermal nevi; actinic cheilitis; keloids; warts; removal of LASER from benign epidermal lesions, including cysts and superficial skin lesions; keratoses; treatment of acne scars.
- GENITOURINARY AND GYNECOLOGY: treatment of lesions of the external genitalia and anus, penis and scrotum; vulvar lesions, polyps, and familiar polyps of the colon; cysts and condyloma.
- PODIATRY, in the treatment of warts, plantar verrucae, large mosaic verrucae and matrixectomy.
- DualMode, ATHENA and INLIFT applicator accessories are indicated for coagulation of the skin, soft tissues and mucous, including the oral and intravaginal mucous.

ZYE ALEX•: ALEXANDRITA 755NM

The ZYE ALEX® system is indicated for the removal of unwanted hairs and their gradual and / or permanent reduction; epidermal lesions (benign pigmentary lesions), such as solar melanoses, hyperpigmentation, melasma and ephelides; non-ablative rejuvenation, with the attenuation of fine lines and wrinkles; treatment of benign skin lesions with vascular component, including port wine stains, hemangiomas, facial and body telangiectasia, erythematous rosacea, angiomas, spider angiomas, poikiloderma of Civatte and superficial venous malformations.

ZYE YAG•: ND: YAG 1064NM

The ZYE YAG® long-pulse applicator is indicated for the coagulation and hemostasis of vascular and epidermal tissue lesions, including the treatment of telangiectasias, superficial varicosities, angiomas and spider angiomas, hemangiomas, rosacea and nevi. It is also indicated for the non-ablative treatment of facial wrinkles and stretch marks, and gradual or permanent removal of unwanted hair, especially in high phototypes (Fitzpatrick V-VI). In DYNAMICS® mode, the general indications for treatment include: thermal peeling (for reduction of fine lines, improvement of skin texture, reduction of pores, control of rosacea) and treatment of onychomycosis. In INTENSE® mode, ZYE YAG® is able to perform transdermal treatments for localized fat reduction and skin tightening.

PATIENT POPULATION

Ages:	Adolescents, adults, and elderly.
Weight:	No known restrictions
Health condition:	Healthy
Nationality:	Diversified
Patient Status:	The patient cannot operate the machine. Sensitivity to treatment, patient must be awake to respond to operator's questions

THE INTERACTION WITH THE BODY

- Skin or tissue surface;
- Natural holes, such as intraoral mucosa and vagina;
- Skin or target tissue in healthy conditions;

INTENDED CONDITIONS OF USE

Environment:

- Medical or aesthetic clinics
- Equipment isolated in a room only with personnel involved in treatment
- See section on "Electromagnetic Compatibility" in this Instruction Manual
- Visibility conditions: Distance from the screen up to 1 m
- Angle of vision: normal on the display ± 50° Physical:
- Temperature: between 20 °C and 25 °C
- Relative humidity: between 40 % and 60 %
- Maximum operational altitude: 2000 m above sea level
- Frequency of use: Continuous and daily.
- Mobility: Equipment with mobility through rotation. Equipped with front and back rings to assist with mobility.

USER PROFILE

- Only qualified professionals who can master the necessary techniques for its use should use it. The qualification of the user varies from country to country. Please, check with the local regulatory agencies;
- The user should, at least, read and understand the accompanying documents of the equipment, understand the interactions of the treatment with the target tissue;
- If the user does not have clinical experience with similar equipment, training is recommended at the training center of the company or with the authorized commercial representative;
- Read English;
- The user should have perfect vision or eye correction;
- The user should not have disabilities that prevent the implementation of procedures.

5 SAFETY

WARNING: After use by authorized personnel, turn off the equipment or lock the screen by pressing the button indicated by a padlock.

WARNINGS:

- Do not remove any labels from the equipment
- ZYE® equipment is electromedical equipment that can cause safety hazards to the operator and the patient under certain circumstances, especially during installation, use, operation, and inadequate maintenance.
- Only use technical support services of the manufacturer or agents authorized and credentialed BY THE MANUFACTURER.

The ZYE® system was developed to adhere to current national and international regulations applied to minimize electrical and radiation hazards.

Because of the typical intrinsic hazards of these devices, as well as the system having been developed, constructed, installed, and used according to established safety regulations, complete safety will only be completed if the equipment is used correctly and carefully.

The CRDH of the FDA and LASER professionals recognize the standards of LASER's Safe Use from the American National Standards Institute (ANSI) as excellent means of establishing and maintaining a safe LASER program. In addition, the Occupational Safety and Health Administration (OSHA) with the Joint Commission Accreditation, Healthcare, Certification (JCAHO) use these standards as guidelines for inspections and audits in addition to their own rules. ANSI Regulation Z136.3 for Safe Use of Lasers in Healthcare Devices has specific guidelines for LASER use. The ANSI Regulation Z136 is the primary source for more detailed information regarding LASER safety. The two regulations must be used when operating this system.

ZYE® has Class IV LASERS. The LASER energy is emitted through the treatment tip. Precautions must be taken to ensure that no accidental wounds are inflicted.

ANSI Regulation Z136.1 uses the definition of a Nominal Hazard Zone, or NHZ. The NHZ is an indication that at a certain distance, the LASER can exceed MPE – Maximum Permissible Exposure and damage the eyes. People in the NHZ under direct or reflective exposure conditions to the LASER can be exposed to levels of radiation above the MPE.

ANSI regulations contain instructions on the protective and administrative procedures of a LASER safety program as well as a sample of the Standard Operating

Procedures. Please follow the recommended ANSI regulations, particularly the use of special safety glasses.

ANSI Z136 and 136.3 contain diagrams and suggestions for how to appropriately prepare a LASER treatment room.

The client and/or operator agrees to take full responsibility and complete understanding and agrees to obey the local, state, and federal laws, rules, and regulations when operating this system.

It is recommended that, in addition to safety training for operating LASER emission and non-LASER equipment, that the operator/institution adopts a training and safety program as described in the latest ASNI Z136.3 Standards, the National American Standards for the Safe Use of LASER healthcare machines.

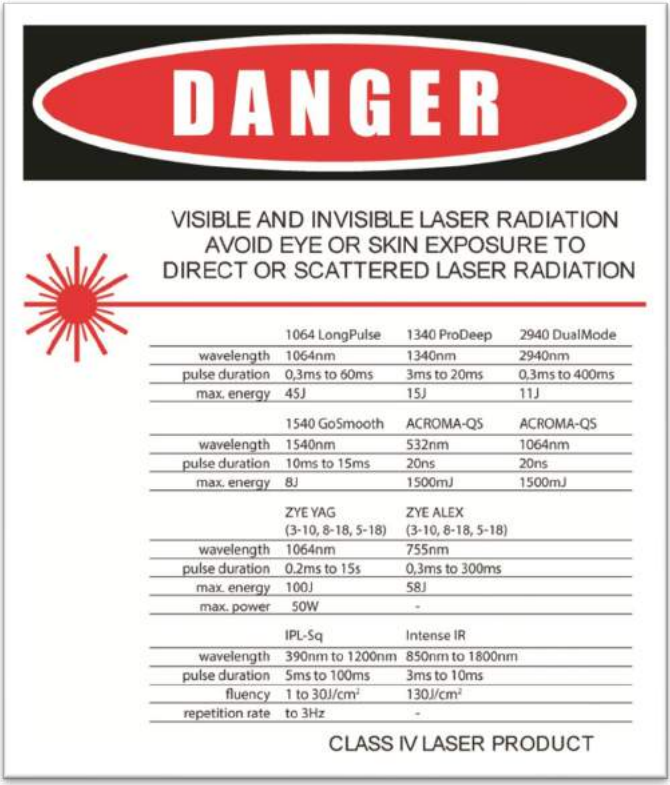
Professionals must consider the following treatment options as well as other available actions:

- A highly regarded treatment;
- Practical training;
- Presence at courses administered during classes or demonstrations
- Continuous medical education programs;
- Credentialed programs.

All physicians managing ZYE®, including their support team of nurses or other healthcare professionals, must complete the treatment program that can include subjects such as basic LASER physics, LASER safety, tissue interaction, LASER operational procedures, LASER definition procedures, potential hazards, demonstrations, and practical experience.

Alternatively, the IEC TR 60825-8:2006 technical report provides orientation to LASER safety procedures that must be followed in medical practice. We recommend consulting this document and adhering to the specified measures. In Section 3.1, the document requires that the organization responsible appoints a LASER Safety Representative and defines their responsibilities.

Treatment rooms must be clearly marked to avoid unexpected entry during treatment. The label shown below must be displayed in the external area of each entrance of these areas to indicate the presence of a LASER and non-LASER light energy source within the environments.



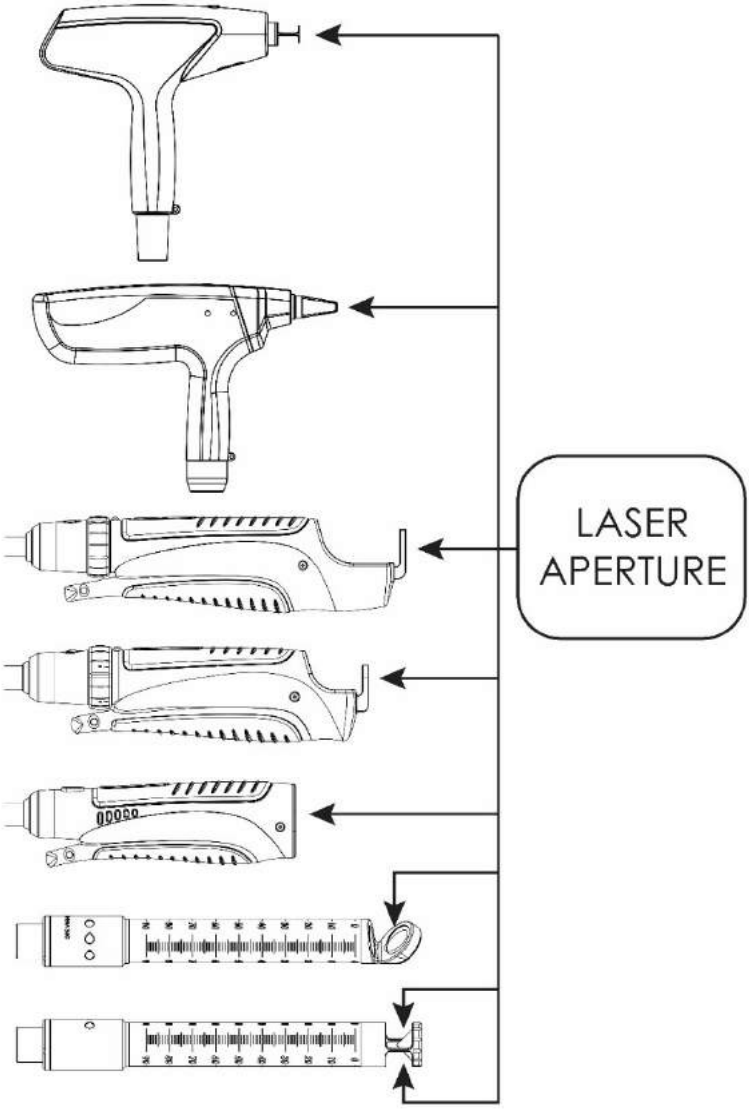
	1064 LongPulse	1340 ProDeep	2940 DualMode
wavelength	1064nm	1340nm	2940nm
pulse duration	0,3ms to 60ms	3ms to 20ms	0,3ms to 400ms
max. energy	45J	15J	11J

	1540 GoSmooth	ACROMA-QS	ACROMA-QS
wavelength	1540nm	532nm	1064nm
pulse duration	10ms to 15ms	20ns	20ns
max. energy	8J	1500mJ	1500mJ

	ZYE YAG (3-10, 8-18, 5-18)	ZYE ALEX (3-10, 8-18, 5-18)
wavelength	1064nm	755nm
pulse duration	0.2ms to 15s	0,3ms to 300ms
max. energy	100J	58J
max. power	50W	-

	IPL-Sq	Intense IR
wavelength	390nm to 1200nm	850nm to 1800nm
pulse duration	5ms to 100ms	3ms to 10ms
fluency	1 to 30J/cm^2	130J/cm^2
repetition rate	to 3Hz	-

OPTICAL HAZARDS: LASER



WARNINGS:

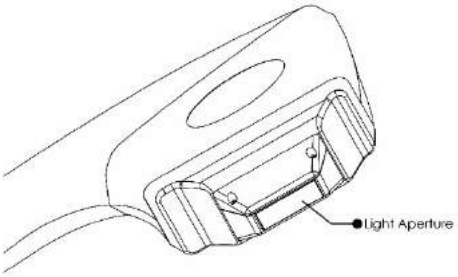
- Do not use safety glasses that do not meet to the specified requirements.
- Closing one's eyes doesn't provide enough protection against the LASER light incidence
- Never look directly at the applicator light apertures, particularly at those marked as LASER Aperture, even if using protective eye gear.
- Put all equipment in "STANDBY" mode when not in use (when in "STANDBY" mode, the laser beams cannot be inadvertently activated.)

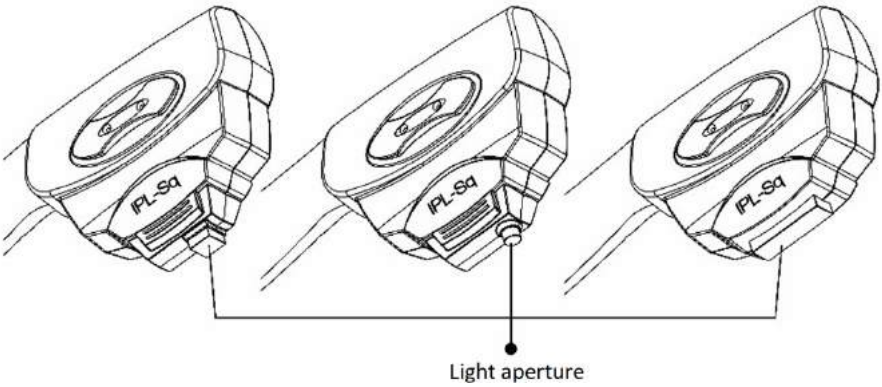
- LASER light can cause damage and permanent eye lesions. Pulsing light generated by these systems contains invisible and visible light and can cause permanent vision damage. Never look directly inside the applicator(s) even when using protective eyewear. Never look directly at the LASER beams, pulsating light, infrared light, or at a diffusing light originating from a metallic or reflected surface.
- VYDENCE Medical is responsible exclusively for the protective eyewear delivered with the unit and deemed appropriate for the wavelength being used.
- There must be a controlled zone with access restricted to trained personnel who are familiar with LASER use and safety procedures.
- In areas where the LASER is being used, the area must remain free of reflective or inflammable materials.
- For each applicator used, whether it is LASER or non-laser, the correct type of eyewear must be used. Please ensure that the operators and patients are using eyewear with the correct specifications as described in the Safety Items.
- All people in the room during treatment must use eye protection.
- Limit the entry of people int he room and take precautions against accidental entry into the environment.
- Cover the windows and other openings to avoid the inadvertent escape of LASER light.
- Position the equipment to ensure quick access to the controls and the emergency switch.
- Direct the activated LASER only at the area receiving treatment.

OPTICAL HAZARDS: NON-LASER LIGHT

Light emitted by the IPL-sq® and intenseIR® can damage human eyes in the case of accidental shots or indirect continuous exposure to radiation.

All individuals present in the equipment operating environment must correctly wear protective eyewear specified for each wavelength.





WARNINGS:

- Do not use protective glasses that do not meet the specified requirements.
- Just closing the eyes does not provide enough protection against light incidence.
- Never look directly at the applicator light apertures even if wearing protective eyewear.
- Put the equipment in "STANDBY" mode when not in use (when in "STANDBY" mode, the light beams cannot be inadvertently activated.)

- Light emitted can cause damage and permanent ocular lesions. Pulsating light generated by these systems contains visible and invisible light and can cause permanent damage to vision. Never look directly at the applicators even when wearing protective eyewear. Never look directly at a pulsating light beam or infrared or a diffused light originating from a metallic or reflective surface.
- VYDENCE Medical is responsible strictly for the protective eyewear to be delivered with the unit and appropriate for the wavelength used.
- There must be a controlled zone with access restricted to personnel who have been trained and are familiar with the equipment use and safety procedures.
- Areas where the equipment is being used must remain free of inflammable or reflective materials.
- The correct protective eyewear must be used for each applicator used. Please ensure that everyone is using eyewear with the correct specifications according to the description in the Safety Items.
- Everyone in the room during treatment must wear protective eyewear.
- Limit the entry of people in the room and take precautions against inadvertent entry into the environment.
- Cover the windows and other openings to avoid the inadvertent escape of light.
- Position the equipment for easy access to the controls and the emergency switch.
- Only direct the light emitted at the area being treated.
- Clearly mark the treatment rooms to avoid unexpected entry during treatment. The label below must be displayed on the external part of each entry of these areas to indicate the presence of a light emission source within the area.

RESPIRATORY HAZARDS

During ablative LASER application, such as the 2940 DualMode®, vaporized tissues generating a smoke that could contain viable DNA or virus particles as reported in the literature that could deposit themselves in the respiratory routes.

WARNING: LASER smoke can contain viable DNA or virus particles. The use of a smoke evacuator is recommended as well as a protective mask for the operator.

FIRE HAZARDS – INTENSE PULSED LIGHT

Light emission does not present significant danger in terms of igniting non-metallic materials. However, we recommend that the area of operation remains free of inflammable objects such as paper, cotton, wool, plastic, and wood.

FIRE HAZARDS – LASER

When LASER beams come into contact with a surface, this surface can absorb the LASER energy increasing the surface temperature, whether that surface is skin, hair, or any flammable substance that can present a risk of fire or explosion. Operators must take the following precautions to prevent LASER-induced fires:

- Use materials, solutions, gasses, non-flammable substance in anesthesia, skin preparation, in instrument cleaning and disinfection.
- Be especially careful when using oxygen or in oxygen-rich environments. Oxygen accelerates gravity and the extent of a fire.
- Maintain a minimum amount of combustible materials (for example alcohol) in the treatment room). If the treatment requires the use of gauze, first soak it in water.

WARNING: When the LASER is used near flammable materials, gasses, solutions, flammable or oxidable anesthetic gasses, adhesive solvents, inflammable solutions used in cleaning or an oxygen-rich environment, this presents a fire or explosion hazard.

ELECTRICAL HAZARDS

ZYE® has high voltage in its system. If the equipment is not properly turned off or declines damage the applicator, do not use the equipment and contact technical support.

Do not use electrical extension cords or share the outlet with any other equipment.

Only authorized technicians may open the equipment. In case of questions or concerns, contact VYDENCE Medical Technical Support.

Grounding is by the central outlet pin connection. Verify with an electrician that there is solid ground in the electrical grid (see Installation Requirements section).

Do not turn on the system if you observe water leaving the equipment or the applicator. If you see water leaving the equipment or applicator with the system turned on, turn the system off immediately.

WARNING: Do not use adaptors or extension cords when turning on the device.
WARNING: To avoid risking electrical shock, the equipment must be connected to a power supply system with grounding for protection.

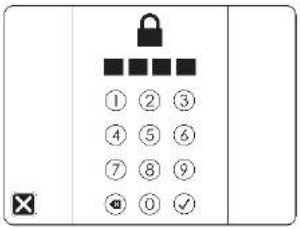
MECHANICAL HAZARDS

Move the equipment slowly and carefully to avoid causing damage.

Handle the applicator carefully and avoid hitting it or dropping it. If it is not in use, leave the applicator in the proper holder. If it is disconnected from the equipment, return it immediately to its packaging kit.

SAFETY ITEMS

ACCESS PASSWORD



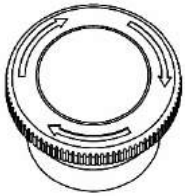
Controls the system's electrical activation. Only authorized personnel with the password may initiate the system. Keep the password confidential to avoid use by unauthorized personnel. The original manufacturing password is "0000.

*Code to reset the password is: "9876"

**If the user loses their password, this code must be used to reset the password.*

WARNING: Lock the system to prevent unauthorized use.

EMERGENCY STOP



Immediately disables the LASER or intenseIR® activating systems

SAFETY GLASSES

The use of safety glasses is required for all people present in the procedure room.

Safety glasses provided with each model comply with the required user protection regulations described in EN 207 and IEC 60825-1.

- **Patient Safety Glasses**

Specifications: The safety goggles should be made of metallic material, totally opaque to passage of light, and cover the eyes completely.

Identify the goggles provided by Vydence: stainless steel ring with silicon case for the patient comfort. Specification of eye protection 315-1400 D L6 + IR L7.

Comments: Protection Goggles are not suitable for use on eyelids and periorbital regions.

VYDENCE Code: 007277

- **Glasses for Intense Pulsed Light (IPL-sq™)**

The safety Goggles for this applicator must have, at least, an optical density of 3 (OD≥3).

Protection Goggles Model "3PL#35" provided by the company.

VYDENCE code: 4201

- **Glasses for infrared (IntenseIR™)**

Safety glasses for this applicator must have a minimum optical density of 3 (OD≥3).

Glasses Model “3PL#35” provided by the company.

VYDENCE Code: 004201

- **Glasses for LASER Nd: YAG 1064nm (1064 LongPulse®)**

Safety glasses for this applicator must have a minimum optical density of 5,3 OD≥6 (according to IEC 60825-1) for a 1064 nm wavelength.

Glasses model "YG3#38", with specifications for >950-1070nm OD7+ and >950-1070nm D L5 + IR L7, are provided by the company.

VYDENCE Code: 008110

- **Glasses for LASER Nd: YAP 1340 nm (1340 ProDeep®)**

Safety glasses for this applicator must have a minimum optical density of 4,5 OD≥5 (according to IEC 60825-1) or I L6 (according to EN 207) for a wavelength of1340nm.

Glasses model "IRD#38", with specifications for >950-1400nm OD7+and >820-1400 D L5 + IR L6, provided by the company.

VYDENCE Code: 008109

- **Glasses for LASER Er: YAG 2940 nm (2940 DualMode®)**

Safety glasses for this applicator must have a minimum optical density of 2 OD≥2 (according to IEC 60825-1) or I L2 (according to EN 207) for a 2940nm wavelength.

Glasses model "ERB#38", with specifications for 2940nm OD6+ and 27802940 + 10600 DI L2, are provided by the company. VYDENCE Code: 008108

- **Glasses for LASER Er: Glass 1540 nm (1540 GoSmooth®)**

Safety glasses for this applicator must have a minimum optical density of 2 OD≥2 (according to IEC 60825-1) or I L3 (according to EN 207) for a wavelength of 1540nm.

Glasses model "IRD2#38", with specifications for 830-1700nm OD3+ and DIR L3, are provided by the company.

VYDENCE Code: 009254

- **Glasses for LASER 1064nm Q- Switched (ACROMA®)**

Safety glasses for this applicator must have a minimum optical density of 3 OD≥3 (1064nm) and 5 OD≥5 (according to IEC 60825-1) or R L6 (according to EN 207) for wavelengths between 1064nm and 532nm.

Glasses model "DBY#38", with specifications >980-1064 OD7+ IRM L7 and >315-534 OD7+ IRM L6, are provided by the company.

VYDENCE Code: 010502

- **Glasses for LASER Nd: YAG 1064nm (ZYE YAG®)**

Safety glasses for this applicator must have a minimum optical density of 5,3 OD≥6 (according to IEC 60825-1) or I L7 (according to EN 207) for a wavelength of 1064nm.

Glasses Model "YG3#38", with specifications for >950-1070nm OD7+ and >950-1070nm D L5 + IR L7, are provided by the company.

VYDENCE Code: 008110

- **Glasses for LASER Alexandrite 755nm (ZYE ALEX®)**

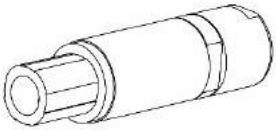
Safety glasses for this applicator must have a minimum optical density of OD7 (according to IEC 60825-1) or I L7 (according to EN 207) for a wavelength of 755nm.

Glasses Model "AXX: EN207", with specifications for >720-810nm OD7+, are provided by the company.

VYDENCE Code: 016962

WARNIGN: VYDENCE Medical is responsible strictly for the protective glasses provided with the equipment and when used according to instructions in this manual.

REMOTE INTERLOCK CONNECTOR (INTERLOCK)



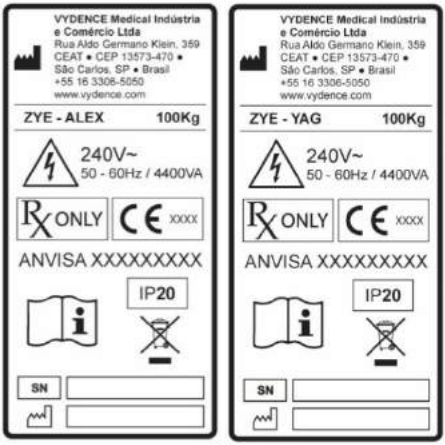
The interlock is a safety measure which, when used by means of wiring to an external portal switch, allows system shutdown even if the door is open.

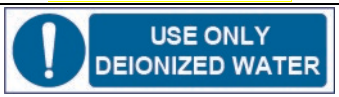
In any event, if the system is not installed, the jack in the figure to the left must be installed for the equipment to function.

WARNING: Each user intending to use this resource in their application must contact the company or distributor to provide the proper wiring diagram.

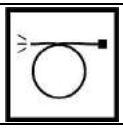
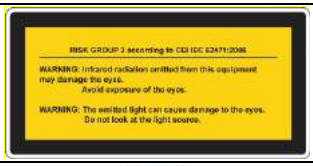
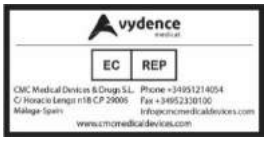
SAFETY LABELS

LABEL MAP

1		Equipment identification label with: includes • Manufacturing Information • Technical Support Contact Information • Equipment Model • Environmental Operating Conditions • Serial Number • Manufacturing Date
2		Pedal Connection
3		Interlock Connection
4		Label for Quality Control-approved.
5		Label for Quality Control-approved.
6		Label for Quality Control-approved.

7		Label for Quality Control-approved.
8		SUPPLY/DRAINAGE
9		ONLY USE DEIONIZED WATER
10		Equipment Cooling System Water Level Min = Minimum Recommended Level Max=Maximum Recommended Level
11		Table to mark and follow Deionizing filter change
12		ACCESS TO DEIONIZING FILTER
13		WATER SUPPLY VENT
14		Visible and invisible LASER radiation. Avoid direct or indirect Exposure to skin or eyes. Class 4 LASER Product
15		Classification of BF Applied Part

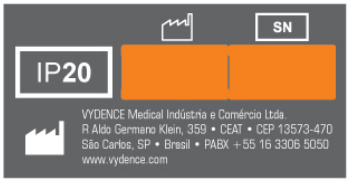
16		Emergency Stop
17		Warning: High intensity optical radiation
18		Warning: LASER radiation
19		Reading instruction manual Is required
20		LASER applicator Instructions: Wavelength Pulse duration Maximum energy
21		LASER radiation emission warning Invisible radiation Avoid eye and skin exposure to radiation directly or reflected. Wavelength Pulse duration Maximum energy Class 4 LASER product
22		Safety seal against equipment tampering Displayed in many places.

23		Warning to use safety goggles
24		Label showing direction of Deionizing filter
25		Indicates the fiber optic output
26		USB outlet
27		Scanner outlet
28		Group Risk 3
29		Emergency Stop
30		Marking label of INMETRO Brasil.
31		Information of the European Authorized representative

PEDAL

	Identification label for pedal included in equipment

APPLICATORS

	Identification label with the following Information: Protection level Date of Manufacture Applicator serial number Manufacturer's information
	LED Marking • Ready
	Button Marking that the system is available • START
	Indicates the open and close function Direction for the applicator connector
	Marking for LASER tips LASER Aperture/Output.
	LIGHT tip marking Non-LASER light aperture/output

IPL-SQ® APPLICATOR

ipl·sq	Applicator model
390nm	390nm IPL-Sq filter
400 nm	400nm IPL-Sq filter
515 nm	515nm IPL-Sq filter
540 nm	540nm IPL-Sq filter
580 nm	580nm IPL-Sq filter
640 nm	640nm IPL-Sq filter
695 nm	695nm IPL-Sq filter

INTENSEIR® APPLICATOR

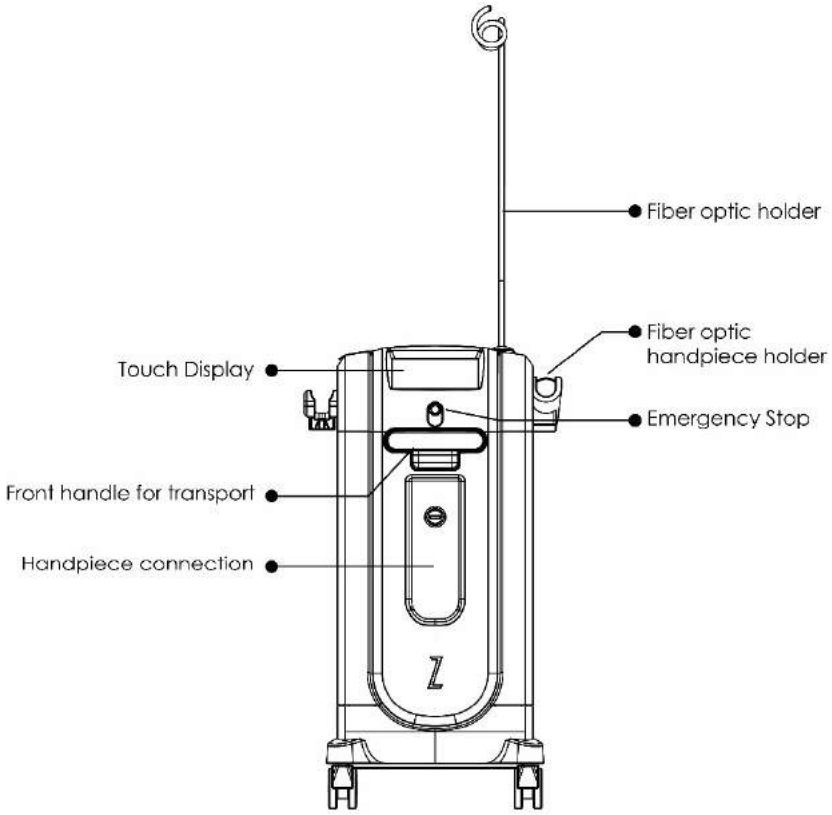
INTENSE IR	Applicator model

LASERS APPLICATORS

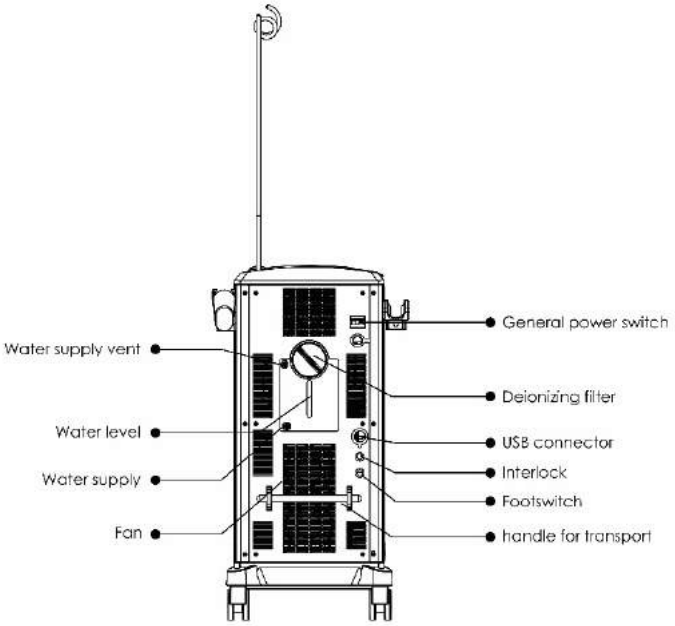
	Applicator model and logo 1064LongPulse®
	Applicator model and logo 1340ProDeep®
	Applicator model and logo 2940DualMode®
	Applicator model and logo 1064QS/532QS ACROMA®
	Applicator model and logo 1540GoSmooth®
3 • 10 ALEX	Applicator model and logo With an optical zoom from 3 to 10mm
3 • 24 ALEX	Applicator model and logo With options to select 3 to 24mm
8 • 18 ALEX	Applicator model and logo With an optical zoom from 8 to 18mm
3 • 10 YAG	Applicator model and logo With an optical zoom from 3 to 10mm
5 • 15 YAG	Applicator model and logo With options to select 5 to 15mm
3 • 24 YAG	Applicator model and logo With options to select 3 to 24mm
8 • 18 YAG	Applicator model and logo With an optical zoom from 8 to 18mm

6 SYSTEM DESCRIPTION

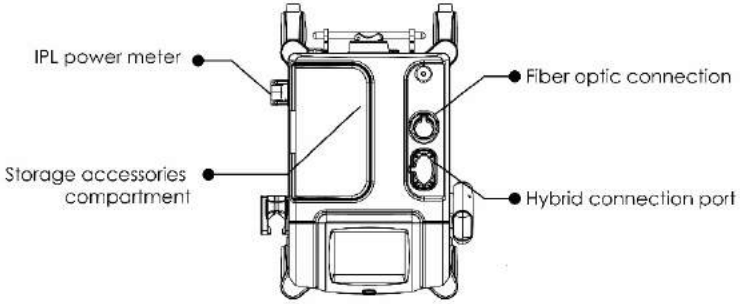
GENERAL PRODUCT OVERVIEW



Front View

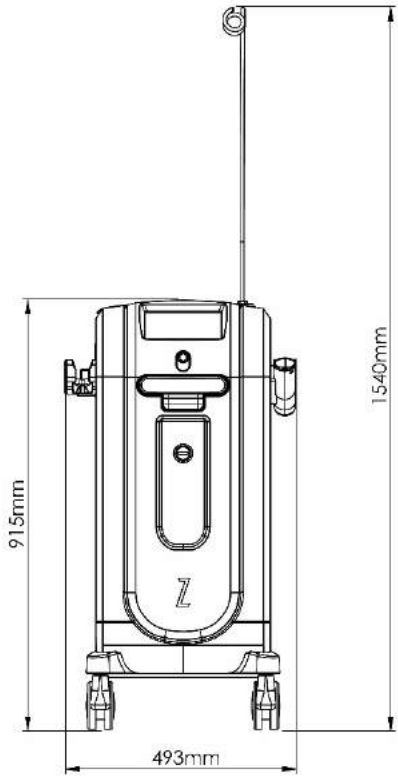


Back View



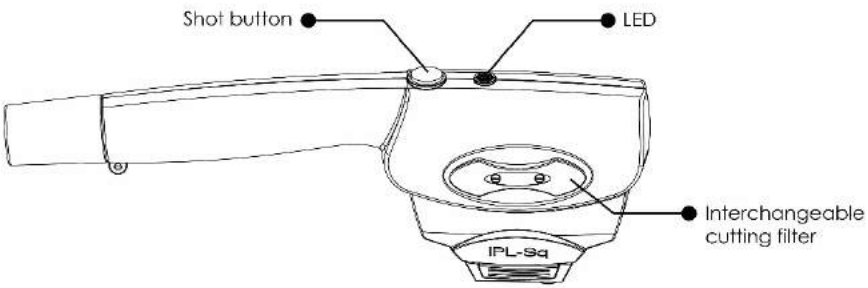
Top View

EQUIPMENT DIMENSIONS



CONTROLS – DISPLAY AND APPLICATORS

IPL-SQ APPLICATOR



The IPL applicator has as the main feature the use of a "Plug In" changing filters system. The setting of the filters in the skin is performed through magnets and the equipment automatically recognizes the connected filter and shows it at the top of the screen.

This system speeds up the treatment, since there is no need to disconnect the equipment to replace the filter, just put it in standby mode.

The filters come within a case for protection.

Shot button – must be pressed when the shot is desired. You can also use the footswitch for shooting.

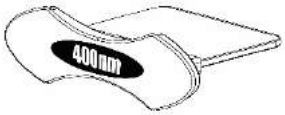
LED indication – Green indicates that the equipment is ready for shooting; when it is off indicating that the equipment is on standby.

IPL-SQ ENERGY VERIFICATION SYSTEM

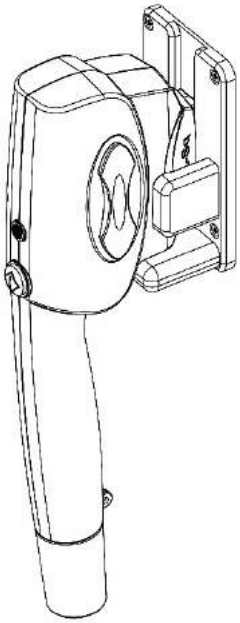
The ZYE® has an energy verification system exclusive for IPL applicator use. This system provides an even more safety use of this applicator.

An unique holder for the IPL applicator, equipped with energy sensors is the core of this system.

The verification process follows the flow described below.

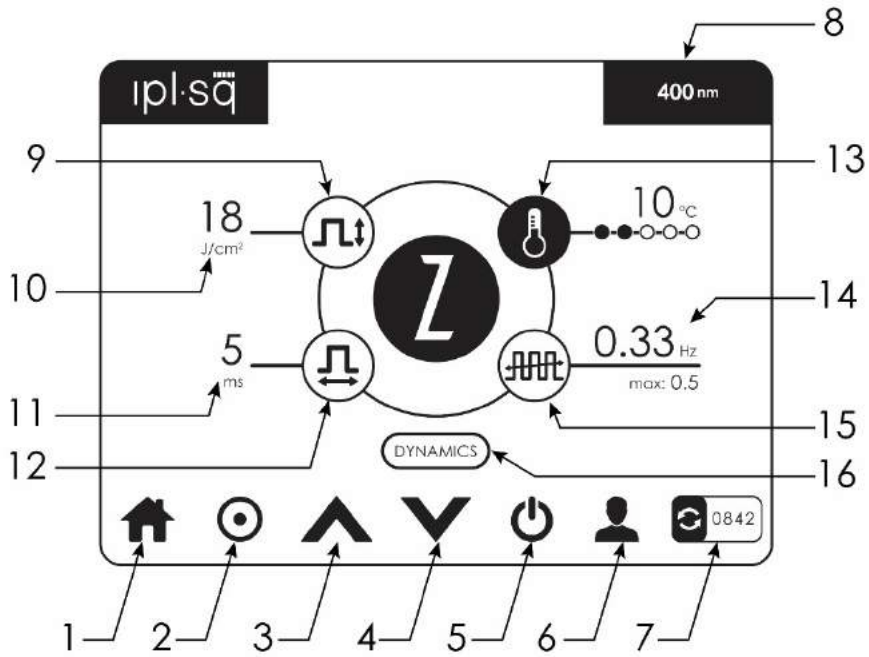


Insert the 400nm filter on the IPL-Sq applicator.



Insert the IPL Applicator on the stand as shown in the picture and press the footswitch when requested.

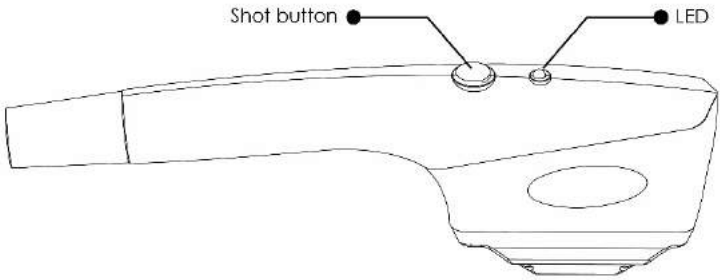
CONTROL DISPLAY – IPL-SQ®



1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode, the button will be green. If the color is pressed nothing will occur. The equipment will continue in "READY" mode. If the equipment is not in "READY" mode the "READY" button will be grey, and when pressed the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY mode.
6	SERVICE	Entry for equipment information.

7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the model of the filter attached to the handpiece
9		Indicate the selected fluency
10	Fluency	Select the fluency parameter. Setting the parameter is possible pressing or .
11		Indicates the Pulse Width.
12	Pulse Width	Select the pulse width parameter. Setting the parameter is possible pressing or .
13	Sapphire Cooling	Shows the level of cooling for sapphire at 5 levels. To change the levels of cooling click on the same button.
14		Indicates the repetition rate.
15	Frequency	Select the frequency parameter. Setting the parameter is possible pressing or .
16		Change to Dynamics mode

INTENSEIR® APPLICATOR

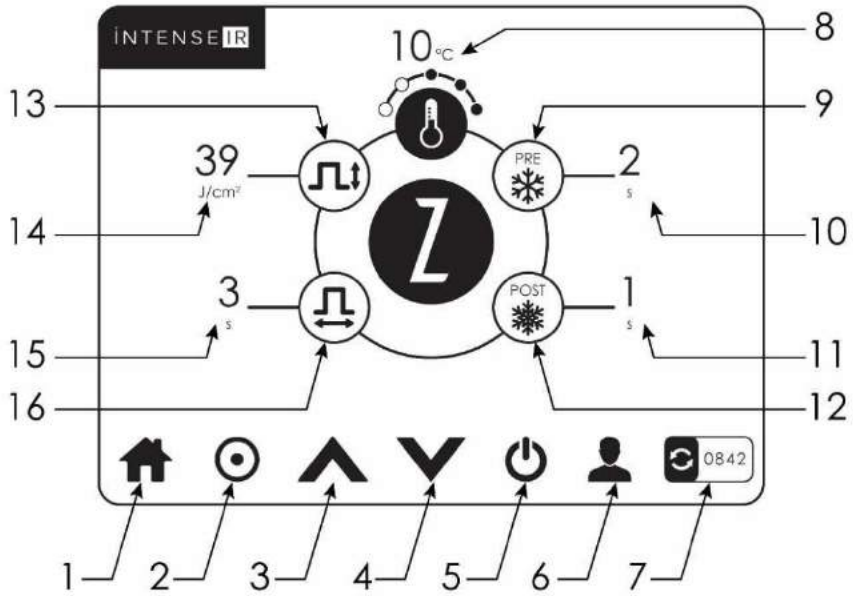


Applicator controls and indicators:

Shot button: Must be activated when wanting to release a shot. You can also opt to emit the shot automatically using the pedal.

LED sign: When green it means the equipment is ready for shots. When yellow, this means that the device is shooting, and when the LED is blue, this means that the system is counting the epidermal cooling time, before or after the shot.

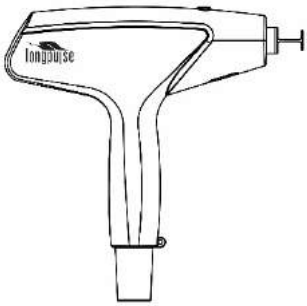
CONTROL DISPLAY – INTENSEIR®



1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode, the button will be green. If the color is pressed nothing will occur. The equipment will continue in "READY" mode. If the equipment is not in "READY" mode the "READY" button will be grey, and when pressed the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode.

		When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY mode.
6	SERVICE	Entry for equipment information.
7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8	TIP COOLING	Indicates the adjusted temperature level. The higher the level, the lower the temperature. Press the button to change the level.
9	PRÉ COOLING	Enables cooling time regulation before shots, in seconds (s).
10		Indicates cooling time before adjusted shot
11		Indicates the cooling time after adjusted shot
12	POST COOLING	Enables cooling time regulation after shots, in seconds (s).
13	FLOW	Enables the flow or energy density setting dispensed in the shot, measured in J/cm^2 (Joules per centimeter squared).
14		Indicates adjusted flow
15		Indicates the adjusted pulse duration
16	PULSE DURATION	Enables the pulse duration setting in s (seconds)

LONGPULSE® APPLICATOR



LASER Applicator Model 013054

TIP OPTIONS

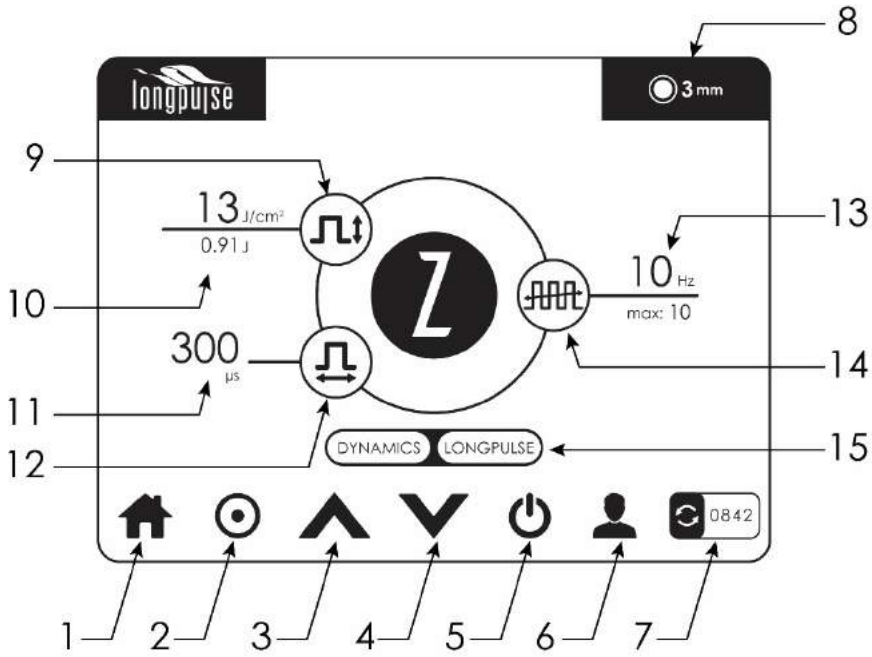
Ø2mm

Ø3mm

Ø6mm

Ø9mm

CONTROL DISPLAY – LONGPULSE®

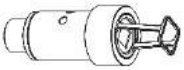


1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode the button will turn green. If the color is pressed nothing will happen and the equipment will continue to be in "READY" mode. When the equipment is not in "READY mode" the "READY" button will turn grey. If pressed, the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY" mode.
6	SERVICE	Entry for equipment information
7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the diameter of the installed tip.
9		Indicates adjusted flow.
10	FLOW	Indicates adjusted flow.
11		Indicates adjusted pulse duration.
12	PULSE DURATION	Enables pulse duration setting in ms (milliseconds).
13		Indicates the adjusted frequency and the maximum permitted.
14	FREQUENCY	Enables the repetition rate setting between shots in Hz (hertz.)
15	SHOT MODE	Alternates between DYNAMICS and LONGPULSE operation modes.

PRODEEP® APPLICATOR

LASER Applicator Model 013057

TIP OPTIONS

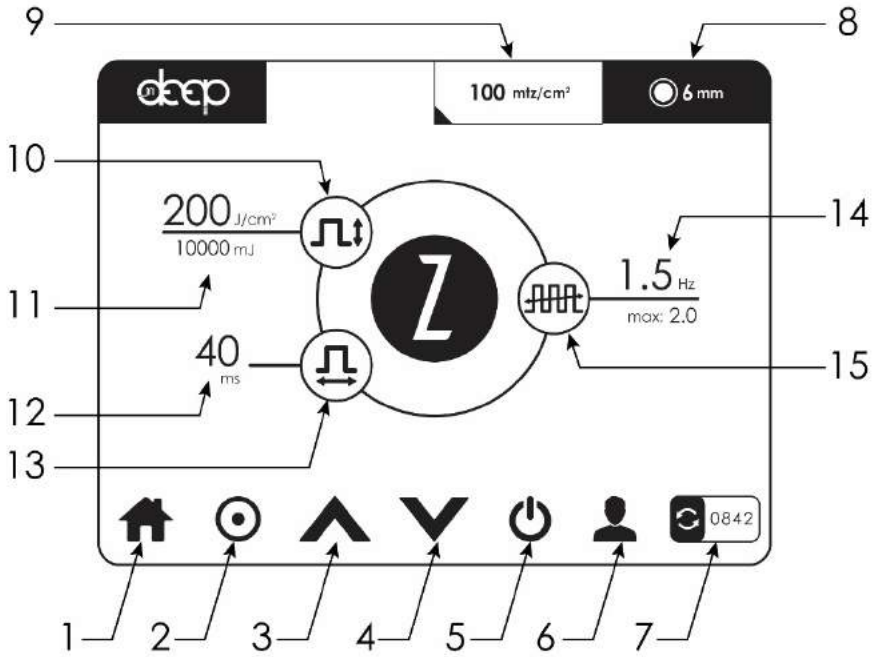


Ø 6mm

□8mm- 100MTZ/cm²

□10mm-400MTZ/cm²

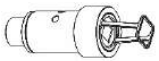
CONTROL DISPLAY - PRODEEP®



1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode the button will turn green. If the color is pressed nothing will happen and the equipment will continue to be in "READY" mode. When the equipment is not in "READY mode" the "READY" button will turn grey. If pressed, the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY" mode.
6	SERVICE	Entry for equipment information
7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the application measure of the point installed
9		Indicates the type of fractional lens with a quantity of micro-zones per centimeter squared.
10	ENERGY	Enables the setting for energy per shot in mJ (milli Joules). When the fractional point is used, it indicates the conversion to mJ/mtz (millijoules per thermal micro zone) and on the collimated tip in J/ cm2 (Joule per centimeter squared)
11		Indicates the adjusted energy value and flow.
12		Indicates adjusted pulse duration.
13	PULSE DURATION	Enables the pulse duration setting in ms (milliseconds.)
14		Indicates the adjusted frequency and the maximum frequency permitted.
15	FREQUENCY	Enables the repetition rate setting between shots in Hz (hertz.)

GOSMOOTH® APPLICATOR

TIP OPTIONS

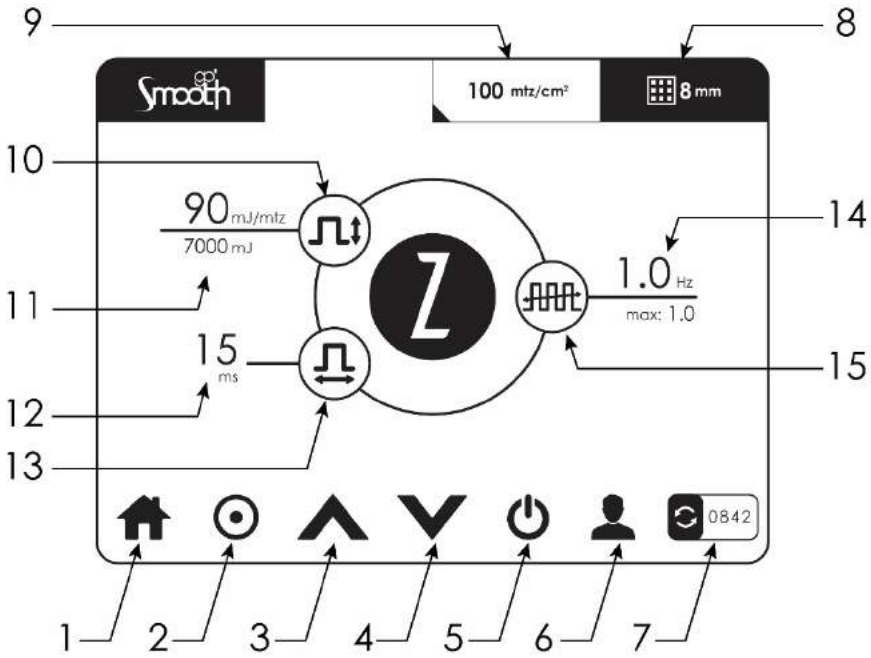


□8mm 100MTZ/cm²

□10mm 400MTZ/cm²

Applicator LASER Model 013056

CONTROL DISPLAY – GOSMOOTH®

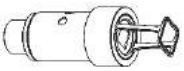


1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode the button will turn green. If the color is pressed nothing will happen and the equipment will continue to be in "READY" mode. When the equipment is not in "READY mode" the "READY" button will turn grey. If pressed, the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY" mode.
6	SERVICE	Entry for equipment information
7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the application measure of the point installed
9		Indicates the type of fractional lens with a quantity of micro-zones per centimeter squared.
10	ENERGY	Enables the setting for energy per shot in mJ (milli Joules). When the fractional point is used, it indicates the conversion to mJ/mtz (millijoules per thermal micro zone) and on the collimated tip in J/ cm2 (Joule per centimeter squared)
11		Indicates the adjusted energy value and flow.
12		Indicates adjusted pulse duration.
13	PULSE DURATION	Enables the pulse duration setting in ms (milliseconds.)
14		Indicates the adjusted frequency and the maximum frequency permitted.
15	FREQUENCY	Enables the repetition rate setting between shots in Hz (hertz.)

DUALMODE® APPLICATOR

Applicator LASER Model 013055

TIP OPTIONS



Ø2,5mm *****

Ø6mm

□8mm – 100MTZ/cm²

□8mm – 400MTZ/cm²

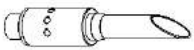
Ø8mm *****

Ø8mm – 100MTZ/cm²

Ø12mm

Ø12mm – 100MTZ/cm² *****

ORAL APPLICATOR

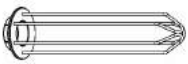


INLIFT®

GYNECOLOGICAL APPLICATOR *

ATHENA90+®*

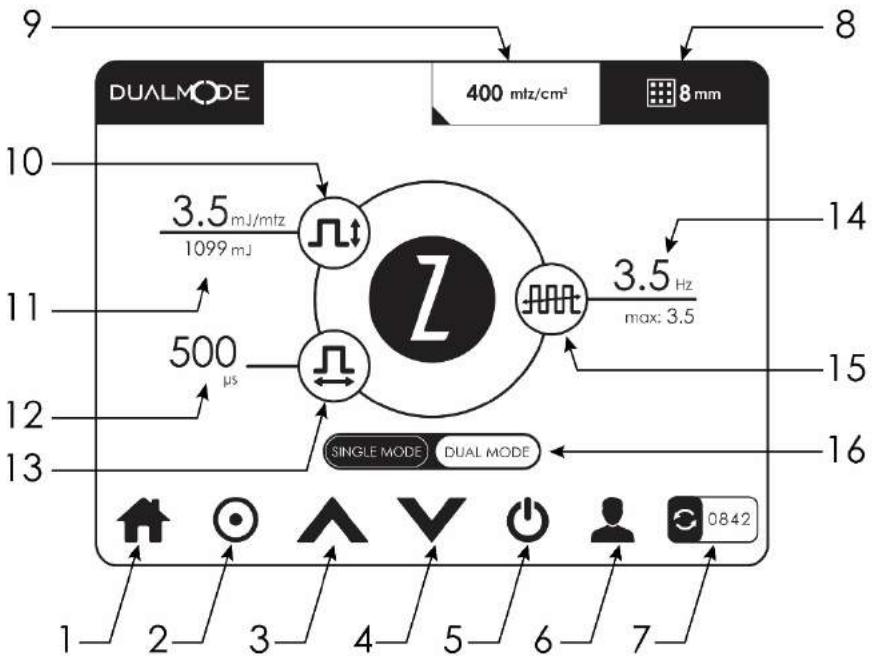
ATHENA360®*



Speculum *

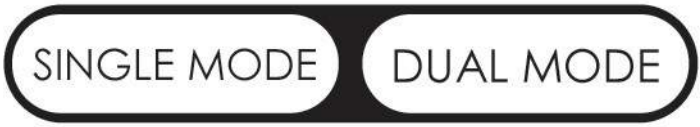
** Accessories sold separately*

CONTROL DISPLAY – DUALMODE®



1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode the button will turn green. If the color is pressed nothing will happen and the equipment will continue to be in "READY" mode. When the equipment is not in "READY mode" the "READY" button will turn grey. If pressed, the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY" mode.
6	SERVICE	Entry for equipment information

7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the application measure of the point installed
9		Indicates the type of fractional lens with a quantity of micro-zones per centimeter squared.
10	ENERGY	Enables the setting for energy per shot in mJ (milli Joules).
11		Indicates the adjusted energy value and flow.
12		Indicates adjusted pulse duration.
13	PULSE DURATION	Enables the pulse duration setting in ms (milliseconds.)
14		Indicates the adjusted frequency and the maximum frequency permitted.
15	FREQUENCY	Enables the repetition rate setting between shots in Hz (hertz.)
16		ALTERNATES THE OPERATION MODES: SINGLE MODE (SINGLE PULSES) OR DUAL MODE (DOUBLE PULSES).



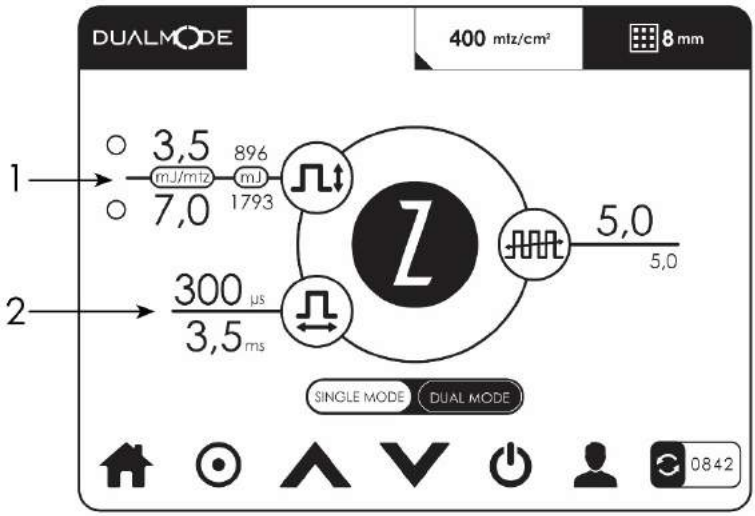
Single Pulse Double Pulses

The system allows for the user to choose the type of pulses used.

If SINGLE MODE is selected, normal LASER shots will be performed within the adjusted frequency.

If DUAL MODE is selected, in the same shot interval, two pulses will be emitted with the possibility of adjusting the quantity of energy and the pulse duration of each pulse.

In DUAL MODE, the screen duplicates the energy indication and adjusted pulse duration, as demonstrated in the following illustration.



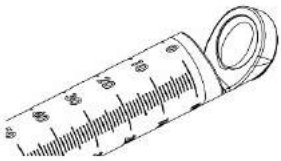
1	Indicates the adjusted energy and flow of the first and second pulses. Units measured in milli Joules.
2	Indicates the duration of the first and second pulses. Units measured in (µs) or milliseconds (ms). When the equipment is not in "READY" mode, the "READY" button will turn grey. When pressed, the equipment will go into "READY" mode.

ATHENA® AND INLIFT® TIPS

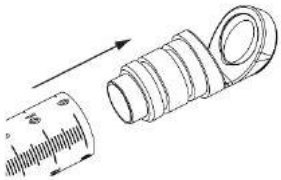
ATHENA 90+® and INLIFT® have the option to be collimated or fractionated. Both have a fractionator that must be either be put in or not on the tip according to the necessity in performing the application. See instructions below for the use of the beam fractionator while using the two tips.

INSTALLING THE BEAM FRACTIONATOR – ATHENA 90+® AND INLIFT®

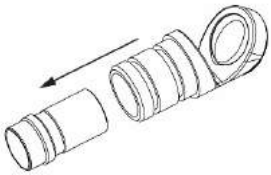
The following figures below show the tips in detail and the place where the beam fractionator with the 100MTZ/cm2 pattern is inserted.



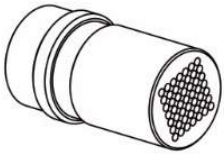
Tip view Athena 90+



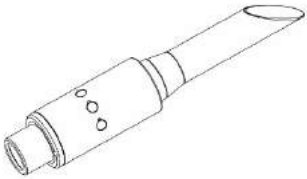
Separation of body and mirror



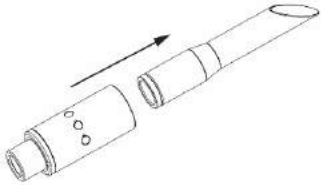
Place of fractionator insertion 100MTZ/cm²



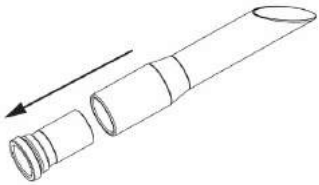
Fractionator



INLIFT® tip view



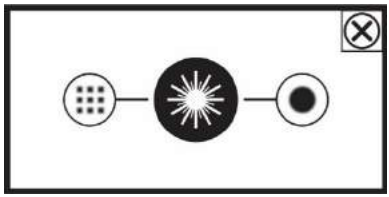
Separation of the applied part from the tip



Point of fractionator insertion 100MTZ/cm2

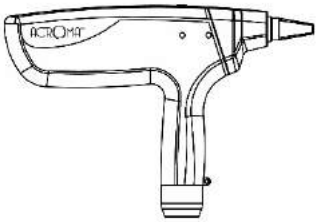
ATHENA 90+® AND INLIFT® TIP RECOGNITION

As these tips have collimated and fractionated options, when inserting them in the equipment, the software will show the user the following screen, so it can choose between the two desired options.



WARNING: The equipment does not automatically identify fractionator insertion. Make sure to correctly select from the options above to guarantee proper operation, treatment efficacy, and patient safety.

ACROMA• APPLICATOR



TIP OPTIONS

Ø3mm

Ø5mm

Ø7mm

Ø9mm • 100MTZ/cm²*

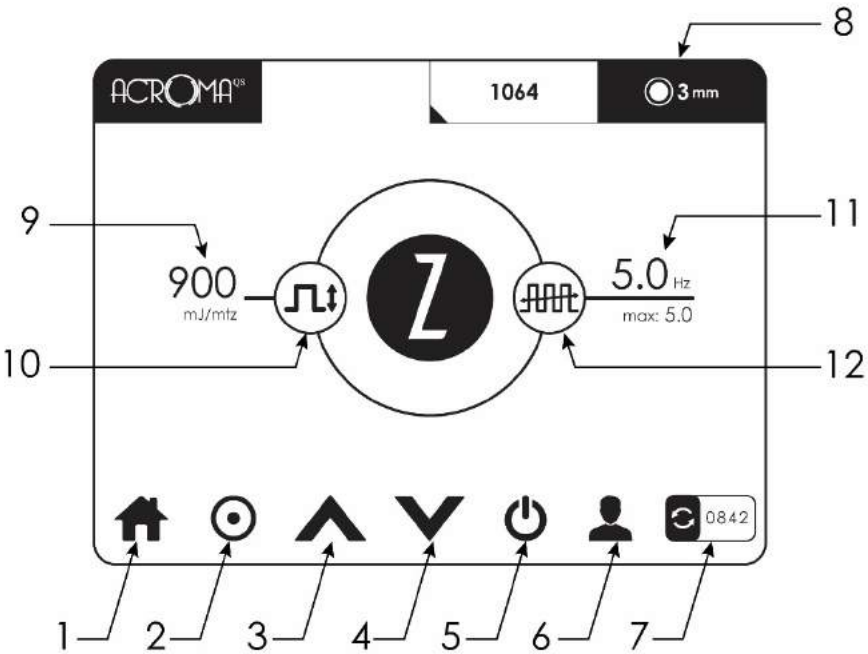
KTP 532nm TIPS

Ø3mm

Ø5mm*

** Accessories sold separately*

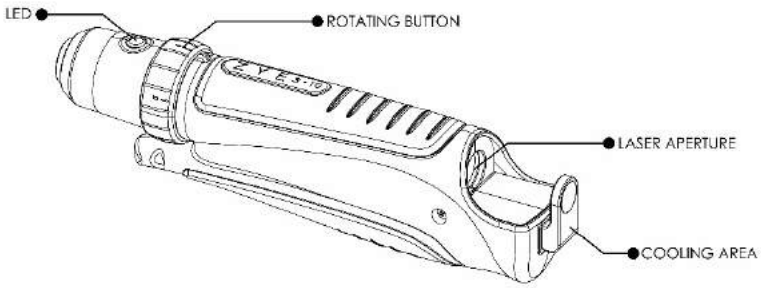
CONTROL DISPLAY - ACROMA®



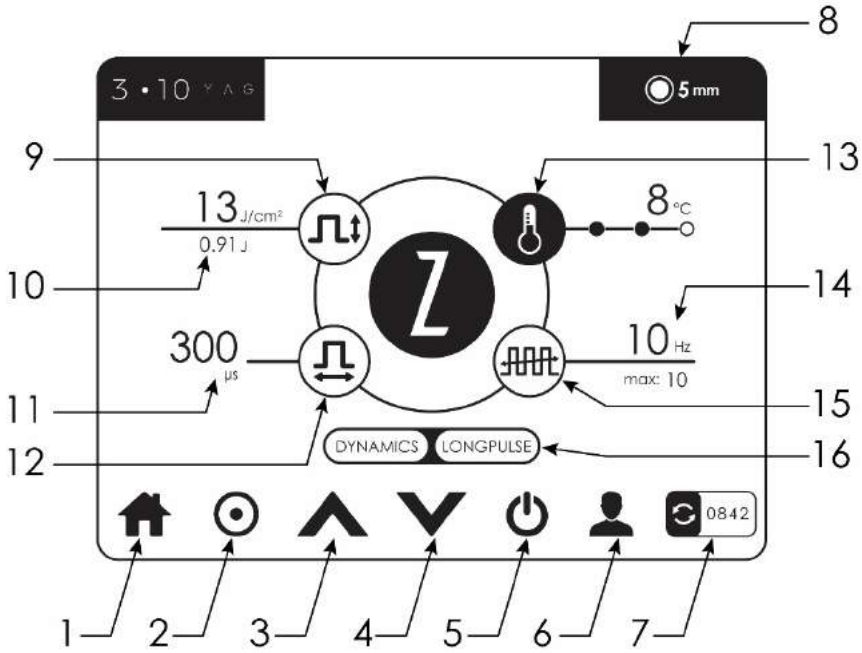
1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode the button will turn green. If the color is pressed nothing will happen and the equipment will continue to be in "READY" mode. When the equipment is not in "READY mode" the "READY" button will turn grey. If pressed, the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY" mode.
6	SERVICE	Entry for equipment information

7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the diameter of the tip installed.
9		Indicates the adjusted energy quantity.
10	ENERGY	Enables the shot energy setting, in mJ (millijoules.)
11		Indicates the adjusted frequency and the maximum permitted.
12	FREQUENCY	Enables the repetition rate setting between shots in Hz (hertz.)

3-10• APPLICATOR

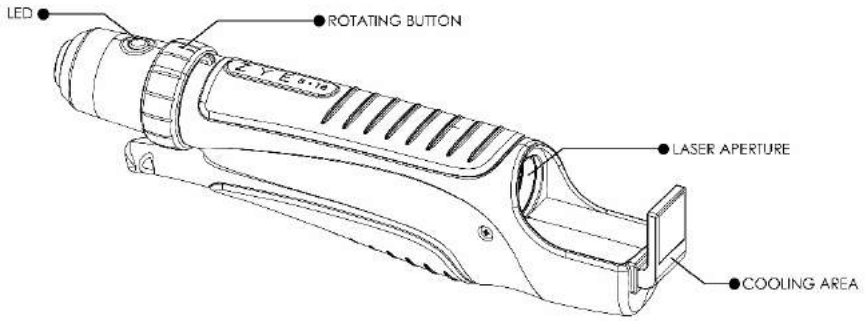


CONTROL DISPLAY – ZYE 3-10®

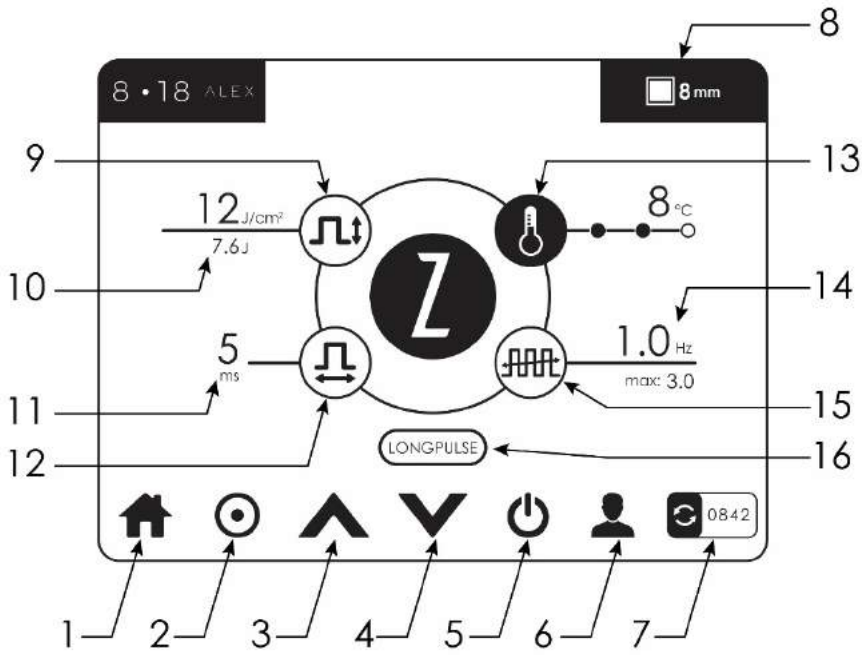


1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode the button will turn green. If the color is pressed nothing will happen and the equipment will continue to be in "READY" mode. When the equipment is not in "READY mode" the "READY" button will turn grey. If pressed, the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY" mode.
6	SERVICE	Entry for equipment information
7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the installed tip diameter.
9	ENERGY	Adjusts the energy of the shot in mJ (milli Joules).
10		Indicates the adjusted energy quantity.
11		Indicates the adjusted pulse duration in microseconds (µs).
12	PULSE DURATION	Enables pulse duration settings in milliseconds (ms) or microseconds (µs).
13	TIP COOLING	Indicates the adjusted temperature level. The higher the level, the lower the temperature. Press the button to change the level.
14		Indicates adjusted frequency and the maximum frequency allowed.
15	FREQUENCY	Enables the repetition rate setting between shots in Hz (hertz.)
16		Alternates between DYNAMICS and LONGPULSE operation modes

8-18• APPLICATOR

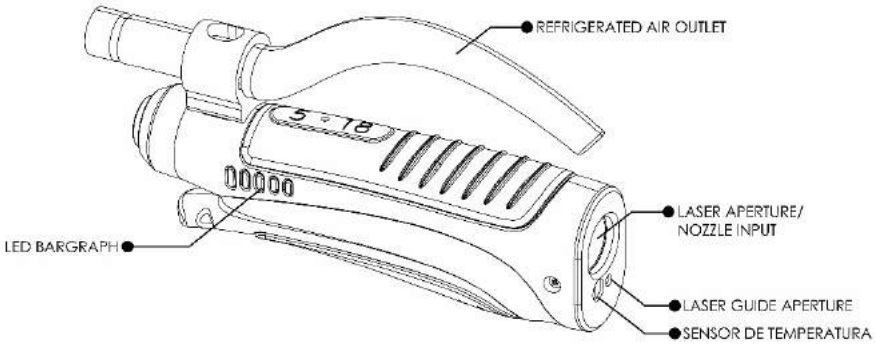


CONTROL DISPLAY - ZYE 8-18®

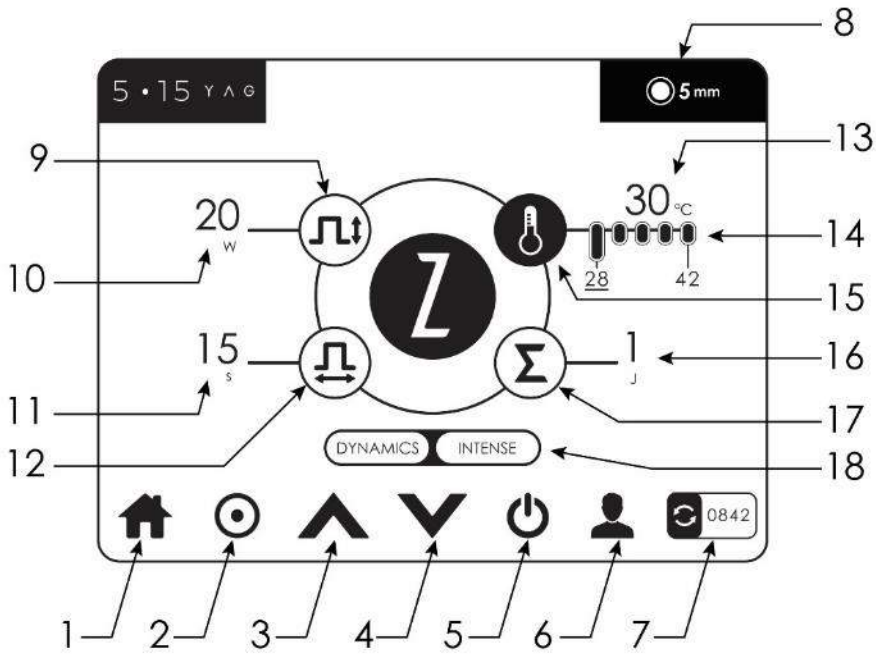


1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode the button will turn green. If the color is pressed nothing will happen and the equipment will continue to be in "READY" mode. When the equipment is not in "READY mode" the "READY" button will turn grey. If pressed, the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY" mode.
6	SERVICE	Entry for equipment information
7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the installed tip diameter.
9	ENERGY	Adjusts the energy of the shot in mJ (milli Joules).
10		Indicates the adjusted energy quantity.
11		Indicates the adjusted pulse duration in microseconds (µs).
12	PULSE DURATION	Enables pulse duration settings in milliseconds (ms) or microseconds (µs).
13	TIP COOLING	Indicates the adjusted temperature level. The higher the level, the lower the temperature. Press the button to change the level.
14		Indicates adjusted frequency and the maximum frequency allowed.
15	FREQUENCY	Enables the repetition rate setting between shots in Hz (hertz.)
16		Changes LONGPULSE' operation mode

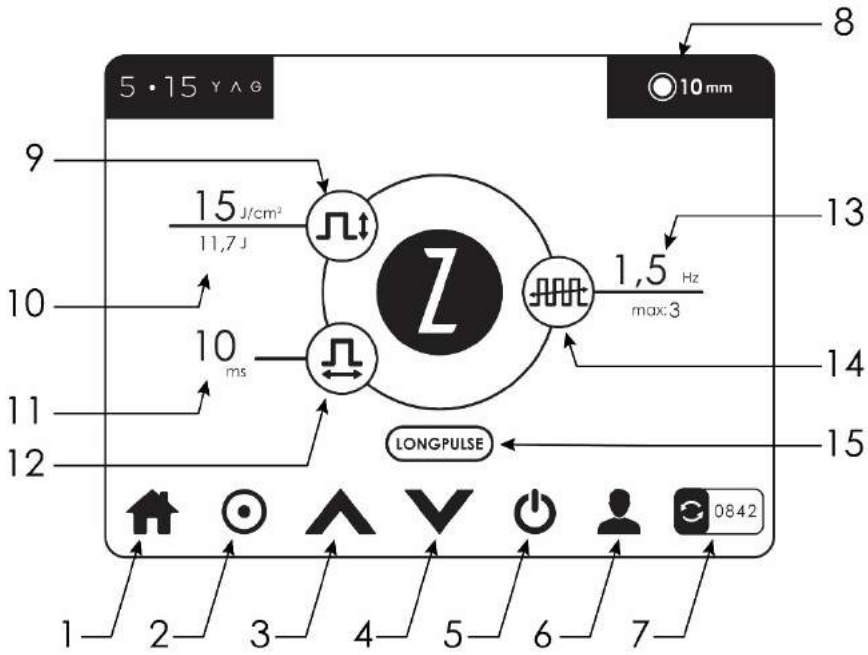
5-15• APPLICATOR



CONTROL DISPLAY - 5-15®



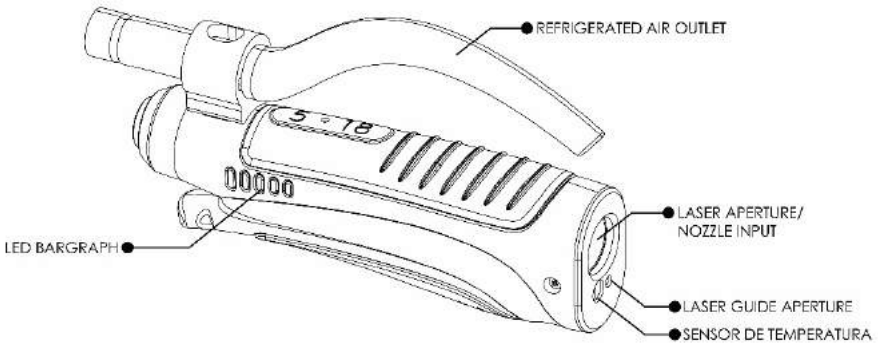
1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode the button will turn green. If the color is pressed nothing will happen and the equipment will continue to be in "READY" mode. When the equipment is not in "READY mode" the "READY" button will turn grey. If pressed, the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY" mode.
6	SERVICE	Entry for equipment information
7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the installed tip diameter.
9	ENERGY	Adjusts the energy of the shot in mJ (milli Joules).
10		Indicates the adjusted energy quantity.
11		Indicates the adjusted pulse duration in microseconds (µs).
12	PULSE DURATION	Enables pulse duration settings in milliseconds (ms) or microseconds (µs).
13		Indicates the temperature level read by the sensor
14		Shows the selected temperatures as maximum and minimum for the LED bar
15	TEMPERATURE INDICATED ON THE LED BAR	Enables the maximum and minimum temperature settings indicated by the LED bar
16		Shows the total energy emitted
17		Reset the energy emission accumulator
18		Alternates between the DYNAMICS and INTENSE operation modes



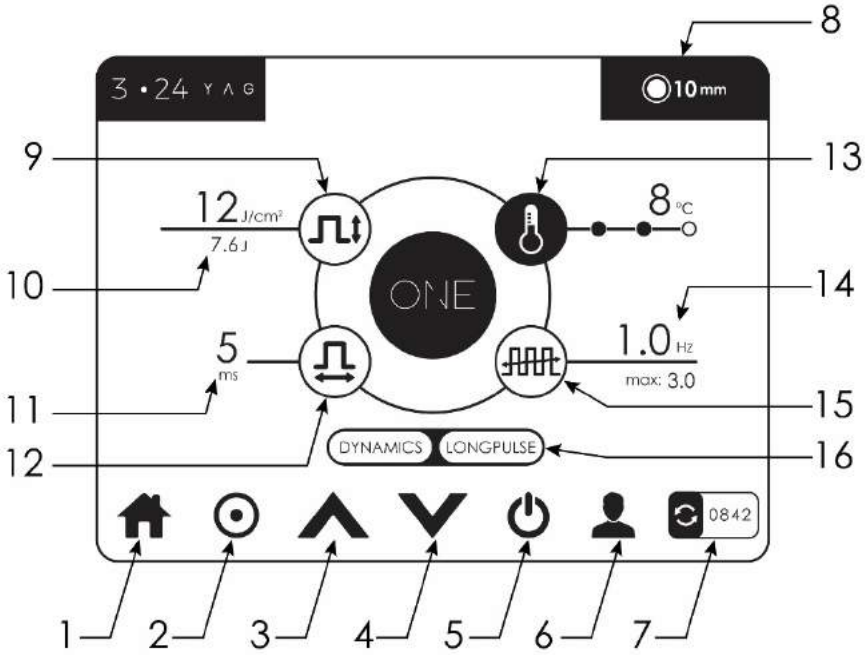
1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode the button will turn green. If the color is pressed nothing will happen and the equipment will continue to be in "READY" mode. When the equipment is not in "READY mode" the "READY" button will turn grey. If pressed, the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY" mode.

6	SERVICE	Entry for equipment information
7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the installed tip diameter.
9	ENERGY	Adjusts the energy of the shot in mJ (milli Joules).
10		Indicates the adjusted energy quantity.
11		Indicates the adjusted pulse duration in microseconds (µs).
12	PULSE DURATION	Enables pulse duration settings in milliseconds (ms) or microseconds (µs).
13		Indicates adjusted frequency and the maximum frequency allowed.
14	FREQUENCY	Enables the repetition rate setting between shots in Hz (hertz.)
15		Shows that this is the LongPulse mode

3-24• APPLICATOR



CONTROL DISPLAY – ZYE 3-24®



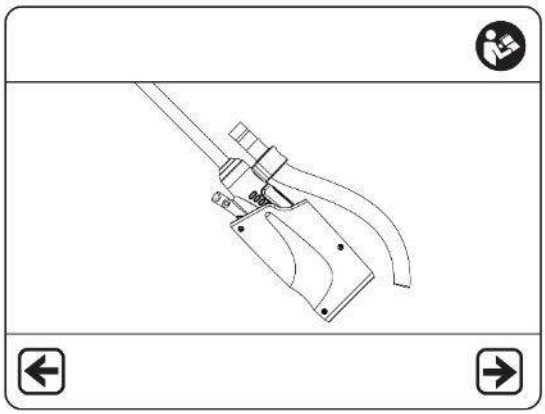
1	HOME	Return button to the application's selection screen.
2	READY	When the equipment is in "READY" mode the button will turn green. If the color is pressed nothing will happen and the equipment will continue to be in "READY" mode. When the equipment is not in "READY mode" the "READY" button will turn grey. If pressed, the equipment will enter "READY" mode.
3		Increases the value of the chosen function.
4		Decreases the value of the chosen function.
5	STAND BY	When the equipment is in "STAND BY" mode, the button will turn blue. Nothing happens when this color is pressed. The equipment will continue in "STAND BY" mode. When the equipment is not in "STAND BY" mode, the button's color is grey. When pressed, the equipment will go into "STAND BY" mode.
6	SERVICE	Entry for equipment information
7	COUNTER	Indicates the number of shots performed during the session. Reset button. Resets the number of shots performed to zero.
8		Indicates the installed tip diameter.
9	ENERGY	Adjusts the energy of the shot in mJ (milli Joules).
10		Indicates the adjusted energy quantity.
11		Indicates the adjusted pulse duration in microseconds (µs).
12	PULSE DURATION	Enables pulse duration settings in milliseconds (ms) or microseconds (µs).
13	TIP COOLING	Indicates the adjusted temperature level. The higher the level, the lower the temperature. Press the button to change the level.
14		Indicates adjusted frequency and the maximum frequency allowed.
15	FREQUENCY	Enables the repetition rate setting between shots in Hz (hertz.)
16		Changes LONGPULSE' operation mode

ATOMATIC ENERGY ADJUSTMENT – INTERNAL® CAVITY

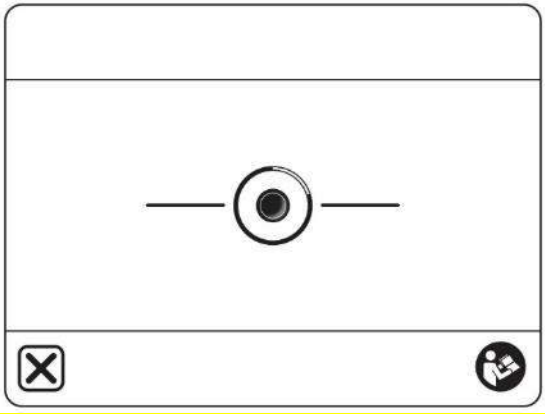
The ZYE® equipment has an automatic LASER energy adjustment of the internal cavity YAG and ALEX, providing safe and effective energy delivery.

The automatic adjustment is typically performed once a day when first using the applicators 3-10, 8-18, 5-15 and 3-24.

In this way, after selecting one of the above mentioned applicators the screen below will be displayed indicating that the applicator should be placed in its holder if it is not already.



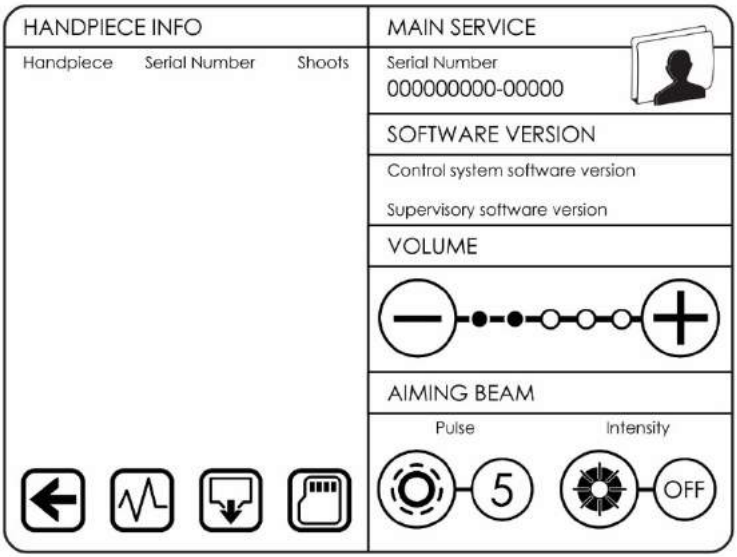
Then press the pedal when prompted for the adjustment process to start.



During the adjustment the screen above will be displayed.
The setting can take up to 10 seconds.

MAIN SERVICE SCREEN

This ZYE® equipment menu shows a few technical facts about the equipment.



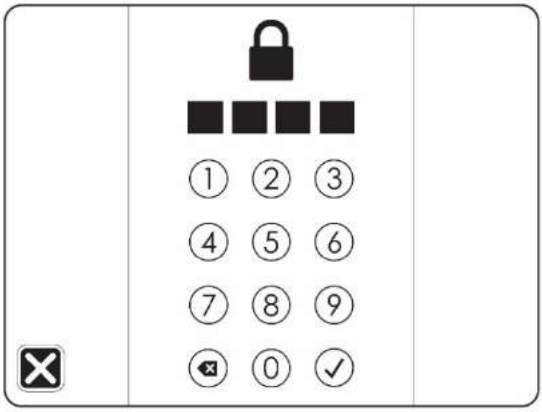
APPLICATOR INFO – (APPLICATOR INFORMATION)	
Type (Applicator Type)	Indicates the last applicators connected to the equipment. If the user has more than one applicator of the same model, the equipment will always indicate the last piece connected to the equipment.
Serial Number (Serial number)	Indicates the serial number of the applicators.
Shots (Number of shots)	Indicates the number of shots accumulated in the applicators.
MAIN SERVICE – (GENERAL INFORMATION)	
Serial Number (Serial number)	Indicates the serial number of the applicators.

Software version – (Version the software)	
Control system software version (Control System software version)	Indicates the system software version
Supervisory software version (Monitoring software version)	Indicates the supervisory software version

	Button to return to the home screen
	Button to go to "TECHNICAL SERVICE" screen
	Initiates draining system and water reservoir draining system
	Button used to discard the equipment data registry (LOG) in an USB mass storage device in the back of the equipment

TECHNICAL SERVICE SCREEN

	Touching this button enables the keyboard for the password to access the TECHNICAL SERVICE section
	Volume (–)
	Volume (+)
	LASER pulse guide
	LASER intensity guide



This section contains equipment maintenance information. Only an authorized technician has the access password.

CONNECTING TO WI-FI

The Wi-Fi remote connection technology successfully incorporated into the ZYE ALEX / YAG platform - VYDENCE CloudConnect - allows the device to be connected to the cloud and thus to the monitoring system for technical assistance, preventive maintenance and care. This is a tool used to collect technical data and use of the equipment, speeding up the response and assertiveness of the technical assistance services and, in this way, promoting a better service to our client. In this sense, the tool presents several panels of the history of use of the equipment, both for the user and for VYDENCE, allowing a better control and maximization of the use of the equipment, and resulting in better profitability. VYDENCE CloudConnect technology does not allow remote access to the device or its parts, allowing only the sending, by the equipment to the Server, of information related to its usability and technical conditions, except for the possibility of updating the software through a unique and direct user command.

The information collected from the equipment is strictly technical and of use of the equipment, never covering the collection of personal data of the patient or user of the equipment.

It is important to note that the data will be collected indefinitely while the function is enabled, that is, while the WI-FI function is enabled, the data will be received by VYDENCE MEDICAL (SAC 16-3306 5050) and will be handled by the VYDENCE MEDICAL, being stored in a cloud server belonging to AMAZON WEB SERVICES (AWS) and stored there for at least 3 (three) years.

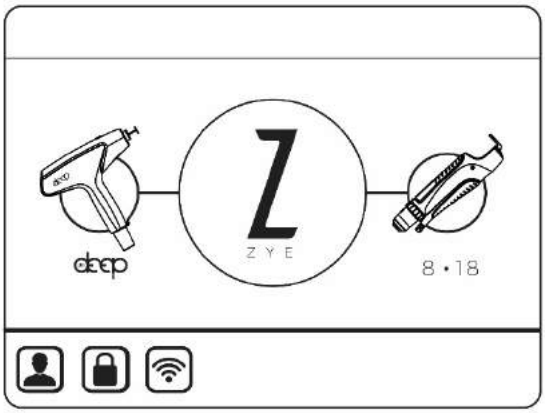
Furthermore, the usability data collected can easily be accessed by the holder of the information through simple web access through the VYDENE MEDICAL portal to

the worldwide computer network, through a login and password provided by VYDENCE MEDICAL, which can be created through of simple online registration in the site www.myvydence.com. Once the registration is made, it is necessary to link the equipment to the newly created account, registering the equipment ID code (delivered with the equipment) in the user profile configuration menu, in the equipment tab.

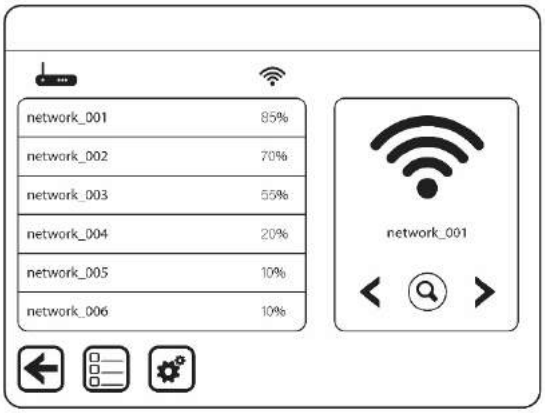
It is worth remembering that data is only sent if the WI-FI function is enabled and properly connected, so that the equipment memory is limited and depends directly on the volume of use and it cannot be guaranteed that the usage information is sent to the server if the WI-FI function is delayed enabled or disabled, even for a short time, either by the user's choice or by lack of connection to the internet.

Lastly, we inform you that the data collected will be stored in an absolutely secure and protected system, including security protocols established by AMAZON WEB SERVICES, including information encryption, firewalls and, also, HIPAA requirements, with specific access protection unauthorized and accidental or unlawful situations of destruction, loss, alteration, communication or any form of inappropriate or illicit treatment. Eventual occurrence of a security incident that could lead to risk or significant damage to the holders will be communicated to the national authority and to the holder, as determined by the legislation.

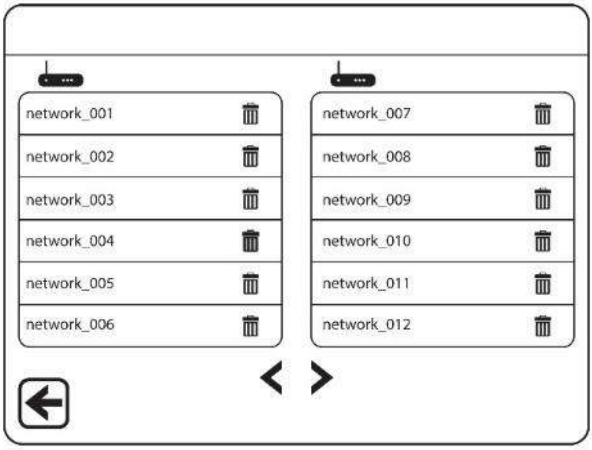
On the home screen press icon  to enter the network connections screens.



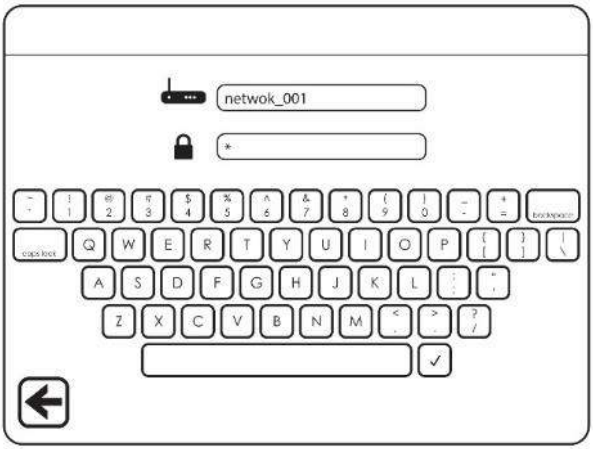
When connecting the ZYE ALEX / YAG platform, the WI-FI connection icon remains opaque until a connection is made, if the icon is green, the connection was successful, if it is red, the device is connected to the network, however, without internet access.



To list the networks already registered, press the icon  . To delete them, press the network icon  .



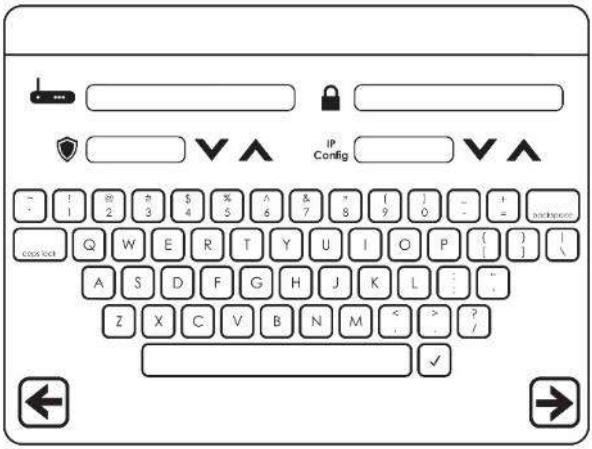
New networks can be searched using button . Use and to browse through the list of found networks. Select the desired network by tapping its name.



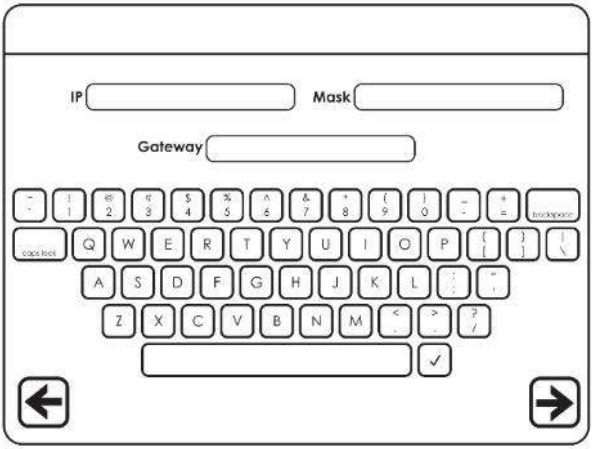
Enter the network password using the virtual keyboard and press the button  to end.

To add a network manually, press the button  .

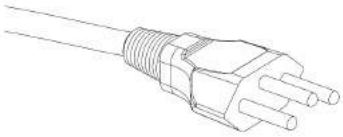
On the new screen that appears, fill in the information appropriately and press the button  .



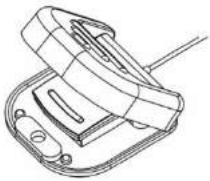
If the STATIC option is selected in IP Config, the icon  , a new screen opens, fill in the parameters and press  again.


IP
Mask
Gateway
caps lock
backspace

ACCESSORIES INCLUDED WITH THE PRODUCT

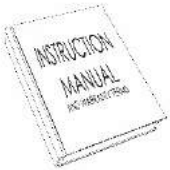


Power Cord



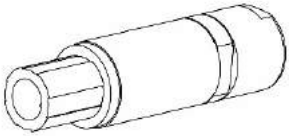
Footswitch pedal

Patient protective glasses (See section on “Safety Glasses”)



Instruction Manual and Warranty

Supply and system water draining cooling kit



Remote interlock connector

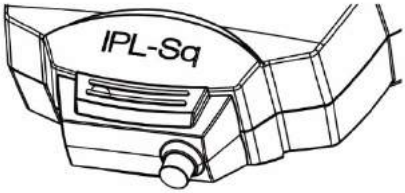
Protective eyewear for operator

Deionized Water

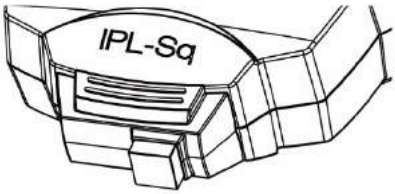
Room safety label

APPLIED PARTS

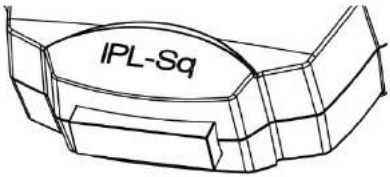
APLICADOR IPL-SQ



Round spot
Material: Sapphire
Dimension: Ø8mm



Square spot
Material: Sapphire
Size: 12 x 12mm



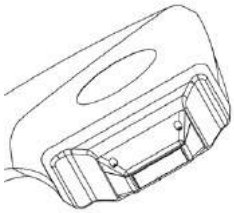
Rectangular spot
Material: Sapphire
Size: 12 x 40mm

Sapphires, both the IPL-sq handle and IntenseIR, are considered applied parts.

The plastic part of the IPL-sq Handle is not considered as an applied part but rather as a likely part of being touched.

WARNING: The square tips (12x12mm) and round (Ø8mm) tips are also cooled as the rectangular tip (12x40mm), but they have a smaller interface for heat transfer and their cooling is not as effective as the rectangular tip. If a firing sequence is performed the temperature in these tips (Square and Round) can reach a maximum of 43°C. Carefully read the usage protocols related to the use of these Tips.

INTENSEIR® APPLICATOR



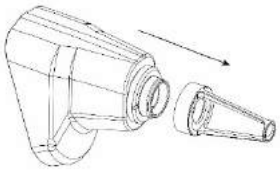
intenseIR® – Rectangular Top
Material: Sapphire
Dimensions: 12 x 40mm

The sapphire of the intenseIR® applicator is considered an applied part. The plastic part of the intenseIR® applicator is not considered as an applied part but as a likely part of being touched.

WARNING: The rectangular tip is cooled. When a firing sequence is carried out the temperature may reach a maximum of 43 ° C. Read carefully the protocols of use related to the use of these tips.

FIRST GENERATION LASER APPLICATORS

ACROMA®

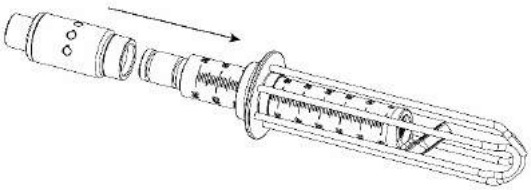


The aluminum spacer of the LASER tips is considered an applied part. The body of the LASER TIPS is considered a part that is likely to be touched.

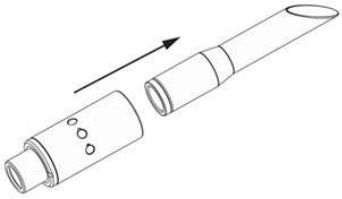
WARNING: Limiters of the LASER tips can reach temperatures higher than 41 ° C, but not higher than 43 ° C. In addition to the fact that the surface touched is very small and the operating mode of the tip is dynamic, no undesirable clinical effects can be observed if the tip reaches a maximum temperature of 43 ° C.

SECOND GENERATION LASER APPLICATORS – ALL MODELS

The aluminum spacer of the LASER tips is considered an application part. The body of the LASER TIPS is considered a part that is likely to be touched.



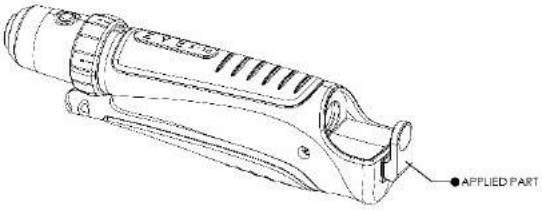
The ATHENA® tip of the DualMode® is used in conjunction with a speculum. In this mode, the speculum is considered an applied part of the tip and an extender while the body of the LASER pointer is considered a part that is likely to be touched.



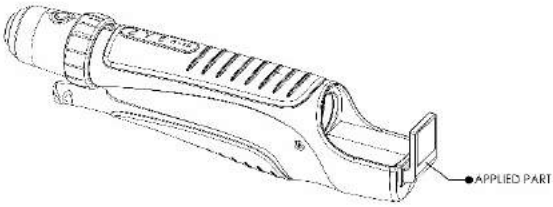
The INLIFT® tip of the DualMode® applicator has an extender that is considered an applied part. The body of the LASER tip is a part that is likely to be touched.

WARNING: The LASER tip restrictors can reach temperatures greater than 41 °C but do not exceed 43 °C. Aside from surface touched being very small, and the operation mode of the is dynamic, no undesirable clinical effect can be observed if the tip reaches the maximum temperature of 43°C.

LASER APPLICAORS WITH FIRTS GENERATING OPTICAL FIBER – ALL MODELS

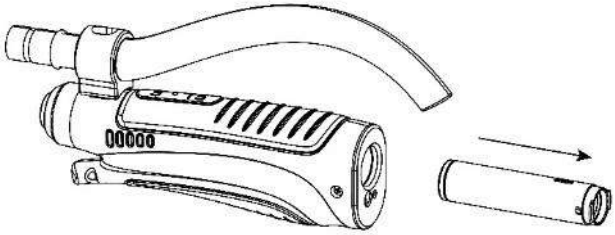


ZYE 3-10mm•
(ALEX AND YAG)



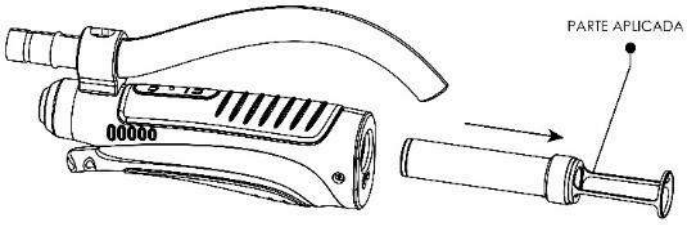
ZYE 8-18mm•
(ALEX AND YAG)

The piece containing sapphire is considered an applied part. The rest of the applicator's body is considered a part that is likely to be touched.



5 -15•
(YAG)

The 5-15mm applicator aluminum tips are considered as likely parts to be touched.



3 -24•
(ALEX E YAG)

Only the aluminum spacer of applicator tips 3-24 are considered as applied part. The body of the LASER tips is considered as likely to be touched.

WARNING: The sapphire windows are refrigerated; in shot sequence situations, the interface temperatures can reach higher temperatures than the selected value. No undesirable clinical effect should be observed due to this variation.

LASER APPLICATOR INDICATORS

Indicating LED: Ready

On-When the "on" button is on continuously it means that the system is ready to perform shots.

Flashing -When shots are activated

Turned Off – Stand by

LASER activation (shot):

There are no shot devices (buttons) on the LASER applicator. Shots are performed even through using the pedal.

Indication of LASER output:

Sounds – A beeping sound is made during shots

Visual -It is possible to see a flashing light in the indicating LED (besides the LASER aiming beam for applicators that have it, if turned on) during shots.

Applicators with LASER guide:

LongPulse®, 3-10®, 8-18®, 5-15® and 3-24® applicators have LASER guidance for positioning reference for application.

WARNING: LASER aiming beam do not represent the real geometry of the LASER emitted during treatment. These are used strictly for a center reference of the LASER. The LASER aiming beams are real and are not perfectly concentric or superimposed.

WARNING: As the guiding beam passes through the same optical path as the real LASER, it can be used to verify the LASER emission system's integrity. If the guiding beam is not present in the emission system's distal output, the intensity will be reduced or seem fuzzy. This is a possible indication of damage in the LASER emission systems

7 UNPACKING AND CONTENT VERIFICATION

1. Carefully inspect the equipment box before opening it. In case of apparent damage, refuse the delivery and contact the company or distributor immediately.
2. With the box in the position indicated by external symbols and with the help of a cutter or scissors, open the box.
3. Remove the box, carefully pulling it vertically above to not damage the equipment.
4. Remove the internal polyurethane protections and inspect the content again to search for damage from transportation. If there is no damage found, remove the equipment from the box.
5. Check to make sure there is no damage from transport.
6. Contact the transporter and VYDENCE Medical if there are clear signs of damage due to transport.
7. Check to make sure that all accessories in the list below are present:
    - 1 (one) pair of stainless-steel protective glasses for the patient
    - 2 (two) pairs of protective eyewear
    - 1 (one) power cord.
    - 1 (one) footswitch
    - 1 (one) Kit for supplying and draining water from the cooling system.
    - 2 (two) liters of deionized water
    - 1 (one) door safety label
    - 1 (one) instructions for use
    - 1 (one) remote interlock connector
    - 1 (one) rod for fiber optic support
    - 1 (one) kit with patient marketing materials
8. Repeat the process with the applicator boxes when necessary.

OBSERVATION: Applicators are purchased individually (they are not part of the accessories that come with the product)

IPL-SQ™ APPLICATOR:

- (one) Case for transport.
- (one) Applicator IPL-sq™.
- (one) Box with the following filters:
    - (one) 390nm filter
    - (one) 400 nm filter
    - (one) 540 nm filter
    - (one) 580 nm filter
    - (one) 640 nm filter
    - (one) 695 nm filter
    - (one) round sapphire windows of ∅8mm
    - (one) square sapphire window of 12 x 12mm
- (two) Safety goggles for the operator.
- (one) Liter of deionized water.

Accessory that can be purchased separately:

- (one) 515nm filter

INTENSEIR® APPLICATOR:

- 1 (one) carrying case for wrapping and transport.
- 1 (one) IR applicator
- 1 (one) pair of protective glasses for the operator.
- 1 (one) liter of deionized water
- 1 (one) clinical reference guide
- 1 (one) quick reference guide
- 1 (one) kit with patient marketing materials

WARNING: Keep and save the packaging for sending equipment to technical support services.

LASER LONGPULSE® APPLICATOR:

- 1 (one) carrying case for wrapping and transport.
- 1 (one) LASER 1064 LongPulse® Applicator
- 1 (one) liter of deionized water
- 1 (one) protective lid for the LASER cavity
- 1 (one) box with the following tips:
  - 1 (one) ∅2 mm tip
  - 1 (one) ∅3 mm tip
  - 1 (one) ∅6 mm tip
  - 1 (one) ∅9 mm tip
- 2 (two) pairs of protective eyewear
- 1 (one) clinical reference guide
- 1 (one) quick reference guide
- 1 (one) kit with patient marketing materials

WARNING: Keep and save the packaging for sending equipment to technical support services.

LASER PRODEEP® APPLICATOR:

- 1 (one) carrying case for wrapping and transport.
- 1 (one) LASER 1340 ProDeep® Applicator
- 1 (one) liter of deionized water
- 1 (one) protective lid for the LASER cavity
- 1 (one) with the following applicator tips;
  - 1 (one) □8mm by 100 mtz/cm² tip
  - 1 (one) □10mm by 400 mtz/cm² tip
  - 1 (one) ∅6 mm tip
- 2 (two) pairs of protective eyewear
- 1 (one) clinical reference guide
- 1 (one) quick reference guide
- 1 (one) kit with patient marketing materials

WARNING: Keep and save the packaging for sending equipment to technical support services.

LASER GOSMOOTH® APPLICATOR:

- 1 (one) carrying case for wrapping and transport.
- 1 (one) LASER 1540 GoSmooth® applicator
- 1 (one) liter of deionized water.
- 1 (one) lid to protect the LASER cavity
- 1 (one) box with the following applicator tips;
  - 1 (one) □8mm and 100mtz/cm2 tip
  - 1 (one) □10mm and 400mtz/cm2 tip
- 2 (two) pairs of protective eyewear
- 1 (one) clinical reference guide
- 1 (one) quick reference guide
- 1 (one) kit with patient marketing materials

WARNING: Keep and save the packaging for sending equipment to technical support services.

LASER DUALMODE® APPLICATOR:

- 1 (one) carrying case for wrapping and transport.
- 1 (one) LASER 2940 DualMode® Applicator
- 1 (one) liter of deionized water
- 1 (one) protective lid for the LASER cavity
- 1 (one) box with the following applicator tips; ○
  - 1 (one) □8mm and 100 mtz/cm2 tip
  - 1 (one) □8mm and 400 mtz/cm2 tip
  - 1 (uma) ∅8mm with reference spacer
  - 1 (one) ø6 mm tip
  - 1 (one) INLIFT® tip with a removeable 100MTZ/cm² fractionator
- 2 (two) pairs of protective eyewear
- 1 (one) clinical reference guide

- 1 (one) quick reference guide
- 1 (one) kit with patient marketing materials

Optional accessories:

- 1 (one) ∅2,5mm tip
- 1 (one) ATHENA 360◦ tip
- 1 (one) ATHENA 90+◦ tip with a removeable 100MTZ/cm² fractionator
- 1 (uma) ponteira de ∅8mm e 100 mtz/cm²
- 1 (uma) ponteira ∅12mm 100 mtz/cm²

WARNING: Keep and save the packaging for sending equipment to technical support services.

LASER ACROMA® APPLICATOR:

- 1 (one) carrying case for wrapping and transport.
- 1 (one) LASER ACROMA◦ applicator
- 1 (one) liter of deionized water
- 1 (one) protective lid for the LASER cavity
- 1 (one) with the following applicator tips;
  - 1 (one) ∅3mm 1064 nm tip
  - 1 (one) ∅3mm 532 nm tip
  - 1 (one) ∅5mm 1064 nm tip
  - 1 (one) ∅7mm 1064 nm tip
- 2 (two) pairs of protective eyewear
- 1 (one) clinical reference guide
- 1 (one) quick reference guide
- 1 (one) kit with patient marketing materials

Accessories that can be bought separately:

- 1 (one) ∅9mm and 100 MTZ/cm² tip
- 1 (one) ∅5mm 532 nm tip

WARNING: Keep and save the packaging for sending equipment to technical support services.

3-10® APPLICATOR:

- 1 (one) carrying case for wrapping and transport.
- 1 (one) 3-10 fiber optic applicator
- 1 (one) protective eyewear
- 1 (one) liter of deionized water
- 1 (one) clinical reference guide
- 1 (one) quick reference guide
- 1 (one) kit with patient marketing materials

WARNING: Keep and save the packaging for sending equipment to technical support services.

8-18® APPLICATOR:

- 1 (one) carrying case for wrapping and transport.
- 1 (one) 8-18 fiber optic applicator
- 1 (one) protective eyewear
- 1 (one) liter of deionized water
- 1 (one) clinical reference guide
- 1 (one) quick reference guide
- 1 (one) kit with patient marketing materials

WARNING: Keep and save the packaging for sending equipment to technical support services.

5-15® APPLICATOR:

- 1 (one) carrying case for wrapping and transport.
- 1 (one) 5-15 fiber optic applicator
- 1 (one) protective eyewear
- 1 (one) liter of deionized water
- 1 (one) pack with the following applicator tips:
    - 1 (one) ∅5mm tip
    - 1 (one) ∅10mm tip
    - 1 (one) ∅15mm tip
- 1 (one) air blower for engaging in cooling equipment
- 1 (one) clinical reference guide
- 1 (one) quick reference guide
- 1 (one) kit with patient marketing materials

WARNING: Keep and save the packaging for sending equipment to technical support services.

3-24® APPLICATOR:

- 1 (one) carrying case for wrapping and transport.
- 1 (one) 3- 24® fiber optic applicator
- 1 (one) protective eyewear
- 1 (one) liter of deionized water
- 1 (one) pack with the following applicator tips:
    - 1 (one) ∅3mm tip
    - 1 (one) ∅5mm tip
    - 1 (one) ∅6mm tip
    - 1 (one) ∅10mm tip
    - 1 (one) ∅12mm tip*
    - 1 (one) ∅14mm tip
    - 1 (one) ∅16mm tip*
    - 1 (one) ∅18mm tip
    - 1 (one) ∅20mm tip
    - 1 (one) ∅24mm tip
    - 1 (one) ∅26mm tip*
- 1 (one) air blower for engaging in cooling equipment

- 1 (one) clinical reference guide
- 1 (one) quick reference guide
- 1 (one) kit with patient marketing materials

* Accessories that can be purchased separately.

WARNING: Keep and save the packaging for sending equipment to technical support services.

8 EQUIPMENT DISPLACEMENT AND TRANSPORT

To move the equipment, follow the procedure described below:

1. Turn off the equipment and put away the power cord.
2. Disconnect the installed applicator and keep it safely in your carrying case for wrapping and transport.
3. Put away the Interlock plug
4. Position yourself at the side of the equipment and lift it by the front and back handles. Safety lifting the equipment requires two people.

TRANSPORT

It is important that all steps in the following section are followed to avoid damage to the equipment during long transport periods or transport to places where the temperature could fall below 0°C. This temperature could freeze the cooling system's water causing damage to the equipment and its applicators.

The water must be drained from the entire system, and it is important to check the original packaging provided with the equipment.

DRAINING THE RESERVOIR

To drain the reservoir:

1. Put the VENT connector,
2. Then connect the hose with the funnel marked DRAIN.
3. Lower the funnel (leaving the hose stretched out) to a level below the reservoir and let the water drain into the appropriate place or receptacle.
4. Connect an applicator. Secure the applicator in the highest position possible above the equipment display so the water from the hoses returns to the equipment using gravity.
5. On the SERVICE screen, press the draining button. 
6. The equipment will activate the water pump, so it can drain the water in the applicator
7. After a period, a message requesting an applicator change or turning off the device will appear.

WARNING: Equipment must always be transported vertically.

9 INSTALLATION

INSTALLATION REQUIREMENTS

ENVIRONMENTAL CONDITIONS FOR USE

Temperature:	20 a 25 °C
Relative humidity:	40 a 60%
Maximum operational altitude:	2000m above sea level

ZYE® equipment must be placed in a room specifically designed to accommodate the device according to the pressure, humidity, and temperature conditions.

To ensure the appropriate operation of the ZYE® equipment, the equipment must be installed correctly under the following conditions:

- Equipment must not be exposed to heat sources or put in areas subject to exposure to water or humidity.
- Avoid placing the equipment in direct sunlight.
- The floor where the ZYE® equipment is installed must be flat without any indentations or ripples.
- The space around the equipment must not be less than 50 cm to assure ventilation and adequate cooling of the internal machine parts.

WARNING: Equipment must be placed at least 50 cm from the wall in its back part for optimal equipment cooling.

WARNING: After positioned for use, lock the casters of the equipment to prevent any unwanted movement.

ELECTRICAL INSTALLATIONS

Complying with the electrical and environmental requisites, position the equipment on a flat, firm, stable surface, leaving a space of at least 50 cm without any surrounding obstacles, including in the back, so nothing will obstruct or impede the access to the switch on the back of the equipment. Turning off the general switch is a form of simultaneous disconnection of two phases of power and must not be obstructed for rapid disconnection if necessary.

With the help of an electrician, check to make sure the power takeoff and the building wiring are well-sized and in good condition before turning on the device. IT is recommended that the installation of the power takeoff that will be used has wires with a gauge that is greater than or equal to 2,5 mm and must be a specific use socket or used exclusively to power the equipment. Also verify the system voltage; the device is designed to work exclusively with 220 Volts AC nominal voltage, 50/60 Hz, and 240 Volts maximum. No device or socket connectors can be turned on between the equipment and the outlet.

The power cord plug should match the local rules where the device will be installed.

WARNING:

-Do not install or use equipment without protective grounding. Do not turn on the equipment protective grounding on the neutral thread of the electrical energy concessionary. These conditions present a safety hazard for the operator and the patient.

-Do not install equipment that prevents access to the general switch located on the back of the equipment. Disconnection of the general switch is a form of simultaneous disconnection of the two phases of power and must not be obstructed for rapid disconnection if necessary.

-Electrical installation of the socket indicated for use with this equipment must contain wires with gauges greater than or equal to 2,5 mm. We also recommend that the socket is used exclusively to power this equipment.

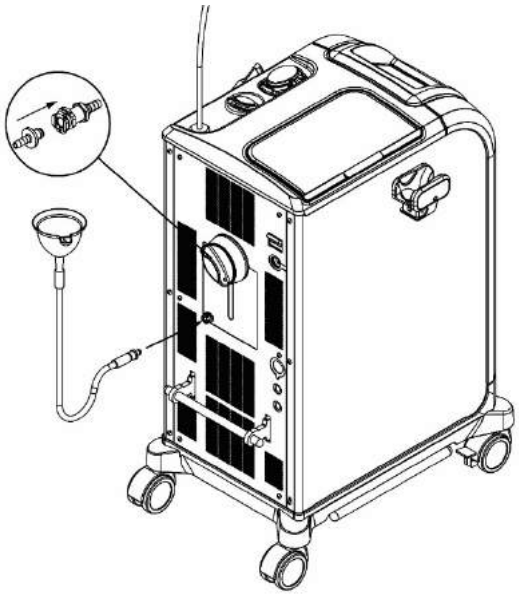
-The use of inadequate electrical installation or installing: line filters, stabilizers, no breaks, and/or outlet connectors can cause equipment failure or damage.

WARNING:

-Equipment grounding will only be efficient and safe to the user and patients if it is done by means of an earthing rod for the equipment.

-The power cord is not removable. If it is necessary to substitute it, this must only be performed by a technical support team member.

RESERVOIR SUPPLY



1. With the equipment completely disconnected, including the power cord, connect the quick hitch to the VENT connector.
2. With the FILL/DRAIN connector, install the hose with the funnel.
3. Keep the funnel above the water reservoir. Drain the water into the funnel, filling the reservoir until it is filled to the maximum level.
4. Remove the vent connector and then disconnect the hose with the funnel.

FIRST SUPPLY

The equipment and applicators arrive from the factory completely drained. When using the equipment for the first time, it is necessary to fill the entire internal circuit with water. Follow the procedure described below:

1. Before turning on the equipment, fill it with deionized water up to its maximum level.
2. Connect the first applicator and turn on the equipment. The reservoir level should be low, then part of the water will fill the applicator hoses.
3. Turn off the equipment, including the power cord and fill it up to the maximum level, repeating the process until the level is adjusted and stabilized.

4. Repeat the procedure until all applicators are installed.

WARNING: Supplying the cooling system can only be done with deionized water. Not complying with this recommendation can compromise the equipment and accessories' operation, as well as decreasing the equipment's lifetime. Read information about the water provided and where to find it in this instruction manual.

WARNING: When new ZYE® applicators are first connected, they still can't contain water in their hydraulic circuit. This situation can cause the equipment to make more noise than normal. This does not represent a risk to the operator or patient, nor can it cause equipment damage. If the noise occurs, turn off the equipment, connect the vent to the pack part and turn on the equipment five minutes later.

INTERLOCK – REMOTE INTERLOCK

The equipment is adjusted for remote system interlock usage. Inactive equipment (in stand-by mode) as well as the connector are removed (see label on the back of the equipment.)

Interlock is an optional safety resource that can be turned on by wiring to an external door switch, allowing the system to be turned off while the door is open.

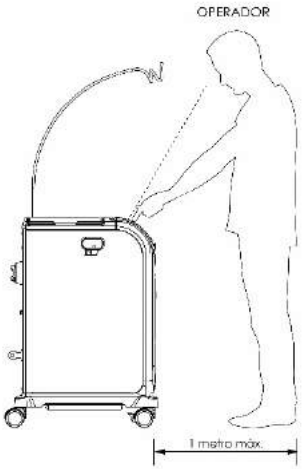
If this resource is used, according to equipment standards, a connector is provided that must be installed for its operation. See the back and accessories where the connector installation is indicated.

WARNING: If the user intends to use this resource in their application room, the company or distributor must be contacted to supply the adequate electrical schema.

RECOMMENDED POSITION OF USE

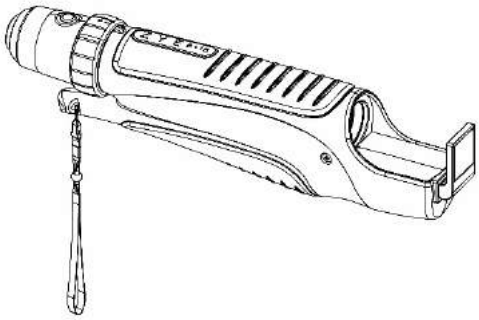
For the best ZYE® equipment usage experience, it is recommended that the user positions the equipment at its side but no more than one meter away from them. It is suggested that the patient is in front. In that position, it is possible to turn around to have access to the controls and guarantee that all information shown on the screen is clearly visible in the designated distance.

Before starting any procedure, choose the best equipment position.



The recommended time of use should not exceed eight hours in a period of 24 hours for the operator and one hour for every 24 hours for the patient. To avoid discomfort due to noise emitted from the machine, is not recommended for the patient and operator to be less than 30 cm away from the device.

PRECAUTIONS FOR HANDLING APPLICATORS



All ZYE® applicators have a wristband installed in the body of the applicator, as shown by the illustration. The purpose of this wristband is to avoid accidental dropping.

Keep the wristband on the wrist while handling the applicator. Keep the wristband evenly on the wrist.

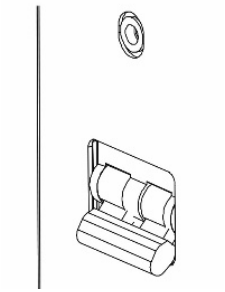
Always check the applicator before turning the instrument on. Check to make sure the applicator tips or filters are in place.

WARNING:
Do not use the applicator without properly putting the wristband on the wrist.
All applicators, LASER spots and filters have parts that are sensitive to dropping and being knocked over. Always use with care! If the device is dropped, do not use it and immediately contact technical support services.

TURNING ON EQUIPMENT

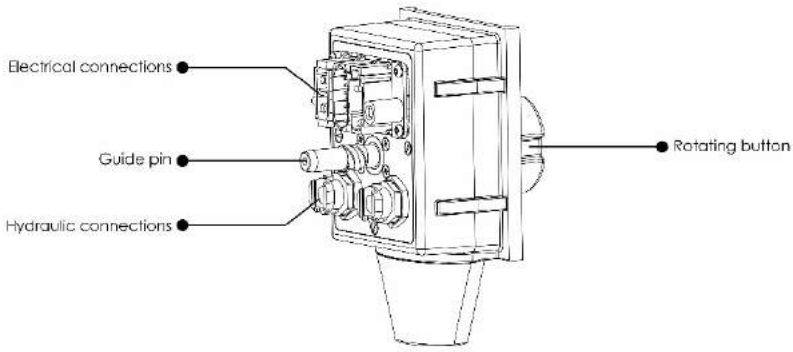
The electrical grid must conform to the specifications (see: installation requirements). Follow the procedure below:

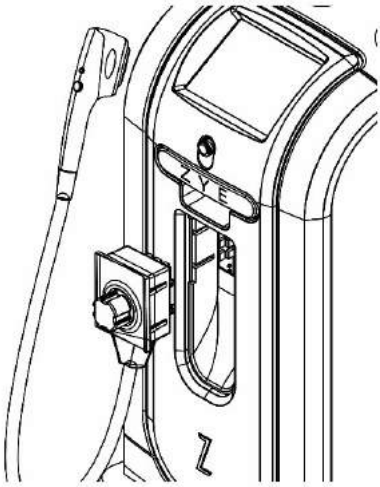
1. Connect the plug to the electrical grid.
2. Activate the general power switch.



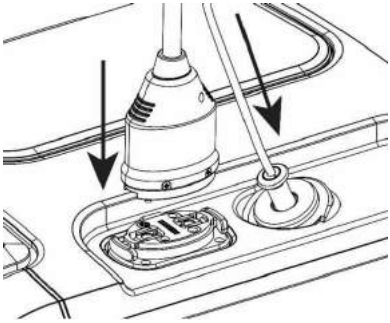
3. Enter the access password in the main screen and make sure that the emergency switch is not activated. If it is activated, the emergency switch will indicate that it is unblocked. Slowly turn the switch in the direction indicated to unblock it.
4. Connect the triggering pedal. Note the correct way to place the connector in the correct position on the back.
5. If the user wishes to use LASER applicators, disregard items six and seven, and place the applicator's connector in the front part of the equipment. Direct

the applicator brace pins (figure below) in the connector's equipment guide. Slowly turn the rotating button clockwise until the end of the course can be heard. Below is an illustration of the connector and its parts.

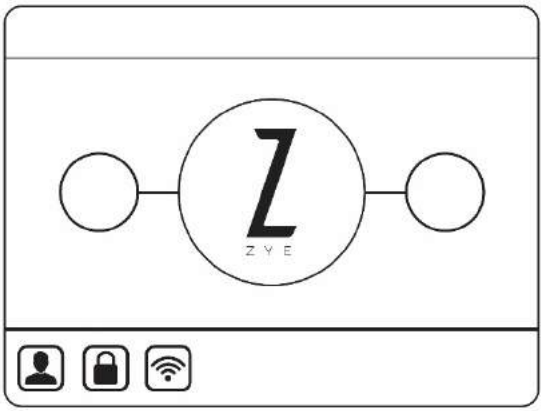




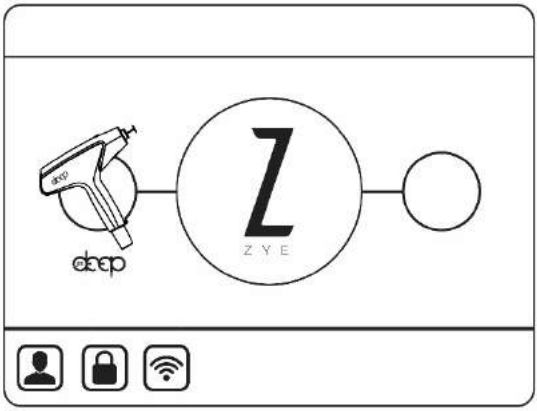
6. Correctly connect the intenseIR® applicator in the front part of the equipment.
7. If the user wishes to use the ALEX or YAG applicators, connect the connectors to the top part of the equipment.



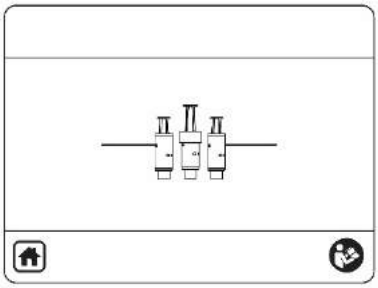
8. Turn on the switch located on the back of the equipment.
9. The system's initializing screen will remain active for a few seconds. Wait until the password screen appears.
10. If the equipment is turned on without installing the applicator or if the applicator is not properly connected, the home screen will appear empty as shown below.



11. Equipment automatically recognizes the applicator that is being installed, and its name will appear at the top of the screen.

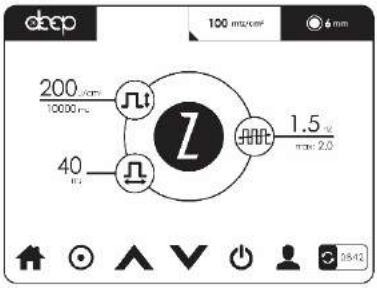


12. Press the applicator icon. If all installation procedures are correctly followed, the "system loading" screen will start up. During this time, the applicator must be positioned in the holder at the side of the equipment.
13. If no tip is connected to the applicator, an alert message will appear on the screen as shown below.



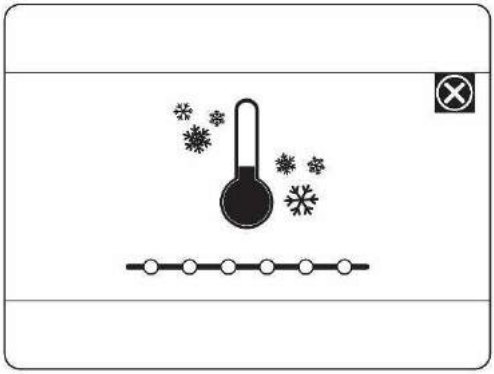
Warning: connect a tip

OR



PRODEEP® Parameter Screen

14. Leave the applicator in the holder while the system boots up.
15. The initial parameter setting screen will appear, as shown by the illustration in the "CONTROL-DISPLAY AND APPLICATORS" section. Equipment is ready. Now it is possible to adjust the settings for the desired application.
16. Adjust the necessary parameters and press the START button to start. It can take a few seconds while the system is loading to reach the adjusted temperature. The screen indicating that the tip is cooling will appear. During this time the sapphire will cool according to the adjusted intensity.

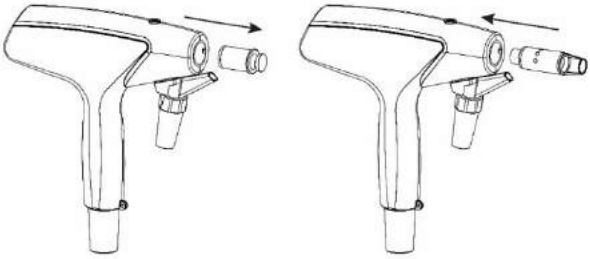


The tip tis cooling

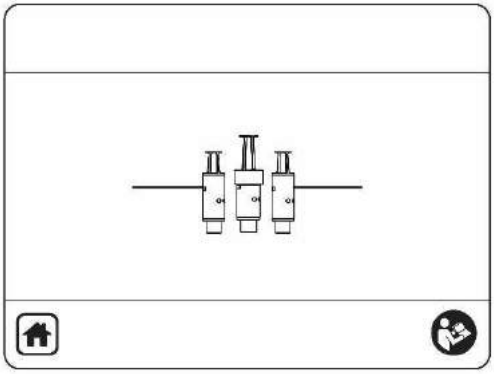
17. After the sapphire cools, if the system fails to recognize this cooling, please contact technical support services immediately.

LASER APPLICATORS

1. If it is in use with another applicator, return to the "HOME" screen, install the LASER applicator chosen, and do the procedure again. The LASER applicator procedure is like the intenseIR®, the difference being that the LASER applicators can be connected to the tips.
2. Remove the cavity lid and install a tip.



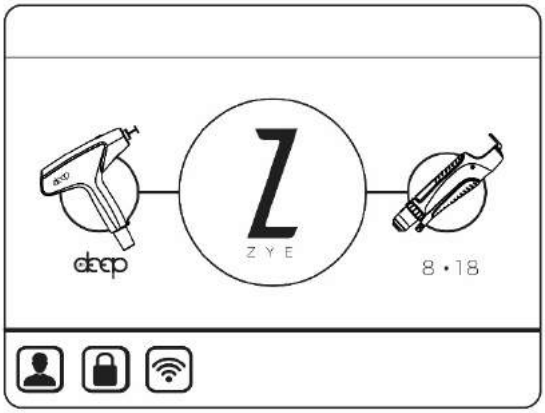
3. Connect the equipment applicator and leave it in the handle (on the left side of the equipment.
4. Press PROCEED to turn on the equipment. The initial control screen of the LASER chosen will appear, according to the "CONTROLS-DISPLAY AND APPLICATORS" section.
5. If the LASER applicator is initiated without any applicator tip, the following message will appear.



Connect the applicator tip

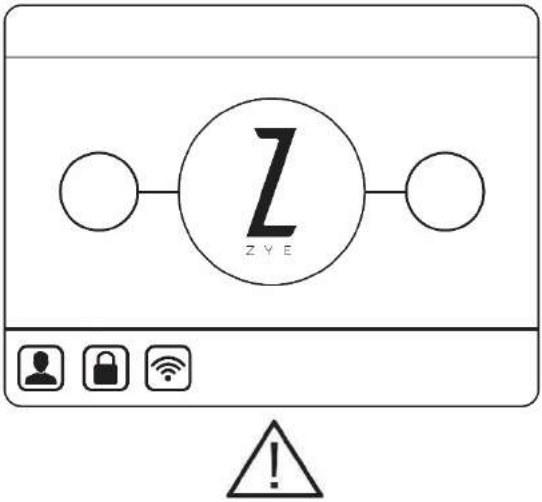
CHANGING APPLICATORS

The ZYE® system has an automatic recognition system for the types of applicators installed. The equipment will recognize which applicator is installed and download the correct system configurations. The indication of the applicator type will be shown with the changing screen.



When connecting any applicator, the equipment: the screen will show the applicators that are available for use. Press the icon referring to the applicator that you wish to use.

This screen will appear only when the equipment is not in use with some applicator.



WARNING: Never disconnect any equipment applicator if parameter screen is in use, or with the cooling system turned on.

ADJUSTING IPL-SQ® APPLICATORS PARAMETERS

Verify that the IPL applicator is properly installed. If not, perform the installation procedure as described in this manual.

Make sure the cutting filter installed is the correct one for your procedure. If it is not, make the exchange.

Place the applicator in the holder and adjust the flow rate, pulse time, frequency, and cooling of the desired tip.

Press the READY key and the unit will automatically go into shooting mode.

Remove the applicator from the holder and watch the green LED lit, indicating that the device is ready for firing.

Put the goggles on all persons in the operating area: operator, patient and others.

Position the applicator in the area to be treated. Always perpendicularly and with a slight pressure.

Press the shutter button or the foot switch. The equipment will automatically charge for the next shot.

WARNING: If the trigger pedal or the shutter button is continuously pressed, the machine will perform continuous shots according to the programmed frequency.

ADJUSTING THE LASER APPLICATORS PARAMETERS

Check to see if the LASER applicator chosen is properly installed. If it is not, perform the installation procedures according to this manual.

Check to see if the applicator tip installed is the correct tip for your procedure. If not, change the tip.

Put the applicator in the holder and adjust the flow value, pulse time, and frequency.

Press the READY  key and the equipment will automatically go into the mode to perform shots.

Remove the applicator from the handle and ensure that the green LED is on, indicating that the equipment is ready to perform shots.

Put the correct protection glasses for the LASER used on all people in the operating area.

Position the applicator to the area that is to be treated. Always position it perpendicular and with the applicator tip leaning against the skin.

Press the pedal (according to the configuration). The equipment will automatically load for the next shot.

WARNING:
- If the pedal or the shot button are continuously pressed, the equipment will perform continuous shots according to the programmed frequency.
- The LASER applicator tips have a length designed to work from the exact distance necessary for treatment.
- Use of controls or settings or the execution of other procedures not specified in this manual can result in harmful exposure to radiation or undesirable effects.

TURNING OFF THE EQUIPMENT

The sequence below must be followed for the correct disconnection of the equipment.

1. Put the equipment in “STAND BY” mode.
2. Press the “HOME” screen.
3. Put the applicator away and perform the cleaning procedures according to the descriptions in this manual.
4. Turn off the equipment with the general switch located in the back of the equipment.
5. Put away the power cord.

10 CONTRAINDICATIONS

WARNING: The equipment is not to be used for self-application.

This equipment is indicated for use in the healthy population from adolescence, but as in many procedures, there are certain clinical conditions not suitable for treatment.

They are as follows:

- Tanned skin;
- Active herpes;
- Open and undiagnosed wounds;
- Allergy to sunlight;
- Anticoagulants;
- Malignant injuries;
- Pregnancy;
- Photosensitizing medicines, such as: Tretinoin and estrogen;
- Diabetes, unless it is under control;
- History of keloid scars;
- Hormonal disorders, unless under control;
- pilepsy;
- History of coagulopathic haemorrhages;
- Area with previous treatments with fillers that cannot be fully reabsorbed;
- Active infectious processes.

SIDE EFFECTS

The most common side effects described in the literature are:

- Feeling of burning in the area;
- Erythema;
- Edema;
- Hypo or hyperpigmentation;

- Burns;
- Purple;
- Ulcers;
- Thrombophlebitis.

We also stressed the risk of eye damage due to accidental therapeutic light exposure. For this reason, both the patient and the operator must wear goggles during the entire treatment.

After treatment, most patients will experience a slight sunburn sensation, which typically disappears without treatment within 2-3 hours.

Other side effects occur only when the technique is not applied correctly.

Among these, the most common is hypopigmentation or hyperpigmentation, which in most cases resolve around 6 months, but that should be treated and monitored. However, in some cases, especially in the case of hypopigmentations, the change in skin color may be permanent.

PRECAUÇÕES ESPECÍFICAS – IPL-SQ®

- The use of waxes or depilatory creams, tweezers, suntan lotions, is not suggested during the two weeks prior to and after treatment.
- Correctly analyze the area to be treated, checking if the skin has no damage. Assess your skin type and tanning level. In case of unhealed wounds or tan, delay treatment until the problem is resolved.
- Direct sun exposure should be avoided at least 4 weeks prior to application and throughout treatment. Previous sun exposure, even with clothing, should be observed to avoid complications. These cases can cause dyschromia of difficult resolution.
- The patient should use sunscreen in the treated areas, before, during and after the entire treatment.
- Both operator and patient should wear protective eyewear. If the treatment is in the periocular region, always wear goggles that completely block the light.
- Try not to have reflective surfaces in the application room.
- Always clean the sapphire tips with gauze before each procedure. The presence of dirt on the surface can cause points of heat concentration and be harmful to the treatment, and may even cause hypo or hyperchromias.
- The same cleaning care should be applied to the filters. If there is any dirt on your surfaces, heat concentration points can be generated and this will hamper the coating of the cutting filters.
- When in doubt about which parameter to use, make a small test area for evaluation. Choose the least exposed place for this. For I-III skin phototypes,

wait 15 to 30 minutes for evaluation. Phototypes IV - V is interesting to wait, at least 24 hours.

- Whenever more energy is needed, the user can increase flow, reduce pulse time, reduce tip cooling or, in the final instance, decrease the cut filter in case of fine hairs. These variations should be performed after the equipment and technical mastery.

SPECIFIC PRECAUTIONS - LASER APPLICATORS

- LASERS must be handled with extreme caution to prevent accidental ocular exposure. This wavelength has a high penetrability and carries the risk of potential permanent ocular lesions. Make sure that all people that could be exposed during treatment are using the correct protection glasses.
- Do not treat vascular lesions through pigmented or tattoo lesions. Hair covering the lesion must also be removed before treatment.
- Always evaluate the photo types: photo types IV and V are at the greatest risk for post-treatment hyperpigmentation. The use of external cooling and greater pulse times can temper this occurrence.
- Cooling before, during, and after treatment is highly recommended. We recommend using cold air coolers such as Siberian Fit equipment.
- A thin layer of cool gel can also be used to protect the epidermis during application.
- Do not press the vessels with the application tip for application. Draining them removes the targeted chromophore decreasing the treatment efficacy.
- Wait a few minutes after a shot sequence. Results are delayed especially for darker skin.
- Double shots or “stacked” shots are not recommended for this type of LASER. The risk of ulcers is high.
- Ensure that there are no reflective surfaces in the application room.
- The Nd: YAG LASER has a high penetrability. When performing oral treatments, it is recommended that you provide protection between the teeth and lips to avoid dental discomfort.
- Always check the integrity and cleanliness of the tip lenses before each treatment. Never use them if they appear bolted or cracked. If cleaning is needed proceed according to this manual’s instructions.
- If there are any questions on the parameters of usage, test on a small area for evaluation. Choose a less exposed area. For I-III photo types, wait fifteen to 30 minutes for evaluation. IV-V photo types should wait at least 24 hours.

11 MAINTENANCE

WARNING: before any cleaning or maintenance procedure, ensure that equipment is turned off and disconnected from the power source. Never perform any type of maintenance on the equipment while it is in use.

PREVENTATIVE MAINTENANCE

CLEANING AND EQUIPMENT PRESERVATION

Clean the equipment at least once a week with a rag using a neutral soap and water to not damage the paint and plastic parts. Be careful not to soak the rag too much to avoid the water entering the equipment.

Check the equipment air entryways weekly in the back of the equipment. If necessary, clean them with a dry rag or a duster.

WARNING: All potentially contaminated material must be discarded as medical waste. Observe your country's regulation for this type of disposal.

CLEANING THE IPL-SQ™ FILTERS

The filters of the IPL applicator need to be cleaned daily or, when it is necessary. After the workday, check for the integrity of the film. It has to be homogeneous and not present translucent parts.

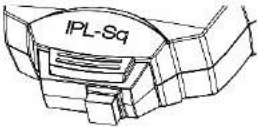
The cleaning has to be performed with cotton or gaze and isopropyl alcohol. In order not to damage the film of filter, clean with care without exerting a lot of strength.

Filter – IPL-sq™

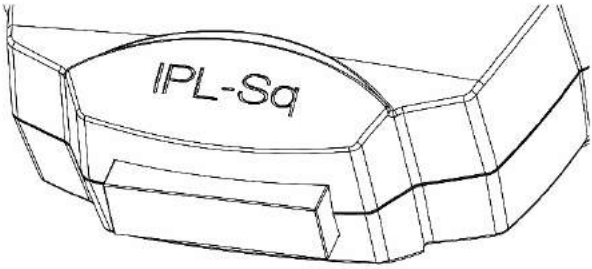
ATTENTION: Any dirt in the interface of the filters during the shot may cause points of heat concentration and cause irreversible damages to it.

CLEANING OF THE IPL APPLICATOR

Rounded vascular tip



Squared vascular tip



12x40mm tip

Always clean the spot before each procedure. The presence of dirt in the interface can cause points of heat concentration and be prejudicial to the treatment.

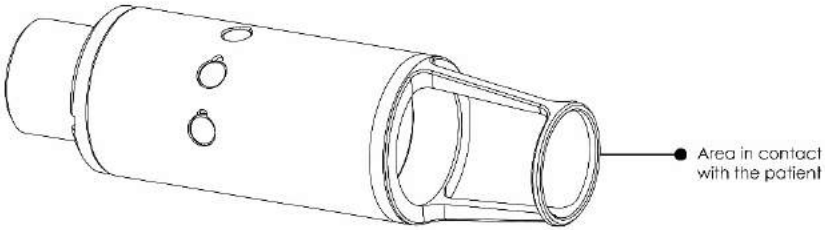
As well as the filters, they can be cleaned with gauze and isopropyl alcohol. Make sure that all the product has evaporated before the first shot and that no gauze lint is present.

Weekly, verifies the integrity of the spot of sapphire spots. The applicator has to be cleaned once a week with a cloth moistened with water and neutral soap. Be careful to prevent entrance of water in the internal part of the applicator.

When the applicator as well as the spot (sapphires) need disinfection, use solution of alcohol 70%. It certifies that the entire product evaporates before the first shot.

CLEANING LASER TIPS

Always clean the applicator tips before and after each procedure.



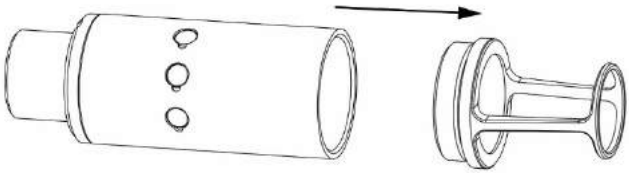
For proper LASER tip cleaning, the spacer must be removed. Turn it counter clockwise and remove it.

The restrictor must be disinfected with a 70% alcohol solution.

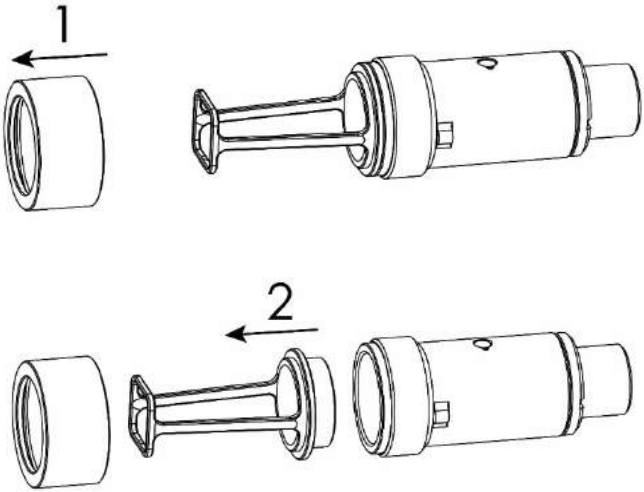
Cleaning the metallic body must be performed with a dry and soft rag.

Avoid touching the LASER lens. To clean it, use a flexible rod with isopropyl alcohol. No filth can be present. Make sure that all the product has evaporated before the first shot.

DISASSEMBLING THE LASER TIPS AND ITS LIMITERS



Disengage the optical base of the limiter by turning counterclockwise. Model with round limiter.

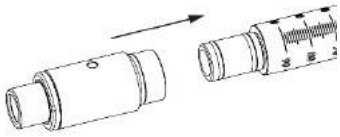


Disengage the optical base of the limiter by turning counterclockwise. Model with square limiter.

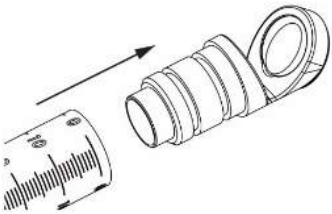
CLEANING PROCESS – ATHENA• AND INLIFT•

For safe use of ZYE® and its applicators, always clean applicator tips that come in contact with the patient after each procedure, following the instructions below.

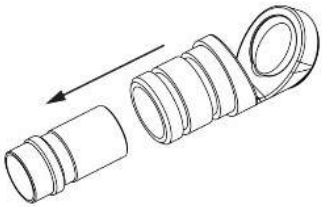
DISASSEMBLING THE TIPS



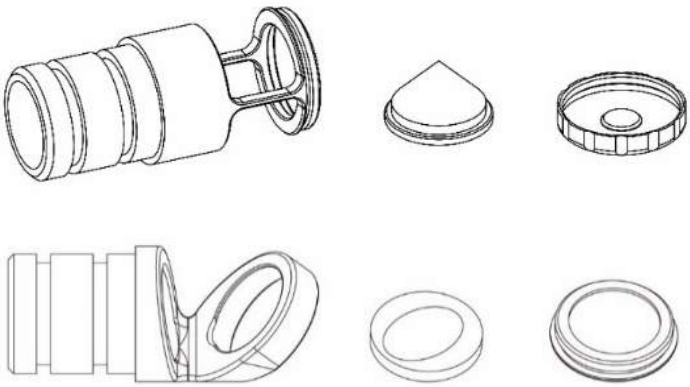
Decouple the optic base of milli metered tube pulling the parts according to the diagrams.



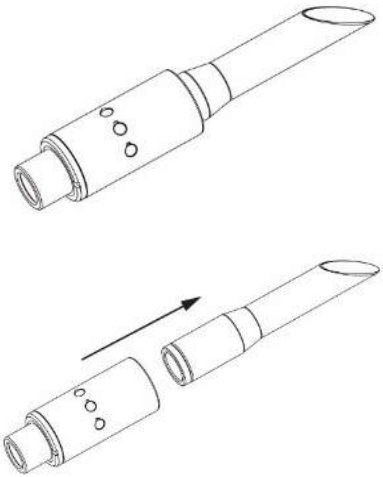
Decouple the 90 or 360◦ tip from the milli metered tube pulling the parts



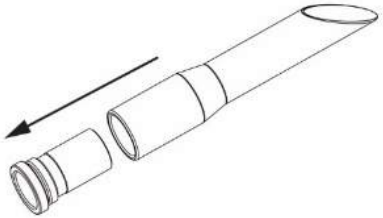
Unscrew the fractionator from the 90+® or 360® tips



Unscrew the 90+® or 360® tip lid and separate the mirrors



Decouple the stainless-steel application tube's optic base, pulling the parts according to the illustration



Unscrew the fractionator from the INOX application tube

OPTIC BASE CLEANING PROCEDURE

The optical base and micro lens illustrated below has a special cleaning procedure and should not be disassembled, cleaned and sterilized as others parts detailed on next pages.

Optic bases of the ATHENA® and INLIFT® tips

Under conditions of normal use, the optic base does not have contact with mucous membranes or exposed tissue. Because it has lenses in its internal parts, it is recommended that only external cleaning with gauze and a 70% alcohol solution is performed. Any other cleaning process can cause irreversible damage to the lenses.

WARNING: Never use the autoclave or other sterilization means that are not recommended for optic base cleaning.

CLEANING PROCEDURE – ATHENA ® AND INLIFT ®

All other pieces of the ATHENA® and INLIFT® applicators that are not the optic bases must follow the cleaning procedures described below.

Photo of pieces that can be taken to the autoclave

1. CLEANING

a. After the complete disassembly of the parts as previously seen, perform immersion in enzymatic detergent, where dilution, temperature and time recommended by the detergent manufacturer should be used.

b. After the immersion time, perform manual brushing with neutral detergent and soft nylon bristle brushes.

WARNING: For the ATHENA 90 and 360 gold-plated mirrors, do not brush with a nylon brush, but use a cotton gauze soaked in neutral detergent, performing gentle cleaning without excessive friction.

c. Rinse in treated water as long as there is no more foam on any of the parts.

2. DISINFECTION

a. After cleaning the pieces, immerse in 70% alcohol for five minutes.

b. Then dry all parts carefully with the aid of a gauze.

3. PARTS DRYING

With the aid of an automatic dryer, perform the procedure below.

a. Remove excess of water from the material.

b. Position the parts inside trays or supports so that hot air penetrates the entire surface. Set the dryer to 70 ° C +/- 5 ° C for 60 minutes.

c. After the drying time, remove the materials and perform inspection observing possible spots of residual moisture.

4. PARTS PACKAGING

a. After drying, inspect the samples again to see if there is no visibility to the cleaning and presence of residual moisture.

b. Assembly again the parts by performing the reverse procedure described in the above disassembly sections. Do not mount the optical base as it should not go through the autoclaving process.

WARNING: Never use the autoclave or other sterilization means that are not recommended for optic base cleaning.

c. Pack the parts mounted on surgical grade paper. Identify the sterilization data, such as date, validity, batch number, material description, etc. in the personalized label packaging.

5. ASSEMBLY AND PACKAGING

a. After the drying process, carefully inspect the parts for residue or moisture.

b. Assemble the parts following the reverse procedure described in the sections above. Do not mount and pack the laser tips with their respective optical base. Optical base must not be autoclaved.

c. Pack the assembled parts using sterilization packaging. Observe the sterilization information on the packaging, such as expiration date, batch, material description, etc.

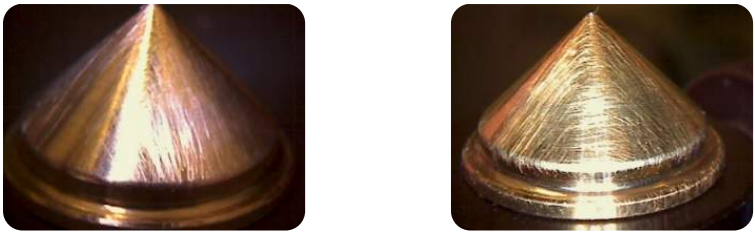
Safeguard for gold mirrors on ATHENA 90 + ® and 360®: Applicators must be made. It is especially important that the user perform a visual inspection and look for scratches or other marks that may degrade the function of the LASER beam reflection.

Any component that needs to be disposed of should be disposed of as hospital waste.

VISUAL INSPECTION OF GOLD MIRRORS

The ATHENA® 90+® and 360® applicator gold mirrors must be visually inspected by the user before assembling the applicator for use. Careful attention must be taken especially during the cleaning process and handling of pieces to avoid scratches or shaking that could affect the LASER reflection and the treatment efficacy. Follow the illustrations below demonstrating pieces in good usable condition or excessively scratched.

360® Gold mirror good for use



360® gold mirror with excessive scratches

CELANING THE ONE TIPS 3-24

Always clean the applicator tips before and after each procedure.

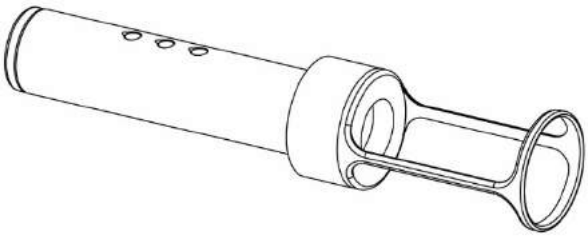
Correct cleaning of the LASERs is necessary to remove the spacer. To do this, turn it counterclockwise by removing it.

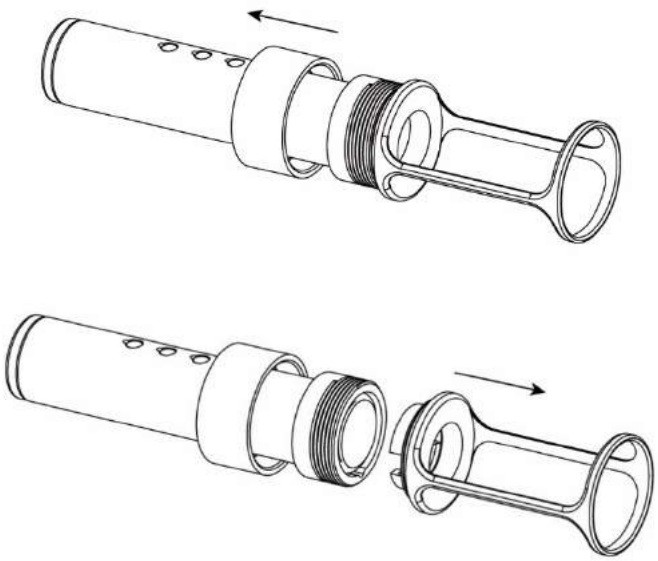
The limiter must be disinfected with 70% alcohol solution.

The metal body must be cleaned with a soft dry cloth.

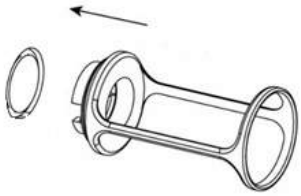
Avoid touching the LASER lens. For cleaning use flexible rod with isopropyl alcohol. No dirt should be present. Make sure all product has evaporated before the first shot.

DISMOUTING THE TIP LASER AND ITS LIMITERS





Disengage the optical base of the limiter by turning counterclockwise. Model with round limiter.



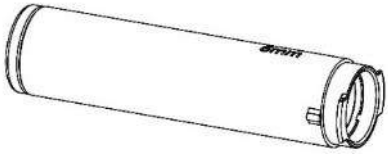
The applicator tips 3-24 have an optical protection window, used to protect the internal lenses during the use of the laser, preventing the burning of the optical elements due to the entry of dirt or particles that are suspended during use.

Easy-to-access disassembly allows quick cleaning using flexible cotton rod with isopropyl alcohol. No dirt should be present. Make sure all product has evaporated before the first shot.

Protective windows are consumable items and should be inspected before and after each use of the equipment. Their shelf-life depends on the type and frequency of treatment plus care in their cleaning.

CLEANING THE APPLICATOR HARNESSES 5-15

Always clean the applicator tips before and after each procedure.



The metal body must be cleaned with a soft dry cloth.

Avoid touching the LASER lens. For cleaning use flexible rod with isopropyl alcohol. No dirt should be present. Make sure all product has evaporated before the first shot.

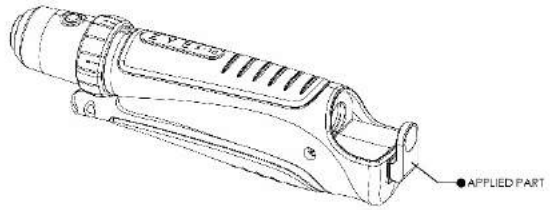
OPTICAL BASE CLEANING PROCEDURE

Under normal conditions of use, the optic base does not come into contact with mucosal regions or exposed tissues. Because it has lenses on its inside, only external cleaning with gauze and 70% alcohol is recommended. Any other cleaning process can cause irreversible damage to the lenses.

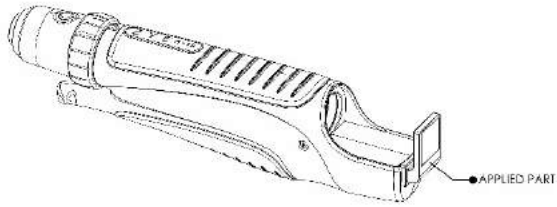
In the case of the necessity of sterilization of the optical base, in view of the potential risk of contamination, the sterilization procedure must be carried out using ETO (ethylene oxide) or cold ionizing vapor, so as not to cause damage to the lenses and optical parts integrated.

CAUTION: Never use autoclave or other forms of sterilization not recommended for optical bases.

CLEANING OF THE ZYE 3-10 AND ZYE 8-18 APPLICATOR



ZYE 3-10°
(ALEX AND YAG)



ZYE 8-18°
(ALEX AND YAG)

Always clean the sapphire before each procedure. The presence of dirt in the interface can cause points of heat concentration and be prejudicial to the treatment.

The sapphire can be cleaned with gauze and isopropyl alcohol. Make sure that all the product has evaporated before the first shot and that no gauze lint is present.

Weekly, verifies the integrity of the sapphire. The applicator has to be cleaned once a week with a cloth moistened with water and neutral soap. Be careful to prevent entrance of water in the internal part of the applicator.

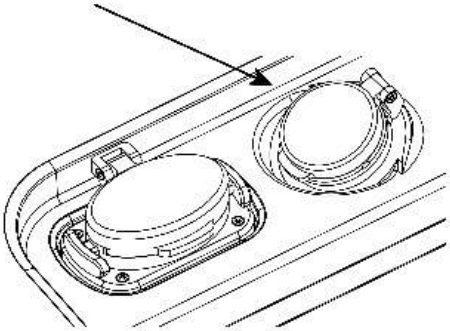
FIBER OPTIC CARE

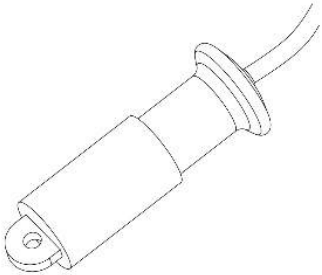
The applicators 3-10®, 8-18®, 5-15® and 5-18® use fiber optics in their operation. The fiber optics cannot and should not be accessed by the user. They should be accessed strictly by Technical Support. The optic interface between the applicator and ZYE® equipment is obtained through a connector specifically developed for the applicators in question, being connected between the applicator and the equipment and automatically identified by the equipment.

Aim not to bend the fiber optics with beams smaller than 40 cm. A good sense of maximum fiber optic curvature can be seen on the protective packaging from the manufacturer.

To avoid damage to the fiber optics or the LASER system, it is important to keep the connecting fiber terminal free of dirt, fingerprints, and scrapes. The best way to achieve this when the applicator's connector is not connected to the equipment is to

keep the LASER equipment output covered as well as the fiber connector. Both have their own lids included for their protection.





The connector should never be leaned nor cleaned with gauze or put on the floor. This damage the LASER in its output and/or has a negative effect on the system performance.

Always visually inspect the face connector/fiber before each use. If it is dirty, burnt, or scratched, VYDENCE Medical Technical Support should be contacted immediately. Not adhering to this recommendation can cause damage to the ZYE® equipment or provide inefficient treatment.

WARNING: when disconnecting the applicator, always remove the electro-hydraulic connector first to facilitate the process and avoid fiber optic damage.

WARNING: fiber optics require careful handling. Never excessively bend. Always check the integrity of the connector adaptable to the equipment.

WARNING: do not touch or insert any tool in the LASER output. This can cause damage to the ZYE® equipment and affect the quality and effectiveness of the treatment.

WARNING: when disconnecting the fiber optic, make sure that the equipment is in standby mode. Disconnecting the fiber when the LASER output has been active can cause irreparable damage to the equipment and the applicator.

WARNING: While the applicator is not connected to the ZYE® equipment, never leave the LASER output of the equipment open without its protection. Any dust or dirt on the LASER outputs can cause damage to the equipment and applicator.

WATER RESERVOIR

Check the cooling system water level weekly. This must always remain between the minimum and maximum level. If refilling is necessary only use deionized water. To fill the water reservoir, connect the supply connector from the kit to the respective equipment entrance and with the help of the funnel, fill the reservoir, paying close attention to fill the reservoir only to the maximum level indicated on the label. Do not forget to put the connector of the KIT at the VENT entrance. See “Reservoir Supply.”

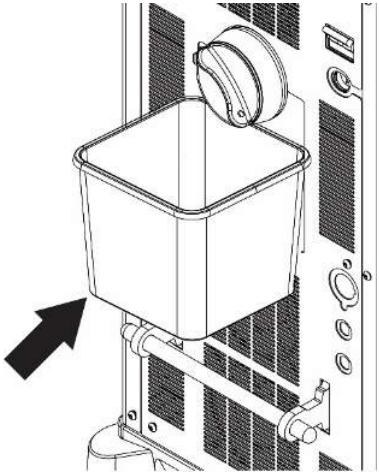
DEIONIZATION AND PARTICLES FILTER- PERIODIC CHANGE

The deionizing and particle filter is used to remove inorganic substances (mineral salts, metal particles, etc.…) that cannot be removed by normal filtration processes.

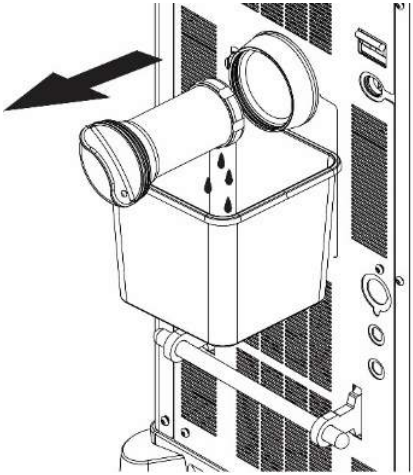
The cooling system filter should be replaced at 6 months interval. It is requested by VYDENCE Medical technical support services. Only the filter specified by VYDENCE Medical should be used.

Perform the following procedure to change the filter:

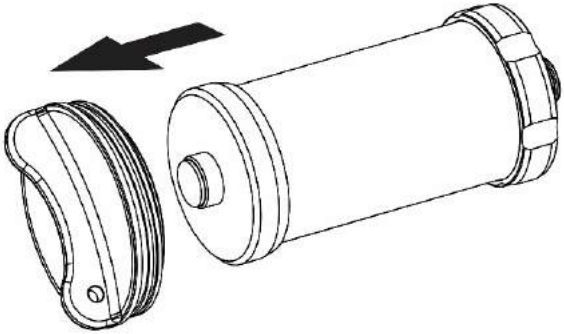
1. Turn off the equipment (take the power cord out).
2. Position a container to collect water under the filter lid.



3. Unscrew the filter lid;



4. Carefully pull the filter out.
5. Unscrew the old filter from the cap and put in the new one.



6. Screw the lid on until it is completely closed.
7. Mark the change date on the label located on the back of the equipment near the filter.

To buy deionizing filters, contact VYDENCE Medical Technical Support and provide the description below for reference "ZYE® deionizing filter."

WARNING: Only use deionized water to fill the reservoir with water. Change the deionizing filter once at 6 months. Not following these recommendations can reduce the lifetime of the equipment and cause damages to the cooling system and optical components. See the section on "Reservoir Supply."

TOUCH SCREEN MONITOR CLEANING

Always use clean hands when touching the screen.

Turn off the device (removing the power cord from the power source) before cleaning.

Use a soft cloth to remove dust. Ideal cloths are microfiber, like those used to clean glasses. Never use porous materials such as sponges. They can damage the touch recognitions system. To protect the monitor from dust and other particle materials, common covers sold in office supply stores are a good solution.

Avoid using alcohol and products such as detergent, solvents, wax, or lubricants.

This procedure must be performed monthly.

ASSESSMENT AND CALIBRATION

ALARM SYSTEM

There is no for the alarm system's functionality to be performed by the operator. The equipment must be assessed and calibrated at least once a year during normal conditions of use to guarantee the correct system operation. This service must be only performed by the company's technical support or by authorized personnel. Contact VYDENCE Medical technical support for more information.

EQUIPMENT

Equipment must be assessed and calibrated at least once a year under normal usage conditions to guarantee the correct output characteristics. This service can only be performed by the company's technical support or authorized personnel. Contact VYDENCE Medical technical support for more information.

TIPS AND APPLICATORS

All tips and applicators of the equipment (intenseIR® and LASER) must be assessed and calibrated at least once a year under normal conditions of usage to guarantee the characteristics of output specified as energy emitted, pulse time, and wavelength. This service can only be performed by the company's technical support or authorized personnel. Contact VYDENCE Medical technical support for more information.

In the case of tip scratching, assessment and adjustments must be made.

CORRECTIVE MAINTENANCE

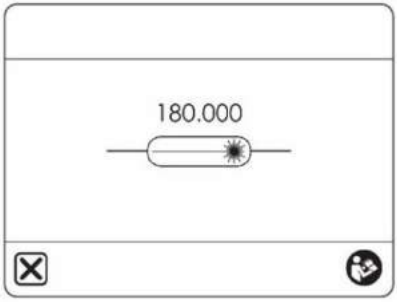
WARNING:
- Do not modify this equipment without the manufacturer's authorization
- Never open the side caps of the equipment to internally access them. Electric shock hazard. This type of procedure is to be performed only by authorized technical personnel.

WARNINGS, ALARMS, AND TROUBLESHOOTING

Many warnings and alarms emitted by the equipment show up on the monitor.

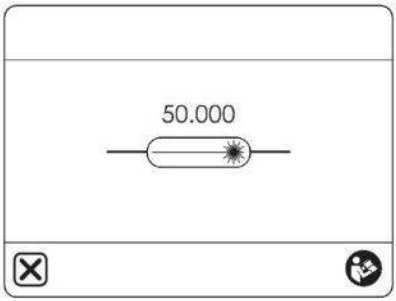
Warnings indicate an action that the user must take to initiate operations with equipment or the state in which the equipment is found. Different from warnings, alarms indicate an incorrect operation or a situation of failure that the equipment experienced in which the equipment will enter safety mode to prevent a risk to the patient or the user. See the table below for a list of equipment warnings.

ZYE® VISUAL WARNINGS



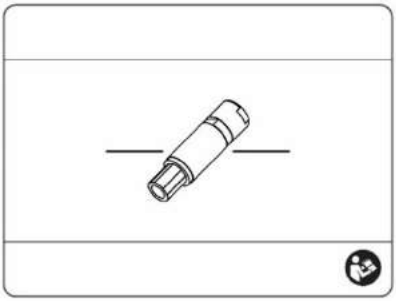
WARNING
180.000 SHOTS PERFORMED

This warning indicates that the lifetime of the lamp is close to the end. The user must contact technical support to schedule periodic maintenance.



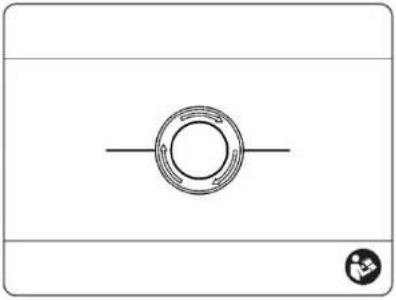
WARNING
50.000 SHOTS PERFORMED

This warning indicates that the lamp has reached the intended end of its life. The user should contact the service center to schedule periodic maintenance.



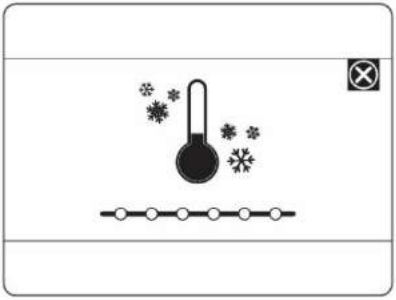
WARNING
CONNECT THE INTERLOCK

The interlock device is not connected. The user must connect the device to initiate equipment operations.

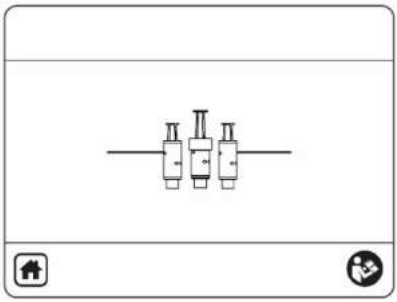


WARNING
EMERGENCY KEY ACTIVATED

The emergency button has been pressed, and the equipment is now disabled. To return to normal operation, carefully turn the button in the direction indicated by the arrows.



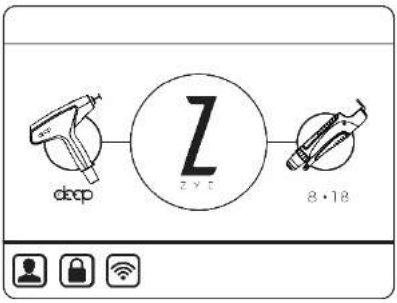
WARNING
COOLING
The sapphire applicator tip in use is cooling. Wait until the tip reaches the desired temperature.



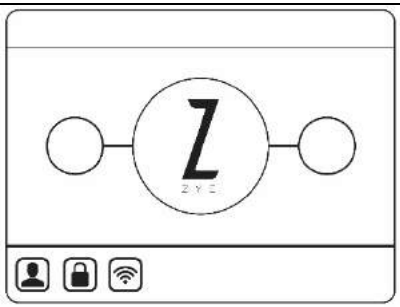
WARNING
CONNECT A TIP
This warning indicates that the lifetime of the lamp is close to the end. The user must contact technical support to schedule periodic maintenance.

WARNING
LOADING

Equipment is initiating the applicator. Wait a few moments.



WARNING
SELECT APPLICATOR
Press the applicator icon that you wish to use.



WARNING
CONNECT AN APPLCIATOR

No applicator is installed. Connect one to start operation.

Alarms alert the user of a failure that was detected by an equipment sensor. The messages for each alarm situation are marked by the following symbol:

Visual icon for low priority alarms.

Alarm condition detection is made automatically with minimal delays. The detection and presentation of failure messages presenting delays of less than 5 seconds when there are simultaneous failures.

The equipment returns to standby mode when there is a detected failure preventing any possibility of incorrect output in the subsequent shots without necessary immediate operator intervention to guarantee safety.

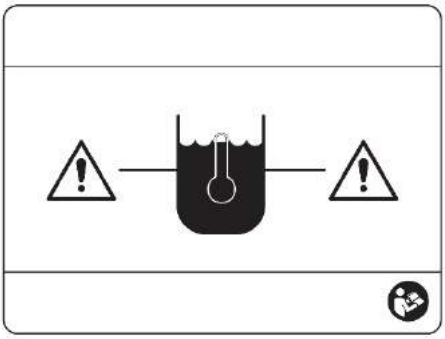
That way all alarms are classified as low priority and are represented by a graphic exclamation point symbol above. A display order for alarms according to the list below from the lowest level of precedence:

- FAILURE IN WATER FLOW
- GENERAL FAILURE
- ENERGY SOURCE FAILURE
- SIMMER CIRCUIT FAILURE
- REFILL THE WATER RESERVOIR
- APPLICATOR COOLING SYSTEM ERROR
- HIGH SYSTEM TEMPERATURE
- SHOT TIME ERROR

The operator must always use the equipment with the screen toward them at a maximum angle of 50° in relation to the norm and from up to one meter, so they can clearly see any type of message shown by the equipment.

The following shows the alarm screens and their causes and recommendations for the user in each case.

ZYE® VISUAL ALARMS

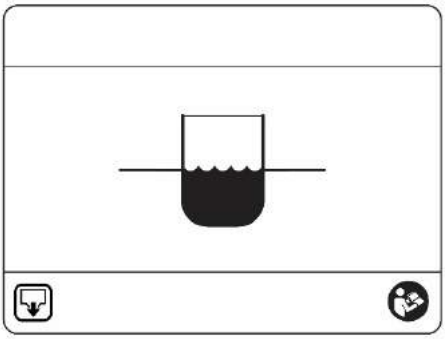


ALARM

HIGH SYSTEM TEMPERATURE

If the internal system temperature is too high, this warning will show, and service will stop to avoid irreversible damage.

- Check environmental installation conditions
- Wait a few minutes before turning on the system again.

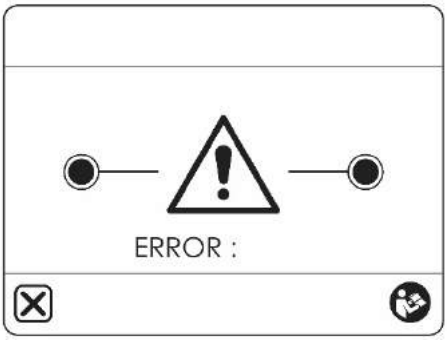


ALARM

REFILL THE WATER RESERVOIR

The water level is low and should be refilled.

- Read the section SUPPLY/DRAINING the reservoir



ALARM

GENERAL FAILURE.

CODE XXX

This alarm has a reference code for the identified failure. Check the following table to see error codes and actions that must be taken. Always contact technical support with the error code readily available.

ERROR CODE	REASON	INSTRUCTIONS
5	The equipment power supply is outside the specification	• Check with an electrician to see if the equipment is connected to a power supply and if it is within the limits specified for ZYE®. Operation. • If the problem persists, contact VYDENCE Medical Technical Support.
21	The water flow is not consistent	• Please see if the applicator is correctly connected. • Check the water reservoir level to see if it is lower than recommended. • If a new applicator is connected for the first time, follow the instructions for the "FIRST SUPPLY." • If the problem persists, contact VYDENCE Medical Technical Support.
Any other	Various causes	• Restart the equipment and try again. • Try another applicator to see if the problem persists. • If the problem persists, provide VYDENCE Medical Technical Support with the error code.

Not all the unit defects are indicated on the display. The next table shows the technical problems not necessarily shown on the equipment screen as well as their causes and suggested solutions.

PROBLEM	CAUSE	SOLUTION
The unit does not turn on.	Low energy	See if there is energy in the grid. See if the power cord connection and the main switch are turned on.
	The emergency stop button is active.	Turn it in the direction of the arrows to disarm it.
	Starter	See if the starter is in the ON position
There are no emissions when the keyboard and/or pedal are pressed.	The system is in STAND BY mode	Activate READY mode
	Pedal is not connected	Connect the pedal correctly to the equipment;
	Button/ pedal failure	Contact technical support.
Equipment does not leave the home screen	User did not proceed to the parameter screen	Press PROCEED to turn the system on.
	Lack of remote interlock device	Correctly install the “Remote interlock device” at the back of the equipment
Dark display appearing turned off	Electrical failure/ equipment is not on	Check the energy grid Check the starter position
	Burnt display	Turn the general switch on and off to restart the system Contact technical support

The messages that the equipment shows in the presence of irregular incidents permit interactivity and quick troubleshooting. Always follow the directions on the screen.

If the corrective measures do not resolve the problem, please contact Vydence Medical technical support.

For any system defect not identified on the list please contact technical support.

Any inappropriate action by unauthorized personnel can result in danger or cause damage to the unit with a loss of the unconditional warranty.

WARNING:

- Equipment cannot be left open by the operator under any circumstances. Any inappropriate action from unauthorize personnel can cause danger or cause damage to the unit with a loss of the unconditional warranty.
- Equipment should not be modified without prior authorization from the manufacturer.

12 TECHNICAL CHARACTERISTICS

EQUIPMENT TECHNICAL SPECIFICATIONS

1. **Origen:**
   VYDENCE Medical – Indústria e Comércio LTDA.
   Street Aldo Germano Klein, 359 – CEAT
   ZIP: 13573-470 São Carlos, SP. Brasil.
   Phone.: +55 (16) 3306-5050 Fax: +55 (16) 3306-5055

2. **Name and commercial model:**
   Commercial Name: Electromedical device of LASER phototherapy and intense pulsed light
   Models:
   - ZYE ALEX®
   - ZYE YAG®

Application function: Equipment for Therapy.
ANVISA Registration Number: 80058580023

3. **Certificate:**
INMETRO: NO RISK 18026

4. **Classification: IEC 60601-1 regulation:**

Type of protection against electric shock	Class I
Degree of protection from electric shock from the application part	BF Application Part
Degree of protection from harmful water-equipment penetration	IP20
Degree of protection from harmful water-application part penetration	IP20
Degree of protection from harmful water-pedal device penetration	IP27
Operation Mode	Continuous

Degree of safety of the application in the presence of mixed anesthetics flammable with air, oxygen or nitrous oxide	Not adequate

5. Classification LASER applicators: regulation IEC 60601-2-22 / IEC 60825:

LASER applicator classification	
Class of LASER risk	Class IV
Degree of protection from electric shock from application parts	Type BF applied part

6. European Directive Classification 93/42/EEC:

Device risk class	Class IIb
CLASSIFICATION RULES	RULE 9

7. ANVISA classification according to RDC 185-200:

Device risk class	Class III
CLASSIFICATION RULES	RULE 9

8. General Description

Operation voltage	200-240 V~
Operation frequency	50-60 Hz
Maximum consumption	4400 VA
Protective device	Bipolar starter 25A, Curve C conforming to NBR NM 60898 and NBR IEC 60947-2.
Equipment dimensions (LxWxH)	60 x 52 x 92cm
Equipment packaging dimensions	63 x 76 x 95 cm
Packaging dimensions of fiber applicators	95 x 56 x 28 cm
Applicator packaging dimensions	42 x 65 x 40 cm
Equipment weight	100Kg
Packaged equipment weight	110kg
Power cord	According to local rules
Wi-Fi Connectivity	Wi-Fi 2.4GHz

9. Applicator technical descriptions

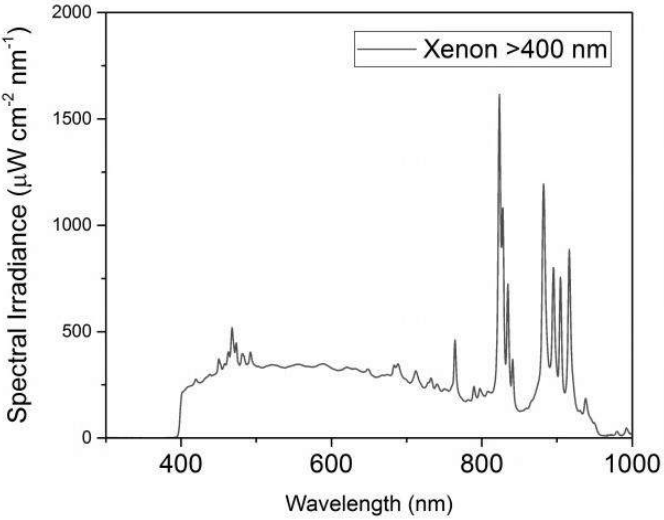
The next section shows the technical descriptions of applicators compatible with ZYE® equipment.

WARNING: For all applicators in the following sections, the parameters without specification errors in the values of energy delivered are considered ± 20% at most for the application area. Increases in these values are not expected during the equipment and applicator lifetimes.

10. IPL-SQ® applicator:

Wavelength	390 to 1200 nm	
Fluence	1 to 30 J/cm²	
Pulse width	5 to 100 ms	
Repetition rate	Up to 3Hz	
Cooling level	5 levels, 1 is the minimum and 5 is maximum cooling	
Available filters	✓ 390nm ✓ 400nm ✓ 515nm ✓ 540nm	✓ 580nm ✓ 640nm ✓ 695nm
Application spot size	Standard: 40 x 12mm Vascular spots: 12x12mm and ∅8mm.	
Applied part material (contact with patient)	Sapphire	
Distance of ocular hazard	50m	
Distance of skin hazard	50m	

The spectral radiance of the lamp used in the IPL-Sq® is given according to the graphic below:



11. IntenseIR® applicator:

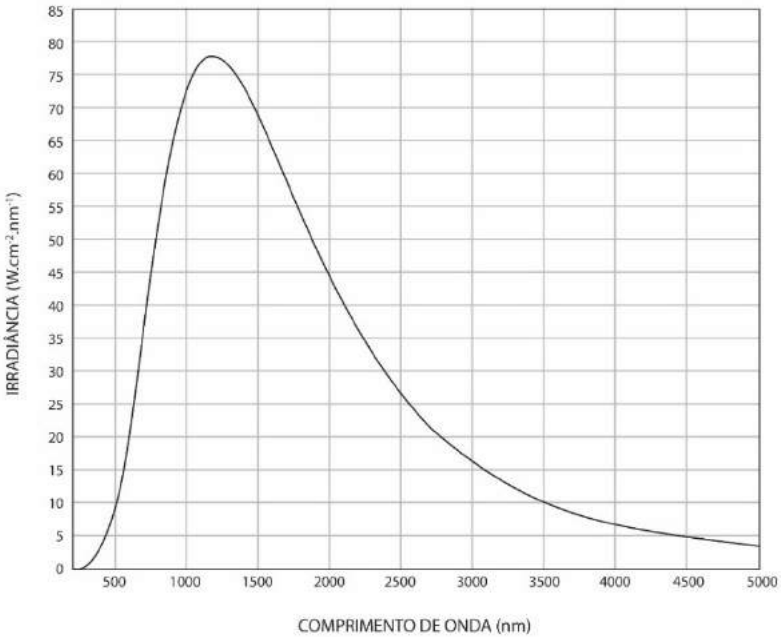
Wavelength	850 to 1800nm
Selectable flow*	19,5 to 130 J/cm2
Pulse time	3 to 10s
Pre-cooling time	0 to 10s
Post cooling time	0 to 5s
Tip cooling	5 levels, level 1 being minimum cooling and level 5 being maximum cooling.
Dimensions of application area	30 x 12mm
Material of application part (contacting patient)	Sapphire and Acetal
Risk group (according to IEC 60601-2-57:2011)	2
Distance of ocular hazard	40m
Distance of skin hazard	40m
Interval between pulses	The interval between pulses depends on the time needed to press the pedal again.

Repetition Rate	There are no automatic re-shots, the pedal must be pressed again to repeat the application.
Number of pulses in a series of pulses	The applicator works with one shot there is not a series of pulses.

* See the following warning.

WARNING: the maximum output variation of the average value for the treatment area for all intended configurations of the equipment is ±20%.
WARNING: the pre-cooling and post cooling time are indicators of treatment that helps the operator monitor the waiting time for the cooling of the treated region
WARNING: pulses are not repeated automatically. For each shot it is necessary to release the pedal and press it again to repeat the treatment.
WARNING: the system works with one pulse (a series of pulses is not used.)

The spectral radiance of the lamp used in the intenseIR® is given according to the graphic below:



12. 1064 LongPulse® Applicator

Wavelength	1064nm ± 5nm
Repetition Rate	Up to 10Hz
LASER Class (IEC 60825-1:2007)	Class 4
Beam provision system	Solid state LASER shooting from the applicator through the xenon lamp.
Application part (contact with patient.)	Aluminum

Applicator Tips:

Tips	Pulse Width Range (ms)	Max. Energy (J)	Divergence (mrad)	Nohd* (m)
∅2mm	0,3 – 20	15	24	9,46
∅3 mm	0,3 – 30	33	49	3,95
∅6 mm	0,65 – 60	45	15	29,57
∅9 mm	20 – 40	45	7	74,05

*NOHD: Nominal ocular hazard distance

13. 1340 ProDeep® Applicator

Wavelength	1340 nm ± 5nm
Repetition Rate	Up to 2,5Hz
LASER Class (IEC 60825-1:2007)	Class 4
Beam provision system	Solid state LASER shooting from the applicator through the xenon lamp.
Application part material (contact with the patient)	Aluminum

Applicator tips:

Tips	Pulse Width Range (ms)	Max. Energy (J)	Divergence (mrad)	Nohd* (m)
□8mm – 100mzt/cm2	3 – 10	12,8	20	3,13
□10mm – 400mzt/cm2	3 – 10	8	236	0,05
∅6mm	3 – 20	11,3	13	6,3

* NOHD: Nominal ocular hazard distance

14. 2940 DualMode® Applicator

Wavelength	2940 nm ± 5nm
Repetition Rate	Up to 5Hz
LASER Class (IEC 60825-1:2007)	Class 4
Beam provision system	Solid state LASER shooting from the applicator through the xenon lamp.
Application part material (contact with the patient)	Aluminum

Applicator tips:

Tips	Pulse Width Range (ms)	Max. Energy (J)	Divergence (mrad)	Nohd* (m)
□8mm – 400mzt/cm²	0,3 – 5	3,45	202	0,39
□8mm – 100mzt/cm²	0,3 – 5	3,36	18	4,53
∅6mm	0,3 – 1	1,52	10	9,35
∅2,5mm	0,3 – 1	1,522	27	3,55
ATHENA 90+®	400	3,01	5	14,56
ATHENA 360®	400	7,69	5	14,56
INLIFT®	400	3,01	5	14,56
∅8mm	400	3,01	5	14,56
∅8mm – 100mtz/ cm²	400	3,01	5	14,56
∅12mm	0,2 – 1	1,52	10	9,35
∅12mm – 100mtz/cm²	400	3,01	5	14,56

*NOHD: Nominal ocular hazard distance

15. 1540 GoSmooth® Applicator

Wavelength	1540 nm ± 5nm
Repetition Rate	Up to 1Hz
LASER Class (IEC 60825-1:2007)	Class 4
Beam provision system	Solid state LASER shooting from the applicator through the xenon lamp.
Application part material (contact with the patient)	Aluminum

Applicator Tips:				
Tips	**Pulse Width Range (ms)**	**Max. Energy (J)**	**Divergence (mrad)**	**Nohd* (m)**
□8mm – 100mzt/cm²	10 a 15	6,08	17	3,1
□10mm – 400mzt/cm²	10 a 15	6,40	209	0,22

*NOHD: Nominal ocular hazard distance

16. ACROMA® Applicator

Wavelength	532nm ± 5nm or 1064 nm ± 5nm
Repetition frequency	Up to 5Hz
LASER Class (IEC 60825-1:2007)	Class 4
Beam provision system	Solid state LASER shooting from the applicator through the xenon lamp.
Application part material (contact with the patient)	Aluminum

Applicator tips:				
Tips	**Pulse Width Range (ms)**	**Max. Energy (mJ)**	**Divergence (mrad)**	**Nohd* (m)**
∅3mm	20	1500	90	8
∅5mm			42	25
∅7mm			10	552
∅9mm – 100mzt/cm²			30	31
∅3mm (532nm)			90	169
∅5mm (532nm)			42	25

* NOHD: Nominal ocular hazard distance

17. ALEX INTERNAL CAVITY

Wavelength	755nm ± 5nm
Repetition Frequency	Up to 20Hz
LASER Class (IEC 60825-1:2007)	Class 4
Beam provision system	Solid state LASER shooting through a xenon lamp in an internal cavity
Application part material (contact with the patient	Copper frame bathed in gold with soldered sapphire.
Applicator tips:	

Applicator	Spot	Pulse Width (ms)	Max. Energy (J)	Divergence (mrad)	NOHD* (m)
3–10	∅3mm	0,2 a 100	35,3	102	19,28
	∅5mm	0,2 a 100	49,0	76	37,59
	∅6mm	0,2 a 300	70,6	72	46,35
	∅8mm	0,3 a 300	70,3	65	65,04
	∅10mm	0,65 a 300	98,1	97	66,55
8–18	□8mm	3 a 300	96,0	65	91,95
	□10mm	3 a 300	100,0	97	94,12
	□12mm	3 a 300	93,6	126	88,28
	□14mm	3 a 300	90,1	141	92,04
	□16mm	3 a 300	92,1	156	95,07
	□18mm	3 a 300	97,2	131	127
5–15	∅5mm	0,2 a 15000	10,79 (J) / 50,0 (W)	76	28,85
	∅10mm	5000 a 15000	50,0 (W)	97	47,06
	∅15mm	5000 a 15000	50,0 (W)	156	44,56
3–24	∅3mm	0,2 a 100	35,3	102	19,28
	∅5mm	0,2 a 100	49,0	76	37,59
	∅6mm	0,2 a 300	70,6	72	46,35
	∅10mm	3 a 300	78,53	97	94,12
	∅12mm	3 a 300	90,47	138	56,95
	∅14mm	3 a 300	92,36	158	58,08
	∅16mm	3 a 300	96,50	127	82,54
	∅18mm	3 a 300	86,51	146	80,58
	∅20mm	3 a 300	86,51	146	80,58
	∅24mm	3 a 300	86,51	146	80,58
	∅26mm	3 a 300	86,51	146	80,58

* NOHD: Nominal ocular hazard distance

18. YAG INTERNAL CAVITY

Wavelength	1064nm ± 5nm
Repetition Frequency	Up to 20Hz
LASER Class (IEC 60825-1:2007)	Class 4
Beam provision system	Solid state LASER shooting through a xenon lamp in an internal cavity.
Application part material (contact with patient)	Copper frame bathed in gold with soldered sapphire.

Applicator tips:

Applicator	Spot	Pulse time (ms)	Max energy (J) []	Divergence (mrad)	NOHD* (m)
3-10	∅3mm	0,2 a 100	35,3	102	19,28
	∅5mm	0,2 a 100	49,0	76	37,59
	∅6mm	0,2 a 300	70,6	72	46,35
	∅8mm	0,3 a 300	70,3	65	65,04
	∅10mm	0,65 a 300	98,1	97	66,55
8-18	□8mm	3 a 300	96,0	65	91,95
	□10mm	3 a 300	100,0	97	94,12
	□12mm	3 a 300	93,6	126	88,28
	□14mm	3 a 300	90,1	141	92,04
	□16mm	3 a 300	92,1	156	95,07
	□18mm	3 a 300	97,2	131	127
5-15	∅5mm	0,2 a 15000	10,79 (J) / 50,0 (W)	76	28,85
	∅10mm	5000 a 15000	50,0 (W)	97	47,06
	∅15mm	5000 a 15000	50,0 (W)	156	44,56
3-24	∅3mm	0,2 a 100	35,3	102	19,28
	∅5mm	0,2 a 100	49,0	76	37,59
	∅6mm	0,2 a 300	70,6	72	46,35
	∅10mm	3 a 300	78,53	97	94,12
	∅12mm	3 a 300	90,47	138	56,95
	∅14mm	3 a 300	92,36	158	58,08
	∅16mm	3 a 300	96,50	127	82,54
	∅18mm	3 a 300	86,51	146	80,58

	∅20mm	3 a 300	86,51	146	80,58
	∅24mm	3 a 300	86,51	146	80,58
	∅26mm	3 a 300	86,51	146	80,58

*NOHD: Nominal ocular hazard distance

*ws: spot with spacer

19. Degree of protection from protective glasses:

See section on "Safety items-safety glasses."

20. Environmental conditions of operation:

Temperature	20 to 25 °C
Relative humidity	40 to 60%
Maximum operational altitude	2000m above sea level

21. Storage and transport conditions:

Temperature	-5° to 70°C
Relative humidity	10 to 80%
Maximum stacking	Stacking not permitted
Maintain away from sun	
Fragile medical equipment transport with care.	
Do not get the packaging wet	
Transport position indicated on the packaging	
Equipment and parts provided are not sterile	

WARNING: Check the packaging integrity when you receive the equipment. If it is damaged or opened, check all accessories and parts to ensure that nothing is missing or damaged.

22. Liquid in cooling system:

Deionized water – water that has had their electrical charge neutralized through the addition or removal of ions. This process removes nitrates, calcium, and magnesium from the water as well as cadmium, barium, lead, and some forms of radium.

Composition: chemically pure water (free of ions) of low conductivity described in the Brazilian Pharmacopoeias, Third edition.

The code for purchasing deionized water through VYDENCE Medical technical support is: Agua deionized (1L): Code VYDENCE 7419.

RULES AND REGULATIONS FOLLOWED

IEC 60601-1:2005 + AMD:2012 – Medical electrical equipment – Part 1 – General requirements for basic safety and essential performance.

IEC 60601-1-2:2014 – Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests;

IEC 60601-1-6:2010 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability.

IEC 60601-2-22:2007 + AMD:2012 – Medical electrical equipment – Part 2 – Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic LASER equipment

For all purposes, Vydence Medical considers the regulations written in territories recognizing the IEC that have active organizations responsible for the internalization of international regulations (such as ABNT in Brazil or ANSI/AAMI in the USA) are automatically adhered to by the equivalent regulations expressed above so that there may be a presumption of express conformity from the presumption of equivalency that can be determined in rules and regulations of each of these territories.

BIOCOMPATIBILITY

Applied parts: all described within this manual.

We declare under our own responsibility that the materials used in the application parts of the ZYE® equipment have been widely used in the medical field for a long time.

Therefore, the material used is considered adequate for its intended purposes not presenting a usage risk.

ELECTROMAGNETIC COMPATIBILITY

RADIOFREQUENCY INTERFERENCE

As well as other electronic medical equipment, ZYE◦ requires special precautions to ensure electromagnetic compatibility with other electromedical devices. To ensure electromagnetic compatibility, (EMC) ZYE◦ must be installed and operated according to the EMC information provided in this manual. See Appendix One, EMC Guidelines and Manufacturer Declarations. ZYE◦ was designed and tested to obey the requirements of IEC regulation 60601-1-2:2014 for EMC with other devices.

WARNING: This system is intended only for use by healthcare professionals. This system can cause radiofrequency interference (RF) and can interrupt the operation of equipment near it. It can be necessary to take measures such as reorienting or repositioning the system or shielding its location.

ATTENTION: Do not use cables or accessories that are not provided by ZYE◦, seeing that this can result in an electromagnetic emission increase or decrease in immunity to said emissions. See below for a list of approved accessories that can be used with the equipment:

WARNING: Mobile equipment or handheld RF communication devices can affect the normal operation of ZYE◦.

WARNING: We recommend that ZYE◦ equipment is not used close to or stacked on top of other equipment

CAUTION: If using ZYE◦ equipment on or near other equipment is necessary, look for and verify normal LASER system normal operation in the configuration where it will be used before using it in a procedure.

ACCESSORIES/REFERENCE
Pedal MKF 1PW SK12 (Manufacturer: Steute)
ACCESSORIES/REFERENCE
IPL-sq® applicator
IntenseIR◦ applicator
LASER 1540nm GoSmooth◦ applicator
LASER 1064nm ACROMA® applicator
LASER 1064nm LongPulse◦ applicator

LASER 1340nm ProDeep◦ applicator
LASER 2940nm DualMode◦ applicator
LASER 8-18mm® applicator (ZYE YAG AND ZYE ALEX)
LASER 3-10mm® applicator (ZYE YAG AND ZYE ALEX)
LASER 5-15mm® applicator (ZYE YAG)
LASER 3-24mm® applicator (ZYE YAG AND ALEX)

EMC GUIDELINES AND MANUFACTURER DECLARATIONS

ATTENTION: In no situation is the essential performance of this equipment characterized by the equipment being able to emit LASER power greater than 1.2 times that shown on the display and adjusted by the user (Energy adjusted +20% of tolerance)

Orientations and Manufacturer Declarations-Emissions		
ZYE◦ is intended for the use in the electromagnetic field specified below. The client or the user must ensure the use of the environment like the one below.		
Emission Test	**Conformity**	**Electromagnetic environment – Orientations**
RF Emissions – CISPR 11	Group 1	ZYE◦ uses RF energy for its internal function. Therefore, the RF emissions are very low and probably don't cause any interference with nearby electronic equipment.
RF Emissions – CISPR 11	Class A	The emission characteristics of this equipment makes it suitable for use in industrial areas and hospitals (IEC / CISPR 11 Class A). If used in a residential environment (for which IEC / CISPR 11 Class B is normally required), this equipment may not provide adequate protection for radio frequency communication services. The user may need
Harmonic Emissions IEC 61000-3-2	Class A	
Emissions due to the fluctuation in voltage/scintillation IEC 61000-3-3	Conforms	

		to take mitigation measures, such as relocating or reorienting the equipment. The equipment is not suitable for use in an electrical network that is directly connected to a low voltage electrical network that feeds buildings used for household purposes.

Separation distance recommended between communication equipment due to portable and mobile RF and ZYE•.

ZYE• is intended for use in an electromagnetic environment where RF disturbances are controlled. The buyer or operator of the ZYE• can help prevent electromagnetic interference maintaining a minimum distance between mobile and portable RF communication equipment (transmitters) and ZYE• as recommended below according to the maximum power of the communication equipment output.

Maximum power of transmitter output declared (W)	Separation distance according to transmitter frequency		
	150 kHz to 80 MHz $d=1,17\sqrt{P}$	80 MHz to 800 MHz $d=1,17\sqrt{P}$	800 MHz to 2,5 GHz $d= 2,3\sqrt{P}$
0,01	11,70 cm	11,7 0cm	23,00 cm
0,1	37,00 cm	37,00 cm	72,70 cm
1	1,17 m	1,17 m	2,30 m
10	3,70 m	3,70 m	7,27 m
100	11,70 m	11,70 m	23,00 m

For transmitters with maximum power of the declared output not listed above, the recommended separation distance (d in meters) can be determined using the applicable equation to the transmitter frequency where P is the maximum power of the transmitter output in (W) according to its manufacturer.

NOTE 1: at 80 MHz and 800 MHz, a separation distance for higher frequencies applies.

NOTE 2: this procedure can apply to all situation. Electromagnetic propagation is affected by the absorption and reflection of structures, objects, and people.

MANUFACTURER'S DECLARATIONS AND ORIENTATION–ELECTROMAGNETIC IMMUNITY			
ZYE◦ is intended to be used in the electromagnetic environment specified below. The buyer or operator of the ZYE◦ that it is in use only in such environments.			
Immunity tests	**Test level of IEC 60601**	**Conformity level**	**Electromagnetic environment – orientation**
			Portable and mobile communication equipment through RF should not be used closer in any way to any ZYE◦ part including cables, the recommended distance of which is calculated from the applicable equation for the transmitter frequency.
RF Conducted IEC 610004-6 RF Irradiated IEC 610004-3 Field next IEC 61000-4-3 Ed.3.0 (2006) +A1 (2007) +A2 (2010)	3 VRMS 150 kHz to 80 MHz and 6 VRMS in the bands ISM between 0,15 e 80 MHz 3 V/m 80 MHz to 2,5 GHz See Table 1: Immunity to near field	3 VRMS 150 kHz to 80 MHz and 6 VRMS in the bands ISM between 0,15 e 80 MHz 3 V/m 80 MHz to 2,7 GHz See table1: Immunity to near field	Recommended separation distance $d=1,17\sqrt{P}$ $d=1,17\sqrt{P}$ 80 MHz to 800 MHz $d=2,3\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer, and d is the separation distance recommended in meters (m). The field generated by fixed RF transmitters, as determined by electromagnetic field research, must be lower than the level of conformity in each frequency beam. b  Interference can occur in the equipment surroundings with the following symbol:
NOTE 1: when there are beams between 80 MHz and 800 MHz a greater beam frequency applies			

NOTE 2: this procedure is not applicable in all situations. Electromagnetic propagation is affected by the absorption and reflection of objects, structures, and people.
a. The intensity of fields generated by fixed transmitters such as phone-based radio stations (cell/wireless) and mobile earth radios, amateur radios, AM, FM, and TV broadcasting stations cannot theoretically be predicted with precision. TO evaluate the electromagnetic environment due to fixed RFs, a study of the electromagnetic fields in the area must be considered. If the intensity of the measured field in the place where ZYE◦ is used exceeds the level of conformity above, ZYE◦ must be observed to verify that the equipment is operating normally. If abnormal performance is observed, additional measures could be necessary such as the reorientation or relocation of the ZYE◦; b. Above the frequency scale of 150 kHz to 80 MHz the intensity of the filed must be less than 3 V/m.

MANUFACTURER DECLARATIONS AND ORIENTATION-ELECTROMAGNETIC IMMUNITY			
ZYE◦ is intended to be used in the electromagnetic environment specified below. The buyer or operator of the ZYE◦ that it is in use only in such environments.			
Immunity tests	**Test levels of IEC 60601**	**Conformity level**	**Electromagnetic environment-Orientation**
Electrostatic discharge IEC 610004-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The floor must be wood, concrete, or ceramic. If the floor is covered with synthetic material, the relative humidity of the air must be at least 30%.
Rapid transient bursts IEC 610004-4	± 2 kV power line ± 1 kV entry line and signal output	± 2 kV power line Not applicable	
Surge IEC 610004-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	

Voltage drops, short interruptions and variations in voltage and power supply. IEC 61000-4-11	<5% Ut (>95% drop Ut) Per 0,5 cycle 40% Ut (60% drop Ut) Per 5 cycles 70% Ut (30% drop in Ut) Per 25 cycles <5% U (>95% drop in Ut) Per 5 s 100% (0% UT) per 0,5 cycle in the angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° e 315° 100% (0% UT) per 1 cycle (single-phase: to 0°) 30% (70% UT) per 25/30 cycles (single-phase: to 0°) Voltage interruptions: 100% (0% UT) por 250/300 cycles and maximum. At any declared nominal frequency.	<5% Ut (>95% drop in Ut) Per 0,5 cycle 40% Ut (60% drop in Ut) Per 5 cycles 70% Ut (30% drop in Ut) Per 25 cycles <5%Ut (>95% drop in Ut) Per 5 s 100% (0% UT) per 0,5 cycle at the angles of 0°, 45°, 90°, 135°, 180°, 225°, 270° e 315° 100% (0% UT) per 1 cycle (single-phase: a 0°) 30% (70% UT) per 25/30 cycles (single-phase: to 0°) Voltage interruptions: 100% (0% UT) por 250/300 cycles and maximum. At any declared nominal frequency.	The quality of the electrical grid must be that of the typical hospital or commercial environment.
Magnetic fields of grid	3 A/m and 30 A/m	3 A/m and 30 A/m	Magnetic fields of the grid frequencies must be levels characteristic of a typical

frequency (50/60 Hz) IEC 610004-8			hospital or commercial environment.
Note: Ut is a C.A. grid voltage before the test level application.			

Table 1: Immunity to near field

IMMUNITY TO NEXT FIELD				
Band [MHz]	**Freq. Test [MHz]**	**Service**	**Modulation**	**Test level [V/m]**
380 to 390	385	TETRA 400	Pulse, 18 Hz	27
430 to 470	450	GMRS 460, FRS 460	FM, 1 kHz, Deviation from ± 5kHz	28
704 to 787	710 745 780	Band LTE 13, 17	Pulse, 217 Hz	9
800 to 960	810 870 930	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, Band LTE 5	Pulse, 18 Hz	28
1.700 to 1.990	1.720 1.845 1.970	GSM 1800, CDMA 1900, GSM 1900, DECT, Banda LTE 1, 3, 4, 25, UMTS	Pulse, 217 Hz	28
2.400 to 2.570	2.450	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, Band LTE 7	Pulse, 217 Hz	28
5.100 to 5.800	5.240 5.500 5.785	WLAN 802.11 a/n	Pulse, 217 Hz	9

13 GENERAL INFORMATION

EQUIPMENT LIFETIME

Understanding and adhering to the conditions of operation and maintenance described in this manual, the equipment has a lifetime of at least five years from the estimated original operation.

Equipment can continue to be used after the lifetime of five years if it passes a general factory inspection.

APPLICATOR LIFETIME

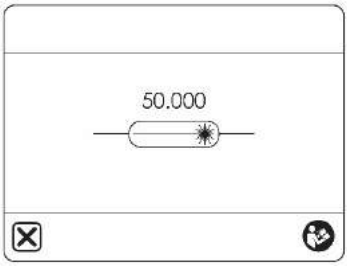
WARNING: When all lamps have reached the end of the life of the lamps, they must be replaced by VYDENCE Medical's service department or authorized representatives. Failure to comply with this recommendation may pose a risk to the application.

IPL-SQ™ APPLICATOR

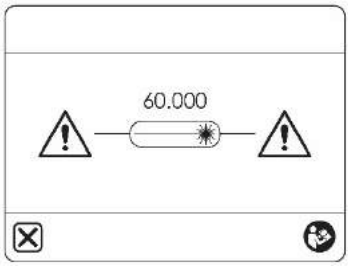
The lamp of the IPL-Sq™ applicator has a total useful life of 60000 (sixty thousand) shots. The system alerts the user in regard to the need of scheduling for change the Lamp.

The warning message about lamp life starts at 50,000 shots and after 55,000 with a subsequent alarm every 1000 shots, up to a total of 60,000 shots.

The Technical Assistance will have to be contacted when the system of alerts is initiated. The messages of alert are indicated in the figures down.



Beginning of the warnings with 50000 shots hit and after 55000 for every 1000 subsequent shots.

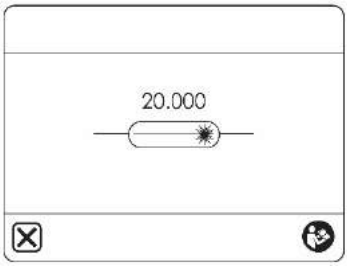


Alarm indicating the end of the lifetime.

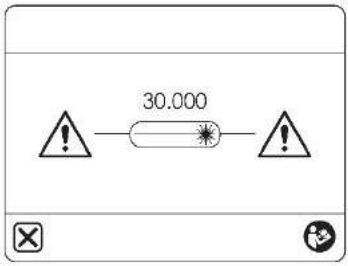
INTENSEIR• APPLICATOR

The IR applicator lamp has a total lifetime of 30000 shots. The system alerts the user of the need to schedule a lamp change. The message alerting the time left in the lamp's lifetime starts at 20000 shots performed with the second alarm following at 25000 shots, and every 1000 shots after, until it reaches 30000 shots.

Technical support must be contacted when alerts are initiated. The alert messages are indicated in the figures below.



The warnings will start when 20000 shots are reached. The following alarm will be. The following with 25000 shots and then at each 1000 subsequent shots.



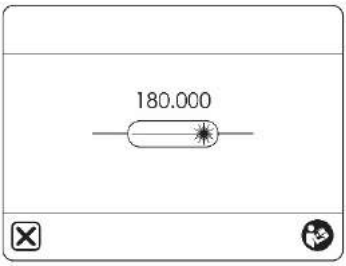
Alarm indicating the end of the lifetime.

LONGPULSE• LASER APPLICATOR @ 1064NM

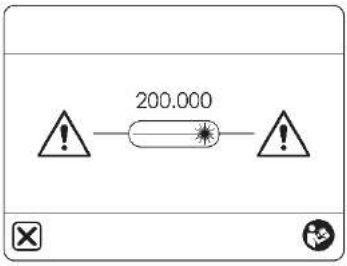
The Nd: YAG 1064 nm applicator lamp has a total lifetime of 200,000 (two hundred thousand) shots. The system alerts the user to the need for scheduling to change the lamp. The warning message about lamp life starts at 150000 shots reached, with a subsequent alarm at 180000 and then every 10,000 shots reached, up to a total of 200,000 shots.

For the "Dynamics" shot mode available in ZYE® equipment, the contents of the lamps are made in a ratio of 1:5; for each five shots the counter adds one more to the pulse total.

Technical support services must be contacted when the system alerts are initiated. The alert messages are indicted below.



Beginning of the warnings, with 150,000 shots hit and every 10,000 subsequent shots.

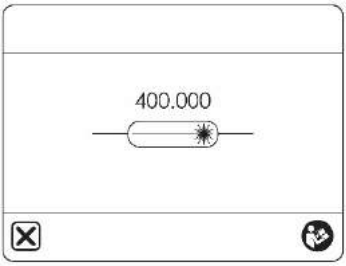


Alarm indicating the end of the lifetime of the lamp.

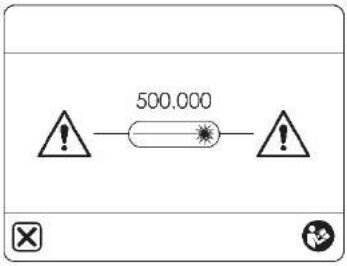
PRODEEP• LASER APPLICATOR @ 1340NM

The applicator lamp Nd: YAP 1340 nm has a total useful life of 500,000 (five hundred thousand) shots. The system alerts the user to the need for scheduling to change the lamp. The warning message about lamp life starts at 400000 shots, with a subsequent alarm at 450000 and then every 10,000 shots, up to a total of 500,000 shots.

Technical Support Services must be contacted when the system initiates alerts. The alert messages are indicated in the figures below.



Beginning of warnings with 450000 shots and providing an additional warning with each 10000 additional lamp shots.

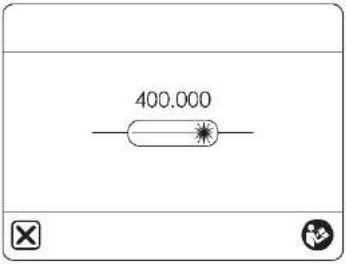


Alarm indicating the end of the lifetime of the lamp.

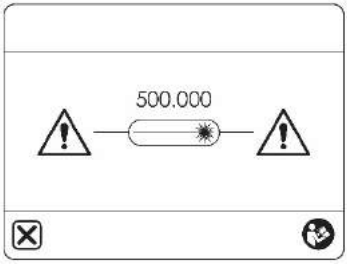
DUALMODE• LASER APPLICATOR @ 2940NM

The lamp of the Er: YAG 2940 nm applicator has a total useful life of 500,000 (five hundred thousand) shots. The system alerts the user to the need for scheduling to change the lamp. The message alerting about lamp life starts with 450000 shots, with a subsequent alarm every 10,000 shots, up to a total of 500,000 shots.

Technical Support Services must be contacted when the system initiates alerts. The alert messages are indicated in the figures below.



Start of warnings, with 400000 shots hit and every 10,000 shots after 450000 exceeded.



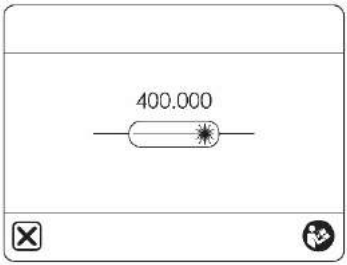
Alarm indicating the end of the lifetime of the lamp.

GOSMOOTH• LASER APPLICATOR @ 1540NM

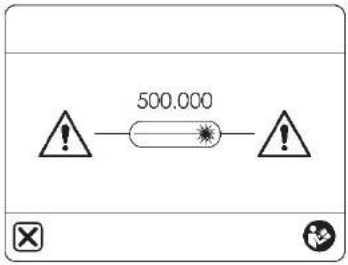
The Er: Glass 1540 nm (1540 GoSmooth®) applicator lamp has a lifetime of 500,000 (five hundred thousand) shots. The system alerts the user to the need for scheduling to change the lamp. The warning message about lamp life starts at 400000

shots, with a subsequent alarm at 450000 and then every 10,000 shots, up to a total of 500,000 shots.

Technical Support Services must be contacted when the system initiates alerts. The alert messages are indicated in the figures below.



Beginning of warnings with 450000 shots and providing an additional warning with each 10000 additional lamp shots.

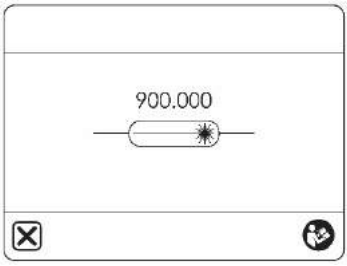


Alarm indicating the end of the lifetime of the lamp.

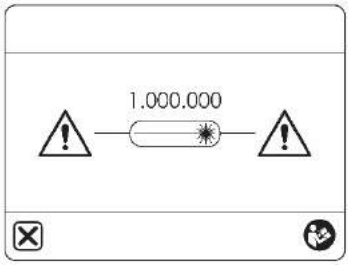
ACROMA• LASER APPLICATOR @ 1064NM/532NM

The ACROMA 1064 nm (ACROMA®) applicator lamp has a lifetime of 1000000 (one million) shots. The system alerts the user to the need for scheduling to change the lamp. The message alerting about lamp life starts at 900,000 shots, with a subsequent alarm at 950000 and then every 10,000 shots attained, up to a total of 1,000,000 shots.

Technical Support Services must be contacted when the system initiates alerts. The alert messages are indicated in the figures below.



Start of warnings, with 950000 shots fired and every 10,000 subsequent shots.

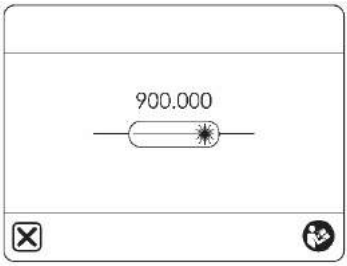


Alarm indicating the end of the lifetime of the lamp.

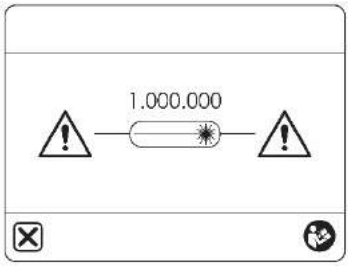
INTERNAL LASER CAVITY @ 1064NM

The internal 1064 nm LASER cavity lamps (ZYE YAG®) have a total lifetime of 1,000,000 (one million) shots. The system alerts the user to the need for scheduling to change the lamp. The message alerting about lamp life starts at 900,000 shots, with a subsequent alarm at 950000 and then every 10,000 shots attained, up to a total of 1,000,000 shots.

Technical Support Services must be contacted when the system initiates alerts. The alert messages are indicated in the figures below.



Beginning of the warnings, with 900,000 shots fired and every 10,000 shots after 950000 exceeded.

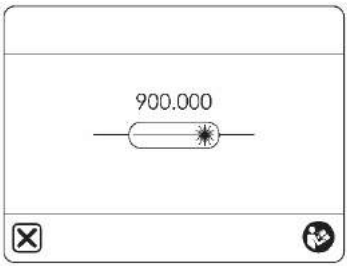


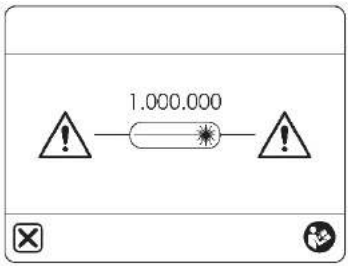
Alarm indicating the end of the lifetime of the lamp.

INTERNAL LASER CAVITY @ 755NM

The internal 755nm (ZYE ALEX®) LASER cavity lamps have a total lifetime of 1,000,000 (one million) shots. The system alerts the user to the need for scheduling to change the lamp. The message alerting about lamp life starts at 900,000 shots, with a subsequent alarm at 950000 and then every 10,000 shots attained, up to a total of 1,000,000 shots.

Technical Support services must be contacted when the alert system is initiated. The alert messages are indicated in the figures below.





Beginning of the warnings, with 900,000 shots fired and every 10,000 shots after 950000 exceeded.	*Alarm indicating the end of the lifetime of the lamp.*

EQUIPMENT DISPOSAL - AFTER LIFETIME

The disposal of this product must follow the applicable regulations of the territory in which it will be disposed. Please observe the applicable regulations for your country.

Within the European Community, Regulation 2002/96 EC (WEEE) requires that the recycling or disposal of electronic devices not damage the environment.

On the symbol, the black strip below the wastebasket indicates that the device was put into circulation after August 13, 2005 (see EN 50419-2005).

Please note that this product is subject to Regulation 2002/96 EC (WEEE) and the applicable laws in your country and must follow environmental laws.

Please consult your representative for information regarding the final product elimination.

TECHNICAL DOCUMENTATION

VYDENCE Medical reserves the right to limit the provision of blueprints, lists of materials, designs, and other documents relative to the product construction, exclusively to the Authorized Technical Support Specialists.

14 TECHNICAL SUPPORT

Assistance:

Technical support services are provided by the factory or by credentialed agents. If you need assistance, call our factory Technical Support Services at:

Telephone: + 55 16 3306-5050
Fax: + 55 16 3306-5055
www.vydence.com

The revision control of this document should not be printed to the end user.

REVISION CONTROL

REVISION	DATE	DESCRIPTION	RESPONSIBLE
1.0	04/10/2018	Document creation	Eduardo Gabriel
1.2	17/01/2019	- Inserted 3-24 - Inserted 5-15 - Updated content of the equipment and the applicators of fiber (cardboard box) - Updated wifi usage instructions and config. -Updated screenshots -Updated images of applicators 5-15 and 3-24 - LASER specification label images updated. - EOL texts of changed lamps	Eduardo Gabriel
1.3	07/05/2019	- Added information on the need to lock the casters. - Corrected equipment limit information for 60601-1-2 4ed	Eduardo Gabriel
1.4	21/05/2019	- Added revision control within the document	Eduardo Gabriel

		-Added considerations on the security and storage of data transmitted via WiFi	