OPERATOR'S MANUAL

SmartXIDE2

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TABLE OF CONTENTS

INDEX OF FIGURES

INDEX OF TABLES

GLOSSARY

The following symbols and abbreviations may be used on the SmartXide2 system and/or in this manual.

Table 1 - Symbols and abbreviations

	Symbol for "Manufacturer"
	Symbol for "Date of Manufacture"
	Electrical protection degree type B
I	Electrical protection type
~	Symbol of alternating current
	Warning on system discarding (Directive 2002/96/EC)
SN	Serial Number
NOHD	Nominal Ocular Hazard Distance
	Symbol of non ionizing radiation

Table 2 - Units of measurement

J	joule - unit of energy
mJ	millijoule - 1000mJ=1J
nm	nanometer - unit of laser wavelength, 1000000nm=1mm
µm	micrometer - 1000000 µm=1m
s	second - unit of time
µs	microsecond - 1000000µs=1s
min	minute - unit of time, 1min=60s
Hz	hertz (cycles per second) - unit of frequency
A	ampere - unit of electrical current
VA	volt ampere - unit of absorbed electrical power
V~	unit of alternating voltage
Pa	pascal - unit of measure of atmospheric pressure

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1. INTRODUCTION

1.1. The SmartXide² system

The SmartXide² system consists in a 10,600nm carbon dioxide laser (CO_2) laser with 60W of maximum power.

As scientifically entirely known, the 10,600nm wavelength is mostly absorbed by water; this characteristic makes this laser particularly suitable for soft tissue surgery.
CO_2 laser surgery is well recognized to be mininvasive and highly effective, as proven by the hundreds of scientific articles written on this kind of laser in surgery and microsurgery in various disciplines and districts for more than 20 years.

The scanner technology (HiScan Surgical) can be used for surgical applications coupled with microspot micromanipulators for microsurgery applications in ENT, gynaecology and neurosurgery.

Another scanner, a miniaturized one, the EndoScan, is connectable with the SmartXide² system. This scanning unit is suited mainly for gynecological application both in colposcopic and laparoscopic procedures, but also for other surgical applications in which quick ablation is needed.

An additional scanner known as HiScan DOT can be connected to the system: this scanning unit is designed for ablative skin resurfacing and gynaecological applications.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the state in which he/she practices to use or order the use of the device.
Federal law and some international laws also require that this device be utilized under the direction of a physician. This device should only be used by healthcare professionals authorized under US state or international laws to treat patients.
All persons treating patients with this device should determine whether they are authorized healthcare professionals under the applicable US state or international laws.

1.2. About the Manual

The SmartXide² Operator's Manual provides operators with the following information about the system:

- Indications for use
- Safety
- System description
- Installation
- Use of the system
- Scanning units
- Clinical Applications
- Faults and troubleshooting
- Maintenance
- Accessories

Before using the system for the first time, please familiarize yourself with the information and instructions of this manual. This is essential to ensure an effective and optimal use of the system, to avoid damage to people or to the device and to obtain good results of treatment.

In this manual we use different colours to highlight warnings:

- warnings on a grey background are remarks for a correct use of the system and of its accessories;
- warnings on a grey background and with a yellow triangle are remarks concerning safety.

Operators must read and follow all the remarks.

CAUTION ***Possible risk for patient/operator***	**Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous laser radiation exposure.**

2. INDICATIONS FOR USE

The SmartXide² system with its accessories is a medical device indicated for incision, excision, ablation, vaporization and coagulation of body soft tissues, in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynaecology, neurosurgery, orthopaedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery, and genitourinary surgery.
The use with scanning unit is indicated for ablative skin resurfacing.

The device is not indicated to be used for Prostate Ablation procedure.

The SmartXide² system must not be used for applications different from those specified above.

DEKA M.E.L.A. s.r.l. is not responsible for direct or collateral effects resulting from use of the system different from the intended use specified above.

CAUTION

Possible risk for patient/operator

DEKA M.E.L.A. s.r.l. is not responsible for the direct or indirect effects arising out of or in connection with, or resulting from the application or use of the system that are not a direct consequence of design or manufacturing defects of the device or parts thereof. The manufacturer shall not be responsible of the success of the treatment.

CAUTION

Possible risk for patient/operator

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3. WARNINGS

This manual is not intended to be a complete guide to the use of the system.
DEKA M.E.L.A. s.r.l. recommends that all users first seek training that includes, but is not limited to, the following aspects of operation:

- Basic Laser Energy Physics
- Laser Safety
- Tissue Interaction
- Operating Procedures
- System Set-Up Procedures
- Potential Hazards

DEKA M.E.L.A. Srl shall not be liable nor responsible of the safety and performance in the following cases:

- if the system is not used in compliance with health and safety rules and regulations in force;
- if the precautions and instructions contained in the present manual are not observed;
- if the system is not used by qualified and trained personnel;
- if the installation, any modification, recalibration or maintenance are not performed by qualified personnel authorised by DEKA M.E.L.A. s.r.l.;
- if the environment in which the system is located and used does not conform with all electrical, laser, etc. safety prescriptions specified by the applicable international and local regulations and international guidelines in force.

DEKA M.E.L.A. s.r.l. reserves the irrevocable right to provide, upon written request, maintenance personnel authorised by the same, with electrical diagrams, components lists, adjustment instructions and any information relating to the parts of the system which are considered to be repairable.

WARNING
Do not modify this equipment without authorization of DEKA M.E.L.A. Srl.

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4. PREMISES

The following instructions must be scrupulously observed.

4.1. Delivery – Inspection of goods received

Unless otherwise agreed between the manufacturer and the customer, the delivery of the goods shall be ex works (INCOTERMS 2000) even if it has been expressly agreed that the transport or part thereof shall be the responsibility of the manufacturer on the customer's behalf.
Upon delivery, all risks inherent to the system shall be transferred to the customer. Therefore, any damage to the system during transport shall be to the customer's account.
It shall be the customer's responsibility to inspect upon delivery and in the presence of the carrier, the integrity and condition of the goods received; to verify correspondence between the goods delivered and those described in the transport documentation; to immediately bring to the carrier's attention any divergence and/or damage noticed.

4.2. Working environment

The environment in which the device is located and operated must be suitable and comply with the relative legal requirements and regulations in force, applicable also to the associated systems, concerning the use and storage thereof in complete safety to persons and objects. The operation, workplace health and safety measures and any other activities shall be the exclusive responsibility of the relevant person(s) in charge and must be performed in compliance with local laws and Regulations and, where applicable, in compliance with European Directives (Council Directive 89/391/EEC and subsequent).

4.3. Responsibilities

The manufacturer shall guarantee the conformity of the product with EC safety and hygiene requirements according to the applicable Directives.
The use of the system shall be the exclusive responsibility of the operator who shall be obliged to apply the necessary and adequate diligence and skills.
The manufacturer shall be responsible in terms of and within the exclusive scope of current regulations applicable to the production and marketing of medical devices.

The manufacturer shall not be responsible for unfavourable consequences resulting from installation, use or maintenance which does not comply with the instructions in the present manual or resulting from failure by the user to apply the care, precautionary measures and safety regulations necessary to avoid such consequences.

4.4. Laser Safety Officer

We recommend prior consultation of the IEC TR 60825-8 Safety of laser products, Part 8: Guidelines for the safe use of laser beams on humans (2006-12, Second edition), which is a guideline on how to apply laser safety in medical practices.
In accordance with Point 3.1 of the abovementioned guidelines, we recommend that a Laser Safety Officer be appointed and a precise definition of the relative responsibilities established.

5. SAFETY

This chapter provides a short description of the current safety standard taken in account while designing and manufacturing the SmartXide² system.
This section also covers specific safety features designed to minimize potential hazards.

5.1. General safety

The SmartXide² system is compliant with, but not limited to, the following standards:

- **Standard IEC 60601-1** - Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- **Standard IEC 60601-1-2** - Medical electrical equipment Part 1: General requirements for basic safety and essential performance - 2. Collateral standard: Electromagnetic compatibility - Requirements and tests
- **Standard IEC 60601-2-22** - Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- **Standard IEC 60825-1** - Safety of laser products - Part 1: Equipment classification and requirements

Classification:
- According to Standard IEC 60601-1, the SmartXide² system is classified as "**Class I**" with regard to the type of electrical protection, and "**type B**" for the degree of electrical protection.
- According to Standard IEC 60825-1, the SmartXide² system is in **Class 4**.

5.2. Optical hazard

The SmartXide² system emits a visible/invisible beam of intense energy that can cause serious eye and skin injury with direct or indirect beam contact. Please adhere to the following precautions to minimize optical damage to operators, assisting personnel and patients:

- All persons in the room during treatment must wear **protective eyewear**. See next paragraph for protective eyewear specifications.

- **Never look directly into the handpiece, into the fiber or into apertures labelled "laser aperture", even while wearing protective eyewear.**
- **Limit entry to the treatment room to only those who assist in treatment and are trained in the use of the equipment.**

CAUTION

Possible risk for patient/operator

- Mark treatment rooms clearly to avoid unexpected entry during treatment.
  The label shown in Fig. 1 must be put on the external part of each entrance to these areas in order to point out the presence of a laser source inside.

Fig.1 - Door safety label

Two of these labels are provided with the SmartXide² accessories.

CAUTION

Possible risk for patient/operator

- **Direct the activated laser only at the intended area of treatment.**
- **Remove any metal object such as watches, rings, necklaces and similar items from the operating area and, if possible, do not use reflective instruments or materials.**

Reflective objects could intercept the laser beam causing a deflection to an area other than the intended treatment area. Many surfaces that may seem opaque can actually reflect the CO_2 laser emission wavelength.

- Put the system into the Standby mode when not in use (when in Standby mode, the beam cannot be inadvertently activated).
- Ensure that all trained staff assisting in the treatment know how to shut down the system in the case of an emergency.
- **Always remove the key from the switch when the system is switched off and keep it in a safe place.**

5.2.1. Protective eyewear specifications

Safety glasses must comply with the European regulation EN 207 "Personal eyeprotectors.

Filters and eye-protectors against laser radiation" and with the U.S.

regulation ANSI Z136.7 "American National Standard for Testing and Labeling of Laser Protective Equipment".

The degree of protection has been calculated taking into consideration the worst case scenario in terms of power/energy and laser spot dimensions.

The standard EN 207 suggests calculating the degree of protection for the protective eyewear by considering a direct intra-beam viewing, 100mm from the handpiece, with exposure time of 5s. However, the presence of visual and acoustic warnings in the system and the nature of application, allows us to consider, as a more realistic condition, the viewing of the beam diffused by the tissue at a distance of 300mm from the handpiece with exposure time 5s.

The specifications for the safety glasses are then as follows:

- Direct intra-beam viewing, 100 mm distance, 5s exposure time:
  CO_2 laser radiation: OD≥5 at 10600nm, DLB5 ILB5 at 10600nm
  Aiming diode laser radiation: OD≥0.4 at 635nm;
- Diffused beam viewing, 300mm distance, 5s exposure time:
  CO_2 laser radiation: OD≥4 at 10600nm, DLB4 ILB4 at 10600nm

Contact your area agent or DEKA M.E.L.A. s.r.l. company for information on where to find this type of eyewear.

As a safety precaution, eyes must not be exposed to direct laser radiation, even if protected by glasses.

CAUTION
Possible risk for patient/operator

Safety glasses for CO_2 laser radiation are different from those for diode laser radiation and must not be exchanged.
Always check you are wearing the right goggles: verify that the wavelength of the source you are using is marked on the lens or on the frame. See the example below for CO_2 glasses.

CAUTION
Possible risk for patient/operator

5.3. Electrical Hazard

The SmartXide² system uses high voltages internally. Do not open the protective panels unless trained and authorized to do so.

To avoid the risk of electric shock, this device must only be connected to a supply mains with protective earth.

CAUTION
Possible risk for patient/operator

5.4. Biological Hazard

The laser smoke presents a possible biological hazard. Ablated tissue from the patient is present in the smoke.
Laser smoke may contain viable particles. Use of a laser smoke evacuator is recommended.

CAUTION
Possible risk for patient/operator

5.5. Fire Hazard

When the light or the laser beam contacts an exterior surface, that surface absorbs energy. This raises the surface temperature, whether the surface is skin, hair, clothes, or any flammable substance.
Operators should take the following precautions to prevent a fire:

- Use non-flammable substances for such uses as anesthesia, preparing soft tissue for treatment, and cleaning or disinfecting instruments.
- Be especially careful with the use of oxygen. Oxygen accelerates both the severity and the extent of fire.
- Keep a minimum of combustible materials in the treatment room. If treatment requires the use of a combustible material, such as gauze, first soak it in water.
- Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment.
- Always keep a small fire extinguisher and water in the treatment room.

CAUTION ***Possible risk for patient/operator***	**Never use inflammable gas for gas shield.** **The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided.** **Some materials, for example cotton wool, when saturated with oxygen may be ignited by the laser equipment.** **The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.** **Attention should also be drawn to the danger of ignition of endogenous gases.**

5.6. Radio frequency interference

The SmartXide² system complies with the EN 60601-1-2 standard.
It needs special EMC precautions and needs to be installed according to EMC information provided in this manual - see Appendix -.
Portable and Mobile communication equipment can affect the SmartXide² system.

The SmartXide² system should not be used near other equipment. If this is necessary, observe the SmartXide² to verify normal operation in the stacked configuration in which it will be used.

5.7. Essential performances

The following functions are Essential Performances, i.e. performances necessary to keep risk within acceptable limits:

- ability of the system to prevent any unwanted laser emission;
- ability of the system to stop laser emission as soon as footswitch is released;
- ability of the system to maintain laser output power during treatment within ±20% with respect to the set value.

5.8. Safety labels

The SmartXide² system is provided with the safety labels shown in the following figure.

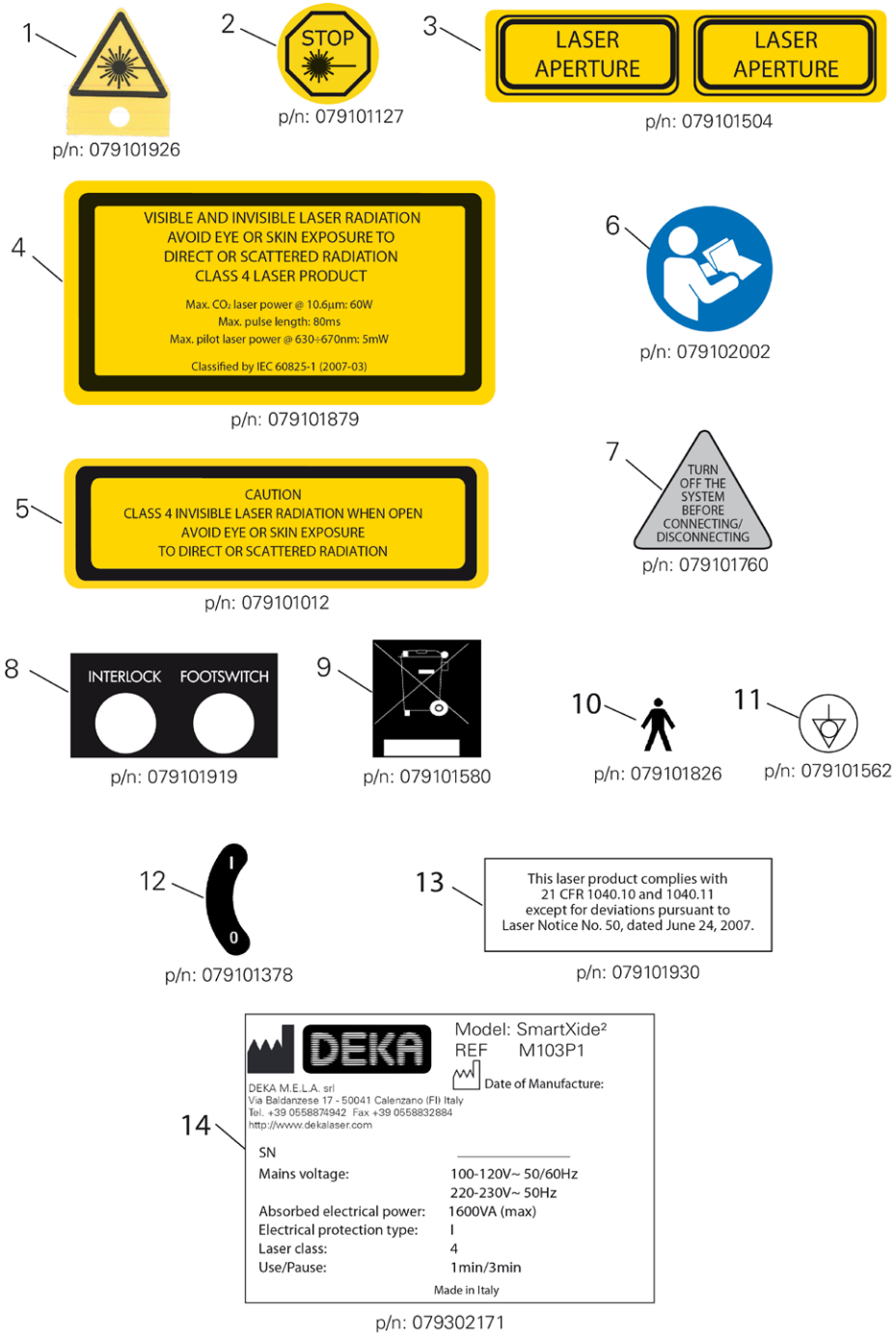

Fig.2 - Safety labels

5.8.1. Meaning of the safety labels

Table 3 gives the descriptions of the meanings of the safety labels shown in Fig. 2.

Table 3 - Meaning of the safety labels

Label Nr	Meaning
1	Emission of laser radiation.
2	Identification of the emergency switch for fast system turn off.
3	Identifies the aperture from which laser radiation comes out.
4	Warning on dangers related to the exposure to laser radiation. Specifications on the characteristics of CO_2 laser radiation.
5	Warning on dangers related to the exposure to laser radiation in case of removal of panels of the chassis.
6	Warning on system discarding (Directive 2002/96/EC).
7	Warning. The operator is recommended to read carefully the operator's manual before using the system.
8	Warning on scanning unit connection/disconnection.
9	Identification of the rear panel's (interlock and footswitch) connections.
10	Electrical protection degree type B.
11	Potential equalization connector label.
12	Identification of the key switch.
13	CDRH certification label.
14	System identification label.

NOTE
All the labels must be kept in their own position, in good condition and immediately replaced if damaged.

5.8.2. Positions of the safety labels

The safety labels shown in Fig. 2 are placed as shown in Fig. 3.

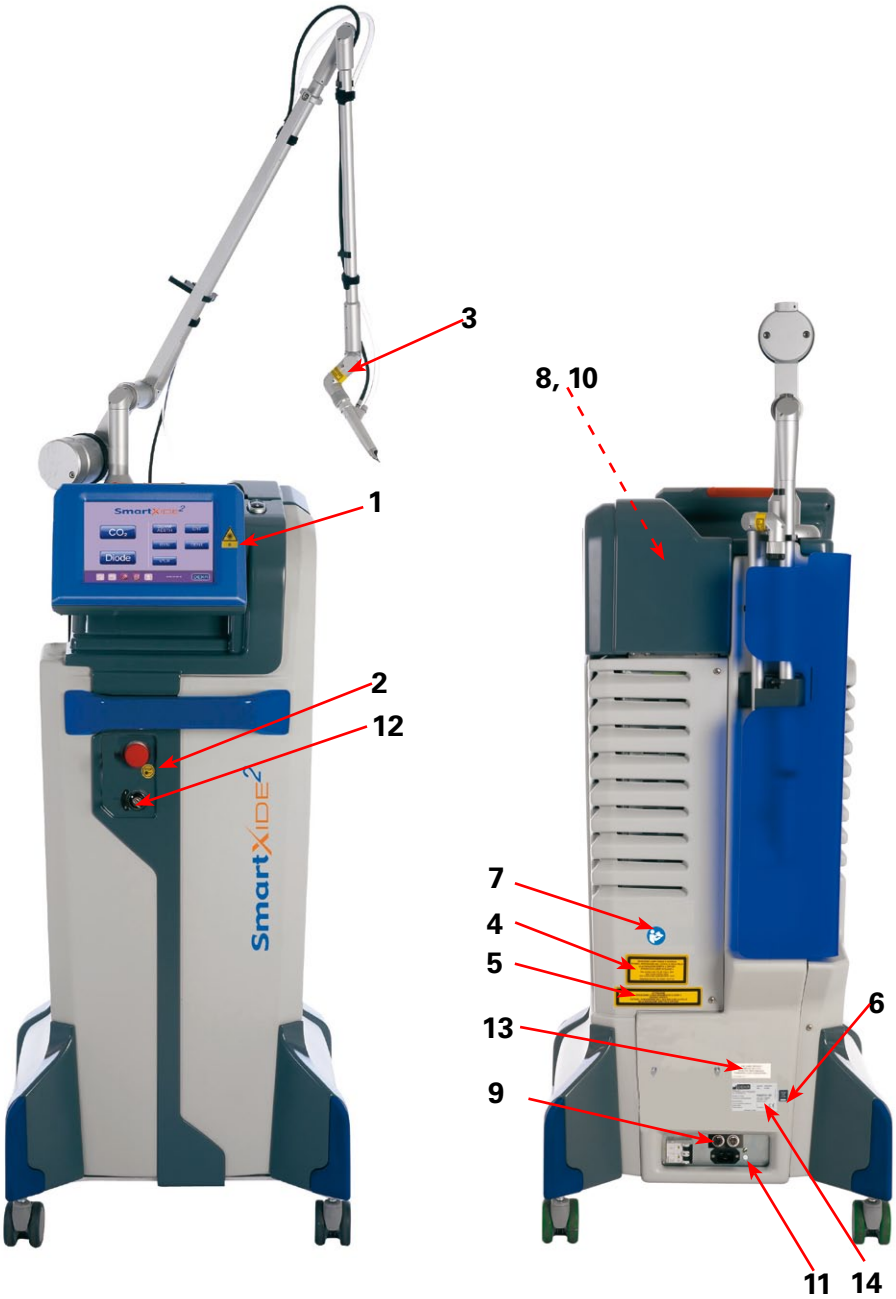

Fig.3 - Position of the safety labels

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6. SYSTEM DESCRIPTION

The operator interacts directly with the following external portions of the system.

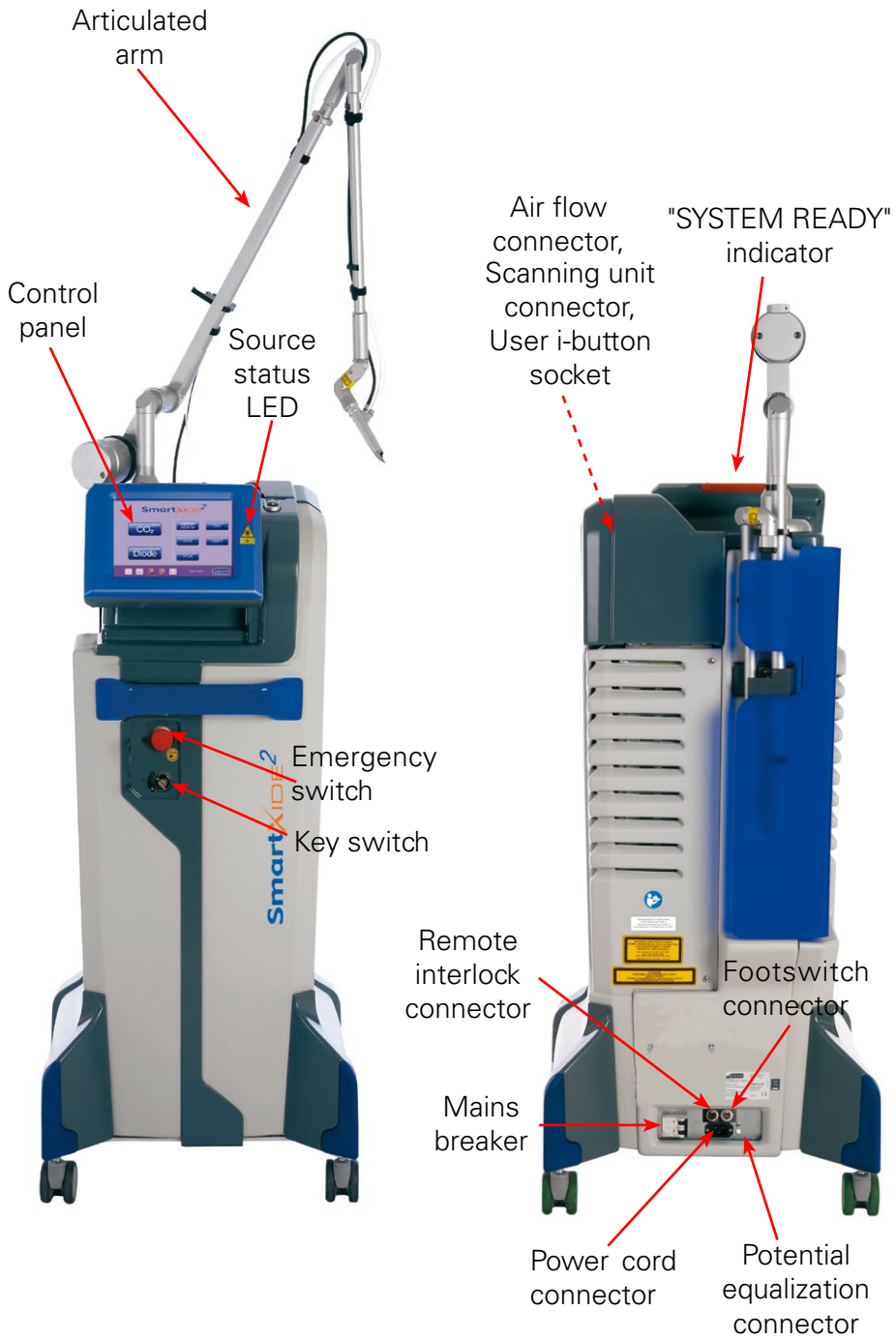


Fig.4 - System's main external components

6.1. Control and signal devices

6.1.1. System switches

The system power controls are comprised of the switches described in detail below. Please refer to Fig. 5 for their position on the device.

Key Switch
To turn the system on and off use the key switch.
It is a double-throw switch (right-left) with removable (only if it is in the "O" position) safety key.
To turn the system on, insert the key and turn the key switch to "I"; to shut the system down normally, turn the key to "O".
The key switch works to turn on the system only if the emergency switch is not pushed in.

CAUTION ***Possible risk for patient/operator***	**The key must always be removed when the system is turned off and must be kept only by authorized personnel.**

Emergency Switch
The emergency switch shuts down the system immediately.
Use it only under emergency circumstances that is in case it is necessary for the operator to stop immediately emission.
To shut down the system, push in the switch button. To reset the switch, rotate the button and pull out.

ATTENTION *Possible equipment damage*	Do not use the emergency switch to turn on and off the system under normal circumstances.

Mains breaker
This switch is located on the bottom side of the rear panel.
Move towards left the lever of the switch (position "I") to supply the system.

6.1.2. Footswitch

When the system is in READY mode, activate the emission by pressing the footswitch, which is an electrical switch intended to be located on the floor and actuated by foot.

6.1.3. Potential Equalization Connector

The potential equalization connector is provided on the lower portion of the rear panel.
Connecting a potential equalization cable from this connector to an appropriately grounded connection in the operating room offers additional grounding of the laser system (potential equalization).

6.1.4. Internal buzzer

The system is equipped with an internal buzzer which produces an acoustic signal in the following cases:

- To warn the operator in case a wrong action has been performed - for instance, if footswitch is pressed when disabled -.
- If a laser treatment is in progress - CO_2 source switched on, footswitch enabled and pressed, shutter open, real power level correct - a sound is produced every 1s. This timed sound is intended to help the operator to 'measure' the treatment time.
- If a laser treatment is in progress - CO_2 source switched on, footswitch enabled and pressed, shutter open, power level mismatch - five sounds are produced every 1s. This faster timed sound is intended to warn the operator that a power mismatch has been detected, that is the real CO_2 output power level no more matches with the power level found by the power evaluation procedure. See also par. 8.7..

6.1.5. "SYSTEM READY" indicator

The "SYSTEM READY" indicator (see Fig. 5) is lighted when the emission is enabled.

6.1.6. Source status LED

This LED (see Fig. 5) is blinking when the start up procedure is in progress, it is orange lit when the "ON"/'READY' status is set; it is red lit during emission. When the system is in stand by, the LED is green lit.

6.1.7. Control panel

The control panel contains controls and displays for operating and monitoring the laser.
It contains a rear-lit touch-screen graphic display. All the functional controls of the device can be set by lightly pressing an area of the screen itself.
In order to have a better view, it is possible to adjust the display visual angle by pressing on the two keys next to the display itself (highlighted in Fig. 6).

Fig.5 - Display adjusting keys

Be very careful while the display is moving: do not keep your hands onto or near the display. *Danger of crushing!*	**CAUTION** ***Possible risk for patient/operator***
Please do not adjust the visual angle moving the display by hands! *Only electronic adjustment is allowed.*	**ATTENTION** *Possible equipment damage*

6.2. Articulated arm and CO_2 handpieces

A wide range of handpieces can be provided with the SmartXide^2 system, having different spot sizes and high performances in specific application field. The system can be provided with a handpiece body which can house different lens assemblies (1.5", 2", 4", 7" and collimated, please refer to Fig. 8).
Moreover, a 5" handpiece and a 8" handpiece are available: each of them consists of the handpiece body (and lens assembly) with interchangeable handpiece spacers. These spacers are either straight, straight with backstop, 90° and 120° delivery for 5" handpiece; straight and straight with backstop for 8" handpiece (please refer to Fig. 9 and Fig. 10).

NOTE

If the 8" handpiece is connected to the EndoScan unit, the user has not to select scanning figures larger than 60%.

The term "spot size" identifies the diameter of the laser beam (and therefore the diameter of the circular area exposed to laser radiation) when the handpiece is hold perpendicularly to the surface to be treated and the laser beam is in focus.
The spot of the collimated handpiece is about 2.0mm (at 86% of output power).
The handpiece is attached to the distal end of the articulated arm.
The articulated arm is an optical assembly that delivers beam laser radiation. It is made up of seven mirrors placed on rotating knuckles: the mechanical accuracy of the articulated arm allows the CO_2 laser beam to travel inside it and along its axis however the arm is oriented.
The field of action of the articulated arm covers a radius of approximately 80 cm, the transfer efficiency of power is greater than 85%. The loss of 15% is balanced by a suitable calibration of the internal power meter.

An air flow is provided by an internal pump in order to avoid dust and particles deposition on the optics during laser operations.
The inlet connector on the handpiece is connected via a plastic PVC tube to the proper output connector located on the rear side of the system. See par. 7.5 for details on the connections.

During system operation never disconnect the air tube.

Fig.6 - Laser handpiece

It is also possible to connect the handpiece to an external smoke evacuator via a flexible hose.

In the lower part of the system side panel there is a suitable holder for the connection hose of an external smoke evacuator.

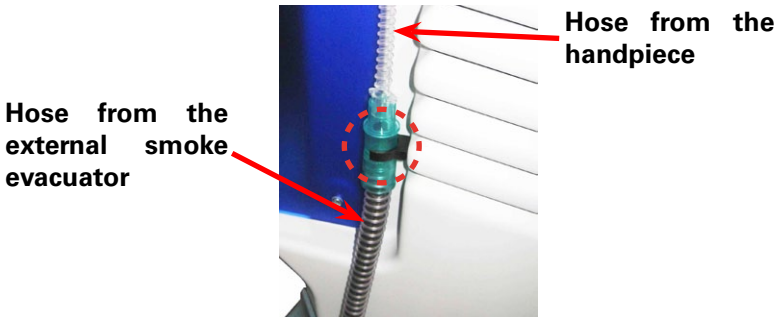


Fig.7 - Positioning of the smoke evacuator hose on the system

As the aiming beam passes down the same delivery system as the working beam it provides a good method of checking the integrity of the laser delivery system. If the aiming beam is not present at the distal end of the delivery system, its intensity is reduced, or it looks diffused, this is a possible indication of a damaged or not properly working system (EN 60601-2-22).

CAUTION

Possible risk for patient/operator

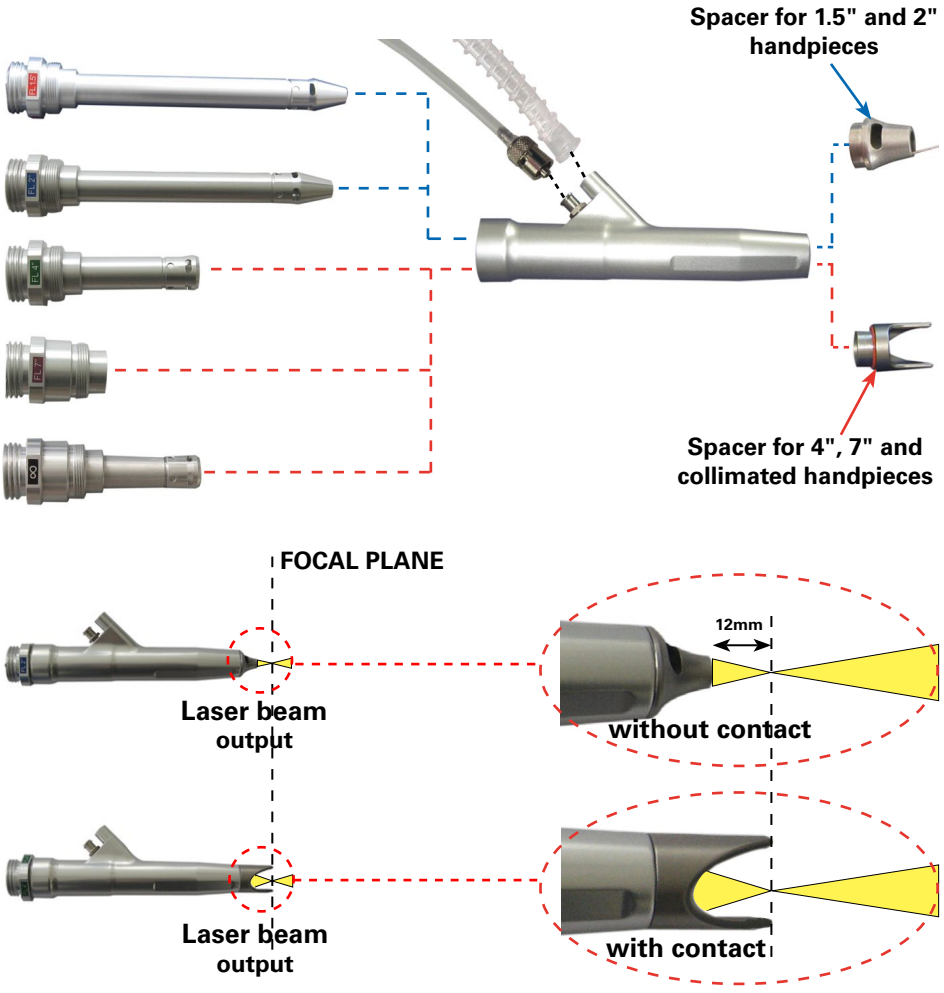


Fig.8 - Assembling the handpieces

Fig.9 - 5" handpiece and spacers

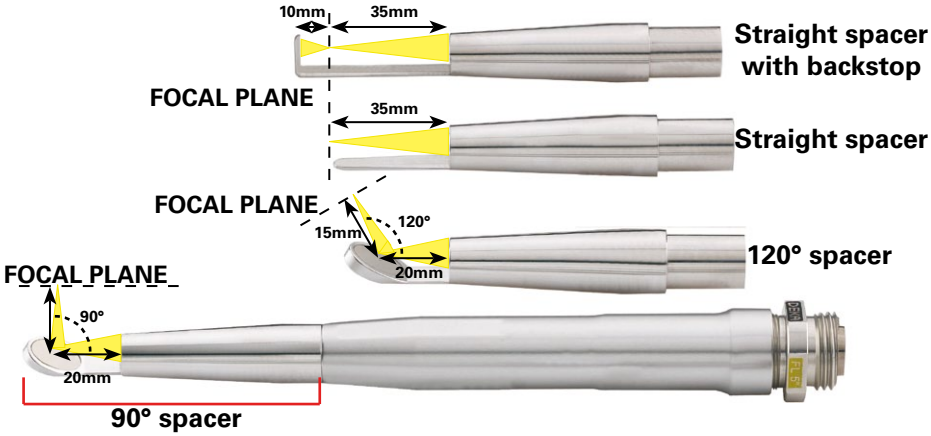
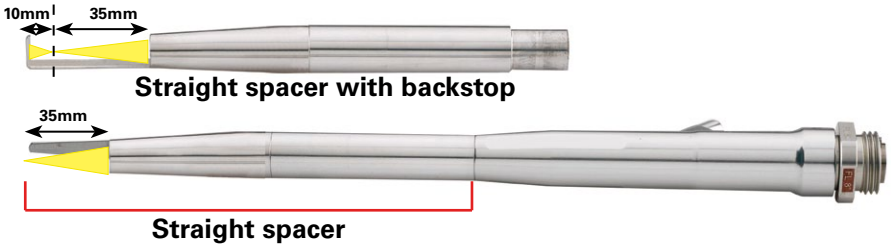


Fig.10 - 8" handpiece and spacers



Changing lens assembly

To change the lens assembly, disconnect the air pipes from the handpiece barrel, then unscrew the handpiece from the articulated arm.
Extract the lens assembly currently screwed onto the handpiece and screw the one to be used.
Connect again the air purge tubing and the smoke evacuator (if present).

CAUTION

Possible risk for patient/operator

Please pay attention to insert the lens assembly you want really to use: the focal length is marked on the holder itself!

Changing handpiece spacer

The handpiece spacer can be easily changed by removing the final part of the handpiece itself and inserting the new spacer.
Use the narrow spacer for 1.5" and 2" handpieces, the open one for 4", 7" and collimated handpieces (please refer to Fig. 8).
Use their own spacers for 5" and 8" handpieces.

6.2.1. CO_2 handpieces for dental applications

he handpieces shown in Fig. 11 and Fig. 12 can be provided for the CO_2 laser source to be used for dental applications for the treatment of soft tissues.
The handpieces consist of the handpiece body and interchangeable handpiece apertures.
The 4" handpiece (Fig. 11) comes with three different apertures: a straight aperture to transmit the laser beam in line with handpiece's axis, and two apertures with mirror to deflect the laser of 105° or 120°. Moreover, the straight and 75° apertures can be used with removable tips to work in contact with the tissue.
The 2" handpiece (Fig. 12) includes three apertures: two straight apertures (either contact or non-contact type) that transmits the laser beam in line with handpiece's axis, and an aperture with mirror to deflect the laser of 120°.

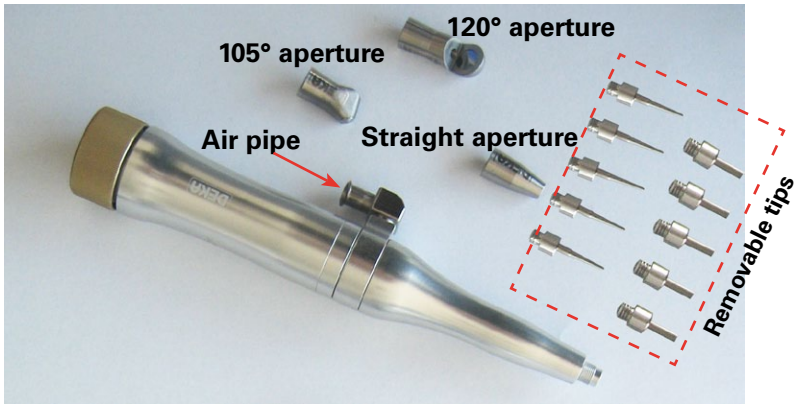


Fig.11 - 4" dental handpiece (N81501)

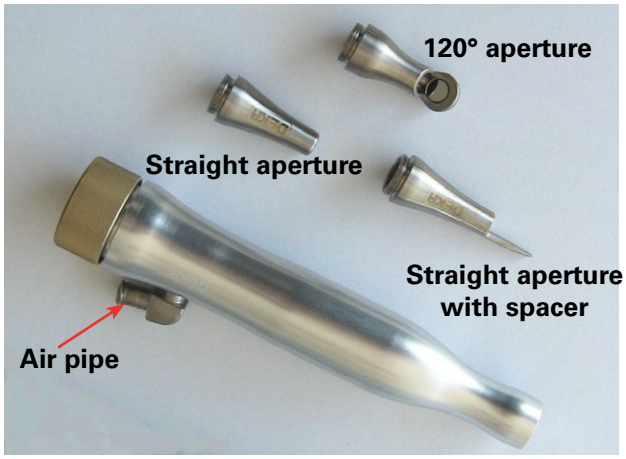


Fig.12 - 2" dental handpiece (N81601)

Changing handpieces
To change handpieces, disconnect the air purge tubing from the handpiece body. Unscrew the handpiece from the articulated arm, screw on the new handpiece and connect the air purge tubing.
Changing handpiece aperture
The handpiece aperture is easily changed by unscrewing the final part of the handpiece itself and screwing the new aperture.
Changing contact tips
Pull on the tip to remove and push the new tip into the hole located at the end of the aperture until it stops.

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7. INSTALLATION

Remove the device from its packaging, position it on a horizontal surface and lock the front wheels by using the locking system provided on them, so that it is stable.

Conserve the packaging in case it is necessary to repack the device for future transport or storage.

Check that the items listed in Section "Accessories" are included inside the box together with the device.

7.1. System requirements

7.1.1. Dimensions and weight

The SmartXide² system has the following dimensions and weight:

Height	210 cm 162 cm (with folded articulated arm)
Width	59 cm
Depth	56 cm
Weight	95kg

Table 4 - Dimensions and weight

7.1.2. Electrical requirements

Please consider the following electrical requirements before installing the system:

- the AC line power requirements for the SmartXide² system are:
  110-120V~ 50/60Hz
  220-230V~ 50Hz
  15 A
- make sure the socket is efficiently earthed.
- the SmartXide² system unit should not share a power line with other heavy power-load equipment. The system should be on a separate power line with a separate circuit breaker.
- The SmartXide² should not be used near other equipment. If this is necessary, observe the SmartXide² to verify normal operation in the stacked configuration in which it will be used.

7.1.3. Environmental requirements

Follow these environmental requirements to properly maintain the system:

- Keep the air free of corrosive substances, such as salts and acids. These pollutants may damage electrical wirings;
- Keep dust particles to a minimum. Dust particles can cause damage to the system;
- Do not place system near heat sources.
- Observe the following temperature, humidity and pressure requirements:

Table 5 - Operating and environmental conditions

Operating temperature	From 15°C to 35°C
Operating humidity	From 20% to 80%
Atmospheric pressure	From 70,000Pa to 106,000Pa

Table 6 - Transport and storage conditions

Storage temperature	From 5°C to 50°C
Temperature during transport	From 5°C to 50°C
Operating humidity	From 10% to 90%
Atmospheric pressure	From 70000Pa to 106000Pa

7.1.4. System specifications

The SmartXide² system is equipped with a CO_2 laser source, emitting an infrared beam, and an aiming laser source, emitting a visible red beam. These two laser sources have the emission specifications listed in Table 7 and Table 8:

Table 7 - System specifications

Type	Value
Mains voltage	100-120V~ 50/60Hz 220-230V~ 50Hz
Absorbed electric power	1600 VA (max)
Circuit breaker	16A delayed
Electrical protection degree	
Electrical protection type	I
Laser class	4
Use/Pause	Intermittent: use 1min, pause 3min

Type	Value	
Wavelength	10.6µm±0.4µm	
Maximum output power	60W	
Method of Optical Output	7-mirror articulated arm	
Output mode	TEM_{00}	
Divergence of laser beam (full angle d_{63} - handpiece's output)	1.5" handpiece	70 mrad
	2" handpiece	52 mrad
	4" handpiece	26 mrad
	5" handpiece	20 mrad
	7" handpiece	12 mrad
	8" handpiece	11 mrad
	Collimated handpiece	3.2 mrad
Diameter of laser beam (d_{63} - handpiece's output)	1.5" handpiece	0.125 mm
	2" handpiece	0.155 mm
	4" handpiece	0.267 mm
	5" handpiece	0.325 mm
	7" handpiece	0.489 mm
	8" handpiece	0.530 mm
	Collimated handpiece	1.5 mm
Power stability on 1 hour	≤20%	
Nominal Ocular Hazard Distance (NOHD)	29m 100m (with collimated handpiece)	
Emission	Controlled by footswich	

Table 8 - CO_2 laser source emission features

Type	Value
Wavelength	635nm
Maximum output power (source output)	4mW
Output mode	Circular
Divergence (source output)	0.6mrad
Diameter (source output)	1.8mm
Laser class (source output)	3R
Relative position with CO_2 source	Coaxial

Table 9 - Specifications for the aiming source of CO_2 laser

Table 10 - Operating characteristics

Type	Value
Aiming Beam	Visible. Intensity selectable between OFF and 100%; step: 2% between OFF and 10%, step: 10% between 10% and 100%.
Operating modes	• **CW** mode: the average output power can be selected from 0.5W to 60W. • **UP** mode: the average output power can be selected from 0.5W to maximum power. • **SP** mode: the average output power can be selected from 0.1W to 15W; the frequency from 5Hz to 100Hz. • **DP** mode: the average output power can be selected from 0.2W to 15W; the frequency from 5Hz to 100Hz. The selectable frequencies depend on the selected power value, as shown in Table 15. • **HP** mode: the average output power can be selected from 0.1W to 8W; the frequency from 5Hz to 100Hz.
Exposure modes	Continuous exposure mode or timed exposure mode. The timed exposure mode allows both single exposure or repeated exposures. When timed exposure mode is selected, the exposure time can be selected between 0.01s and 0.9s. When the repeated exposures mode is selected the "T.OFF" time can be modified from 0.1s to 5s.

7.2. Accuracy of values

The accuracy of all the values mentioned in this manual is reported in the outcome of the project for the SmartXide² system.

7.3. Installation

Proceed as follows:

- Insert the key into the key switch located on the front side: the key can be inserted only in the "O" position, so the system is still switched off. Do not turn the key to the "I" position.
- Make sure the emergency switch is pulled upwards and the mains breaker is in the "I" position.
- Connect the external interlock network to the socket marked "INTERLOCK"; if there is no external interlock chain, connect the interlock connector supplied with the accessories (see also par. 7.7 in this section).
- Connect the footswitch to the socket marked "FOOTSWITCH".

The contacts of the interlock and footswitch sockets must never be connected to the mains otherwise the system should be seriously damaged. Connect these sockets only as specified in this paragraph.	**ATTENTION** *Possible equipment damage*

- Connect the mains cable provided with the system to the proper socket located on the rear side of the system.
- Connect the other side of the mains cable to a wall outlet.

ATTENTION!

- Make sure that the mains plug is always reachable.

• Make sure the wall outlet is properly grounded. • Make sure that the mains specifications are met.	**ATTENTION** *Possible equipment damage*

7.3.1. Installation of the articulated arm's counterweight

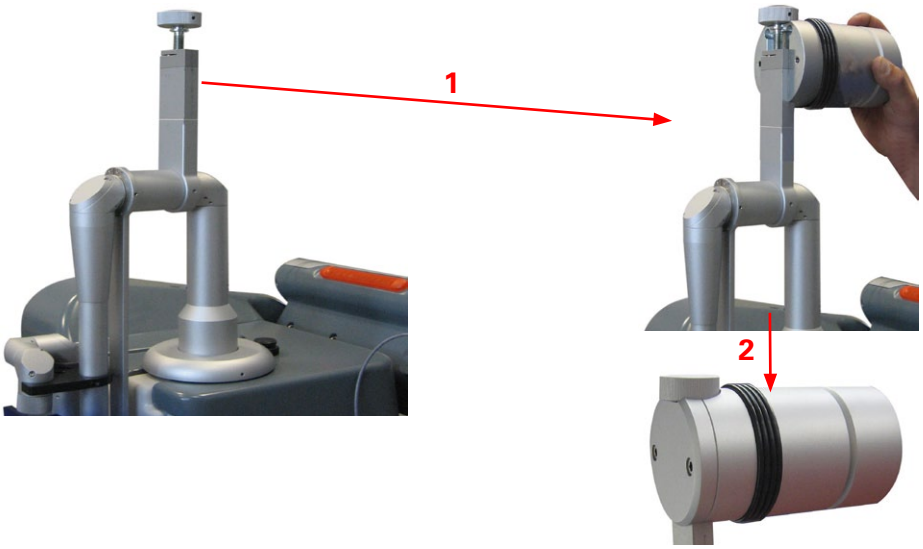
At system first installation, the counterweight of the articulated arm must be installed. Proceed as follows (please refer to Fig. 13):

- first assemble the heaviest component, **paying attention to put this first component on the opposite side of the articulated arm** (as shown in Fig. 13, step 1) and to insert the special washer of the articulated arm into the groove of the counterweight.

Be very careful while handling the couterweight because it is very heavy: in case of fall, it can damage the equipment or hurt someone!	**CAUTION** ***Possible risk for patient/operator***

- install the second component which allows to fix the counterweight: insert the special washer of the articulated arm into its groove and screw it using the provided 5mm Allen wrench.

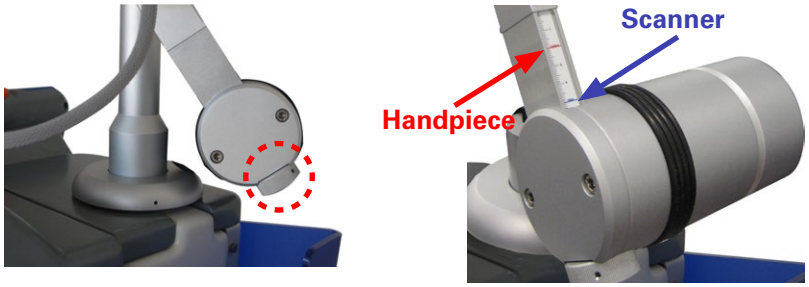
Fig.13 - Installation of the articulated arm's counterweight



ATTENTION *Possible equipment damage*	**The counterweight has always to be removed for long distance transport.** To remove it, put the articulated arm in its resting position and reverse the steps in this paragraph.

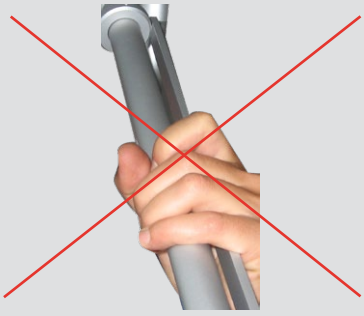
To move the articulated arm to the working position, remove it from its resting position and act on the adjusting knob in order to balance the counterweight according to the accessory connected to the articulated arm. Turn the knob up to reach a position around the mark "HiScan" if a scanner is connected, around the mark "Freehand" if a handpiece is connected.

Fig.14 - Counterweight



To place again the articulated arm in its resting position, rotate it slightly outwards and fold it so as to leave the counterweight upward.
Secure the arm using the provided clamp on the system.

ATTENTION *Possible equipment damage*	Avoid to apply any force to the support cantilever of the articulated arm. *Do not hold the arm as shown in the picture below.*



7.4. User i-button

Handpieces and scanning units for SmartXide² system have to be enabled for use by installing the dedicated i-button.
Ask the local distributor for the activation of the i-button.

Every time the system is used, make sure that the proper i-button, which enables the accessories to be used for that session, is plugged into its dedicated socket.

Pull down the protection panel on the rear side of the system and insert the i-button in its housing, pushing it and paying attention to place its metallic face in the narrow side of the socket (highlighted in Figure, right side).

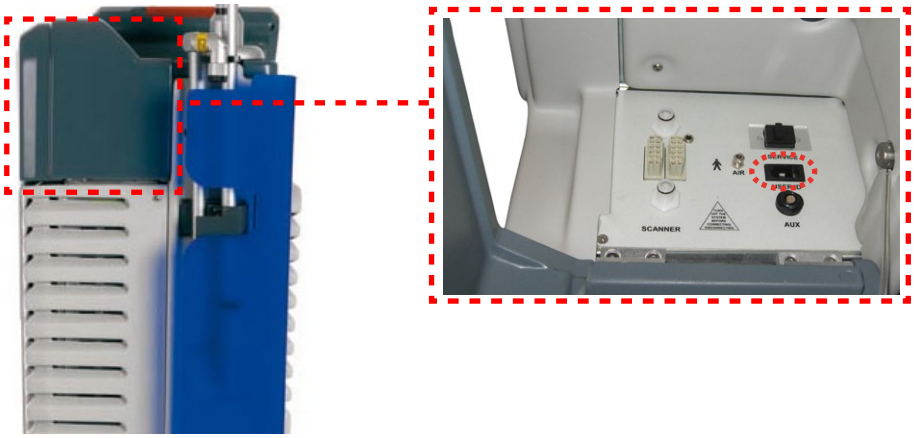


Fig.15 - User i-button socket

7.5. Air flow connections

The SmartXide² system is equipped with an internal pump which produces a continuous air flow which prevents dust and particles from depositing on the optics during laser operations.
Pull down the protection panel on the rear side of the SmartXide² system (Fig. 16) to access the air flow outlet connector (highlighted in Figure below): an internal connection links the air pump to this connector.

Fig.16 - Air flow connector on system

A black tube is provided to connect this outlet connector to the inlet connector located on the handpiece (see Fig. 7).

NOTE

Always verify that the black tube is properly connected to both connectors.

NOTE

Use the proper plastic holders placed on the articulated arm to position the air tube and, if present, the hose for the smoke evacuator; use the larger housing for the scanning unit cable. See the Figure below.

Fig.17 - Tubes holder on the articulated arm

7.6. Articulated arm working position

In order to move the articulated arm to its working position proceed as follows:

- move upwards the lock that blocks the articulated arm (see the enlarged detail in the Figure below);
- move the articulated arm away from its resting position rotating it as shown in the figures below.

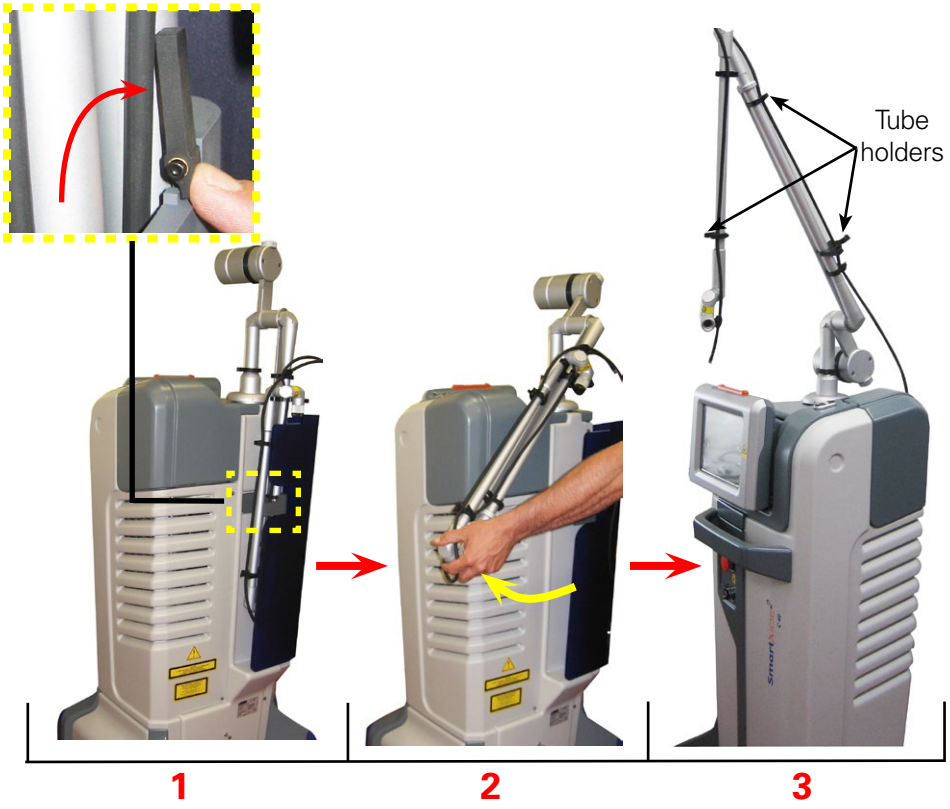


Fig.18 - Articulated arm working position

NOTE

If the articulated arm has been properly taken out from its resting position, the tube holders on the articulated arm are placed externally as highlighted in Fig. 18. *The position shown below is not correct.*

7.7. Remote Interlock

The interlock socket can be used as an additional precautionary measure to stop emissions in case a specific external event occurs.
For instance, all the doors leading to the system operating area can be provided with series-connected microswitches (normally closed). In this case the opening of any of these doors results in an "INTERLOCK" alarm message (see the Section "Troubleshooting") so the emission is immediately stopped.
To connect an external interlock chain, the interlock connector supplied with the accessories can be used.
Note that this connector has a jumper between contacts 1 and 2 (set by factory).

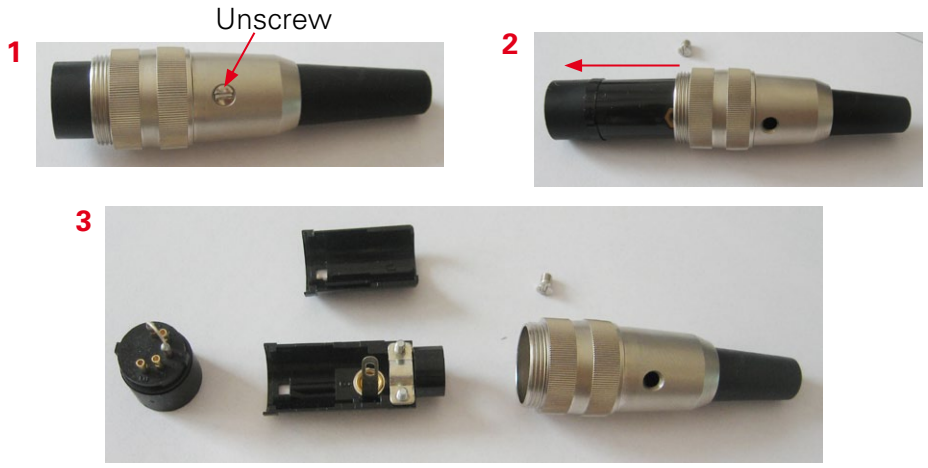


Fig.19 - How to open the interlock connector

To use an external interlock chain, proceed as follows:

- remove the jumper between the contacts 1 and 2;
- connect these contacts to the external network. Note that the interlocks must be normally closed in order to let the system operate otherwise an INTERLOCK fault is stated and the system is stopped.

No voltage level should be applied to the contacts of the interlock connector.

If no external interlock chain is to be used, the interlock connector provided with the system (accessories) must be connected to the interlock socket in order to disable the interlock fault.

7.8. Moving/transporting the device

The device is susceptible to misalignment if not handled properly. It should never be banged, jolted, dropped, turned upside down, tilted or knocked.
Before moving/transporting the system, disconnect all accessories (handpieces, mains cable, footswitch, and interlock connector), **fold the articulated arm,** and pack the accessories in their appropriate cases.

7.8.1. Moving the device

To move and guide the system, unblock the rotating wheels and use the handle located on the front of the system, making sure to move the system at a slow pace. Do not use the rear cord wrap to transport the system.

Inclines
When moving the system up or down inclines, always travel in line with the slope. The system should never be moved diagonally or directly across an incline. Doing so may result in loss of control of the system and damage to the system or injury may result.

Thresholds
When moving the system over a threshold, and if necessary due to the height of the threshold, firmly grasp the front handle and pull the system forward until the front wheels cross the threshold. Depending on the height of the threshold, a slight lift using the front handle may be necessary to get the front wheels started over the threshold. Continue pulling the system forward slowly until the rear wheels cross the threshold. Rapidly moving the system across a threshold can result in system instability resulting in damage to the laser system and/or possible injury.

7.8.2. Transporting the device

When transporting the system by vehicle, store it in its own packaging, if possible, or secure it with a strap or structural support with the wheels locked inside the vehicle, making sure not to bump or press the articulated arm. The system should be protected from the strap using padding or blankets.
Do not transport the device tilted or lying down.

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8. USE OF THE SYSTEM

8.1. Starting up the system

Insert the key into the key selector and turn to the "I" position. The system enters a self-test phase during which the introductory screen "System check" is displayed.

Fig.20 - Start-up screen with "System Check"

ATTENTION
During the self-test phase, the SYSTEM READY indicator light on the top cover of the system and the LED on the control panel will flash. This notifies the user that the system is operating correctly. It is advisable to ensure that the light flashes during this phase. Otherwise, call the Technical Assistance Service.

Once the internal check is finished, any detected problem will appear in the "SYSTEM FAULT" menu: refer to the "TROUBLESHOOTING" section for possible solutions to the problem; otherwise an introductory warning will appear.

The operator and all personnel in the operating area are always required to wear protective eyewear when operating.
Never look directly into the handpiece or into apertures labelled "LASER APERTURE", even while wearing protective eyewear.

CAUTION
Possible risk for patient/operator

Once the "OK" key has been pressed, the system displays the User menu: please refer to the following paragraphs for details.

The options described below are common to all system menus:

	Press this key to go to Favorite menu
	Press this key to go to the Home menu
	Press this key to go back to the previous screen
	Press this key to go to the Set-up menu
	Press this key for information

Keys are greyed out if the related option is temporarily disabled.

The system automatically selects the following status:
- "STAND BY" mode;
- Footswitch disabled.
- aiming source activated;
- exposure parameters previously saved;
- emission and scanning parameters previously saved.

8.2. Management of the laser source

'STAND BY'/'ON' key
The 'STAND BY'/'ON' key allows to switch off/on the selected source.
If it is green light coloured, it means that the key is disabled;
if it is green bright coloured, it means that the key is enabled to switch on the source;
if it is orange coloured, it means that the laser source is ON and it can be switched off by pressing the key itself.

'READY' key
The 'READY' key allows to enable footswitch in order to avoid unwanted emissions which might occur if it is accidentally pressed when the source is switched on.
The operator is suggested to use the READY option to disable footswitch while selecting the parameters as a precautionary measure.
Emission is enabled if both the READY key and the SYSTEM READY indicator on the system upper cover are permanently lit.

'EMISSION' LED
The "EMISSION" LED is under the "READY" key and, when lit, indicates that emission is in progress.

8.3. CO_2 Free Hand mode

The Free Hand mode (see Fig.21) allows the user full control of the emission parameters by "manually" selecting the emission mode, the pulse configuration as well as the power/frequency levels, based on the required treatment and the user's own experience.
The set parameters may be saved for future use.

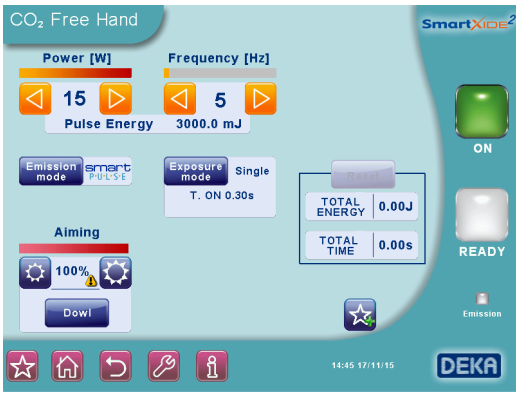

Fig.21 - CO_2 Free Hand mode

Power
The POWER selection keys increase or decrease and display power level. The range of available values changes according to the selected emission mode: please refer to the description of the emission modes in this paragraph.
See also par. 8.6.

Frequency
The FREQUENCY area displays frequency of laser emission; the FREQUENCY selection keys increase or decrease it from 5Hz to 100Hz.
These keys only appear when the SP or DP emission mode is selected.
See also par. 8.6.

Emission mode
The area "EMISSION MODE" alternately selects and displays "CW", "SP", "UP", "DP" or "HP" emission mode.

In **CW mode**, laser emission is continuous: the CO_2 laser source is enabled to emission as long as it is switched on, so it provides a constant output power level whose value has to be selected by the operator according to the treatment to be performed.
The POWER selection keys allow to change the power value from 0.5W to 60W.

In **SP mode** the CO_2 laser source is pulsed.
The operator can select the frequency - that is how many times per second the source is switched on and off - and the power value.
The FREQUENCY selection keys allow to change the frequency value

between 5Hz and 100Hz; the POWER selection keys allow to change the power value between 0.1W and 15W.

In **DP mode** the CO_2 laser source is pulsed.
The operator can select the frequency - that is how many times per second the source is switched on and off - and the power value.
According to the selected power value, the allowed frequency range changes as shown in the Table below.

Table 11 - Power and Frequency selection in DP mode

Power	Available values for the "Frequency" parameter
0.2W≤P<0.5W	up to 10Hz
0.5W≤P<3W	up to 20Hz
3W≤P<4W	up to 50Hz
4W≤P<5W	up to 80Hz
5W≤P<15W	up to 100Hz

In **UP mode** the CO_2 laser source is pulsed.
The system sets an optimal frequency while the output power level has to be selected by the operator according to the treatment to be performed.
The POWER selection keys allow to change the power value from 0.5W to 60W.

In **HP mode** the CO_2 laser source is pulsed.
The operator can select the frequency - that is how many times per second the source is switched on and off - and the power value.
The FREQUENCY selection keys allow to change the frequency value between 5Hz and 100Hz; the POWER selection keys allow to change the power value from 0.1W to 8W.

Exposure

The SmartXide² system allows to control the exposure time during a laser treatment acting on the CO_2 shutter.
The selected exposure mode is displayed on the screen in the "Exposure mode" area. Touch this area to change the exposure mode.
Three exposure modes can be selected:

- continuous - "Contin." on the screen -;
- timed single exposure - "Single" on the screen -;
- timed repeated exposures - "Repeat." on the screen -.

Note that the emission mode - CW/SP/UP/DP/HP - can be changed regardless of the selected exposure mode.

In **continuous exposure mode**, the exposure time is fully controlled by the operator acting on footswitch: as long as footswitch is kept pressed, the shutter is open and therefore laser emission occurs.

When the **single exposure mode** is enabled and footswitch is pressed, the system opens the shutter and keeps it open only for the selected exposure time. Once the selected exposure time is exhausted, the shutter is automatically closed regardless if footswitch is still pressed.
If the operator wants to perform a new exposure, he has to release and

then press again footswitch.
The system allows to select the exposure time between 0.01s and 0.9s acting on the two arrows next to the "T.ON" value. The minimum available "T.ON" value depends on the selected frequency as reported in the following Table.

Frequency	5Hz	10Hz	20Hz	50Hz	80Hz	100Hz
Min. TON	0.10s	0.05s	0.03s	0.01s	0.01s	0.01s

Table 12 - Minimum available TON according to selected frequency

Fig.22 - Exposure mode selection

When **timed repeated exposures mode** is enabled and footswitch is pressed, the SmartXide² system opens the shutter and keeps it open for the selected exposure time.
Once the selected exposure time is exhausted, the shutter is automatically closed then, if footswitch is still pressed, the system waits for the selected "T.OFF" time. Then the shutter is opened again and a new exposure is performed. This sequence is continuously repeated as long as footswitch is kept pressed.
The system allows to change the exposure time between 0.01s and 0.9s acting on the two arrows next to the "T.ON" value and to change the "T.OFF" time between 0.1s and 5s. The minimum available "T.ON" value depends on the selected frequency as reported in the Table 12.

Total Energy and Total Time

The system displays the energy delivered and the time elapsed since the last resetting.
When the system is turned on, these counters are set to zero, then they increase during treatment.
If the "RESET" option is pressed, the "TOTAL ENERGY" and "TOTAL TIME" values are cleared.

Aiming source

The two icons "" and "" in the "Aiming" area adjust the intensity of the aiming beam from OFF to 100% (step: 2% between OFF and 10%, step: 10% for the other values).
It is also possible to switch off the aiming beam while lasing by pressing the "Dowl" ("Diode off while lasing") option.

Set the "Dowl" option ON to have a clear view of the operating field and well distinguish the tissue ablation planes while operating.

CAUTION ***Possible risk for patient/operator***	**CO_2 aiming beam intensities higher than 60% require an optical protection as indicated in par. 5.2.1. The system displays a warning icon next to the selected value (if higher than 60%).**

Scanning unit

Press the area displaying the type of the scanning unit currently connected to the system in order to activate it.

The screen displays a message warning the operator that the delivery system selection has been changed; moreover the operator is reminded to control the scanning unit connections.

8.4. Favorite menu

The  icon allows the user to access a list of user-defined favorite treatment parameters.
Selecting a favorite parameter set offers the convenience of quickly loading the most used parameter values.

To save a favorite parameter set, first select the desired parameter values in the User menu and then touch the  icon; the system displays the following popup:

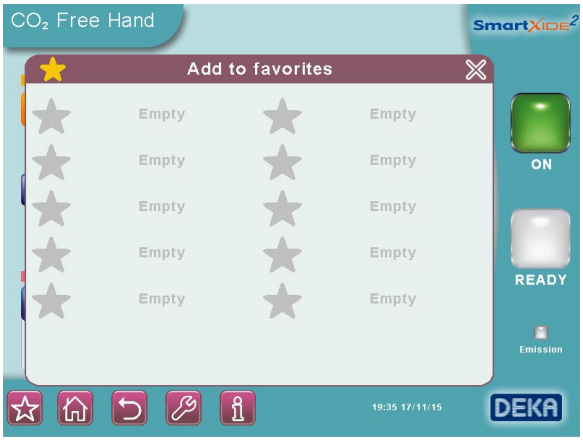

Fig.23 - 'Add to favorites' menu

Press one of the empty rows to select it (the row will be highlighted with a blue background) and then the Save icon  : the system displays a summary of selected parameter values as shown in next Figure.

Fig.24 - Summary of parameter values to be saved

If the values are not correct, touch 'No' and modify them, otherwise touch 'Yes' and insert a name for the favorite parameter set: a keyboard will appear to allow the user to enter the information.
On the keyboard, note that the "  " icon allows the user to switch from upper case to lower case, while the "  " icon allows the user to enter special characters.

Touch the Save icon to save the set of parameters in the list of favorite parameter sets.

To load one of the parameter sets previously saved amongst the favorites, touch the  icon in the bottom of the screen: the system displays the list of saved favorite parameter sets. Touch the desired row (the row will be highlighted with a blue background), then:

- touch the row again to display a summary of the saved parameters, or
- touch the "USE THESE DATA" button to load that set of parameters.

Fig.25 - Loading a parameter set from list of favorite parameter sets

NOTE: After a favorite parameter set is loaded, any changes made to individual parameter values will not be displayed by the system.

8.5. Set up menu

The Set up menu allows to set the system clock and date, to regulate the brightness of the screen, to select the language and other tasks.

To enter this menu, press the "  " area.

Fig.26 - "Set up" menu

From this menu the user can:

- choose between a 12h and 24h time format and a dd/mm/yy, mm/dd/yy, or yy/mm/dd date format; to change a parameter, touch the relative area and use the corresponding arrows.
- change the language.
- adjust the volume of the internal buzzer: press the "+" and "-" keys to adjust the level and the "TEST" key to test the selected level.
- select the time for automatic system switch off between 2 and 20 minutes by pressing "  ": if the system is left unused for the selected amount of time, it will automatically switch off the laser source in order to extend the service life of the internal components.
- change the background colour.
- enable/disable the keys sound.
- choose an air flow mode for the handpiece by pressing "  ": continuos (i.e. the air flows continuosly when the system is in READY status), and timed with emission (i.e. the air flows when the CO_2 laser source is operating).

If some parameters have been modified, the "  " icon is displayed to allow to save changes.

8.6. CO_2 power calibration procedure

The SmartXide^2 system is equipped with an internal power meter which allows to measure the real output power level of the CO_2 laser source.
The power evaluation and calibration procedure is started and continuously performed as the CO_2 source is switched on.

As the CO_2 source is switched on and each time the power level is changed, the system starts flashing the message "POWER EVALUATION" on the screen in order to warn the operator that a power evaluation and calibration procedure for that power level is in progress.
During this procedure, footswitch is automatically disabled so no laser treatment can be started.
Note that if the READY mode was selected, the system will restore this mode only once the procedure will be completed.
The procedure is intended to verify the real power level provided by the CO_2 laser source and in case make it matching with the power level selected by the operator.
At the end of the procedure, the message "POWER EVALUATION" is cleared.
The following two conditions can occur:

- the real power level matches with the selected power level or the procedure succeeds in making them matching: no further message is displayed and the system is ready to operate;
- the real power level does not match with the selected power level AND the procedure fails in making them matching: in this case, a double warning sound is performed and the real power level currently available is flashed on the screen for about 5s to warn the operator.
  After 5s, this value stops flashing and it is taken as the effective treatment power level.

Once the calibration procedure is completed, the SmartXide^2 system starts monitoring the real power level in order to detect power fluctuations.
If the real power level changes so that it does not match anymore with the value displayed on the screen, the system acts as follows:

- if a laser treatment is in progress, that is if footswitch is pressed and as long as it is kept pressed, the new power level is displayed on the screen with black characters on white background and the internal buzzer produces 5 sounds per seconds - instead of 1 sound per second - in order to warn the operator;
  if the power mismatch is recovered, the old power level is displayed on the screen with standard characters and timed sound is again performed one time per second.
- If no laser treatment is in progress, a double warning sound is performed and the new power level is flashed on the screen for about 5s to warn the operator.
  After 5s, this value stops flashing and it is taken as the new effective treatment power level.
- if the detected output power is out of the regulatory limits on respect

to the nominal one, the emission is immediately stopped and the system states a HIGH POWER or a LOW POWER alarm - see Section "Troubleshooting" -.

8.7. System shutdown

To shut down the system in a normal (non-emergency) condition, proceed as follows:

- **press the "STAND BY" key on the control panel**;
- turn the key of the key switch to the "O" position.

In an emergency condition, press the emergency switch - see Section "System description" -.

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9. SCANNING UNITS

The SmartXide^2 system can be provided with three different scanning units that can be connected to the articulated arm and that allow to achieve high performance in specific treatments.

The scanning units are listed below:

- "HiScan Surgical" for microsurgery applications.
- "Endoscan" for surgical endoscopic and microsurgical applications.
- "HiScan DOT" for ablative skin resurfacing and gynaecological applications.

9.1. Installation of the scanning unit

Proceed as follows to install a scanning unit:

- **switch the system off;**
- remove the handpiece from the articulated arm, if connected;
- remove the protection cap (if present) and screw the scanning unit to the articulated arm;
- pull down the protection panel on the rear side of the system to access the connector for the scanning cable and connect it paying attention to make the plug of the cable enter the suitable hole (see Fig. 27);

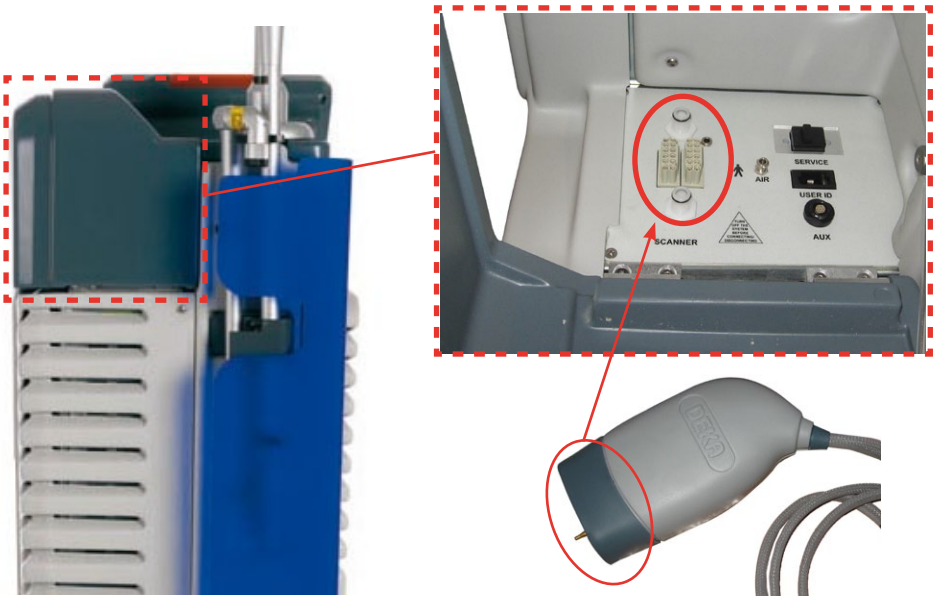
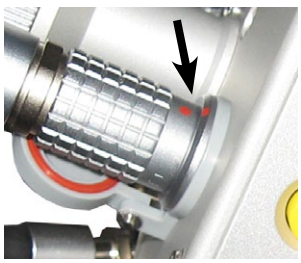


Fig.27 - Connection of the scanning unit

- ***only if not already connected***, connect the other side of the cable to the scanning unit: insert the connector so that the red dot marked on it matches with the red dot on the unit connector, as highlighted in the example alongside.



NOTE
When the scanning unit is disconnected from the system, put again the protection cap on it.

Once a scanning unit is connected, the SmartXide^2 system automatically detects its presence and allows to activate it via the control panel.
The area of the currently connected unit is highlighted on the CO_2 user menu.

ATTENTION *Possible equipment damage*	• The connection/disconnection of the scanning cable has to be performed with the system switched off (key switch has to be in the 'O' position). • **Do not disconnect the scanning head from its cable unless it is absolutely necessary: if you have to remove the scanner, disconnect its cable from the system.**

CAUTION ***Possible risk for patient/operator***	**Each scanning unit has its own cable: be very careful not to exchange the cable with the one of another scanning unit.** **If possible, do not disconnect the cable from the scanning head.**

9.2. Use of the HiScan Surgical unit

Another external scanning unit called HiScan Surgical is available among system accessories - optional - and shown in Fig. 28.
The external HiScan Surgical unit can be used either with micromanipulator or with long focal (4" or longer) handpieces. However the use together with the Deka EasySpot Hybrid micromanipulator or similar, is the best choice: please refer to the *Operator's Manual* of the micromanipulator for its description and use.

Fig.28 - HiScan Surgical unit

NOTE
HiScan Surgical is generally provided already connected to Deka micromanipulator: please do not disconnect the two units, if possible. If the two units are disconnected, screw the connector of the HiScan Surgical unit shown as **(A)** on the micromanipulator; connect the micromanipulator cable to its connector on the HiScan unit **(B)**.
To verify that the two units are correctly assembled, perform an emission on a tongue depressor selecting the "hexagon" shape and verifying that the scanning is performed horizontally from top to bottom.

To activate the HiScan Surgical unit, if properly installed, press the area with the name of the scanner in the CO_2 user menu. The screen changes as shown in Figure:

Fig.29 - User menu when HiScan Surgical unit is activated

Shapes of the scanning pattern

The scanning unit can generate five types of pattern: line, spiral, ellipsoid motion on a circular surface, arc of a circle up to the complete circle, and hexagon (with "normal" or "interlaced" scan mode).
Touch the relevant icon in the "**Shape**" area to select a scanning shape.

NOTE
The HiScan Surgical unit moves the red aiming beam on the outline of the selected scanning area. This function allows to immediately check the characteristics - shape and dimensions - of the scanning area.

ATTENTION!
The ellipsoid motion on a circular surface does not have a uniform delivery of energy on the tissue. Therefore, the "depth" displayed on the screen is an average of the depths of ablated tissue in the whole scanning; moreover, it has to be used with high scanning speed and moving the laser beam on the tissue, to achieve the best result of ablation.

According to the selected shape, the system enables or not the parameters availble in the User menu, as detailed in the following paragraphs.
In particular, ***ONLY for the "hexagon" scanning shape***, it is possible to select two different types of scanning:

- "**Normal**" scan mode
  When this scan mode is selected, the area is treated by scanning the lines from left to right and from right to left, starting at the first line from the top to the last line at the bottom.
- "**Interlaced**" scan mode
  When this scan mode is selected, the area is treated by first scanning the odd lines and then the even lines. Once the scan of the odd lines has been completed from the top to the bottom the even lines are scanned from the bottom to the top.
  The interlaced scan mode is advisable for reducing the thermal effects during treatment.

To select either one or the other scan mode, press the "**Scan Mode**" area (*this area is displayed only when the "hexagon" shape has been selected*).

Size of the scanning pattern
The "**Size**" option allows to change the dimension of the scanning area:
- the size is shown as percentage of the maximum available scanning area for all shapes except for spiral;
- the diameter of the spiral is shown in mm and can be selected from 0.3mm to 1.1mm (step: 0.1mm).

This parameter is available for all the scanning shapes and can be changed in one of the following ways:
- pressing the "**Size**" area of the User menu and acting on the arrows of the "**Select Dimension**" menu;
- by the ***red key*** located on the scanning head - see Fig. 28 -;
- by the remote command (central position) on the micromanipulator joystick. The change of the scanning area dimension occurs on releasing the remote command key. By keeping pressed this key for more than 4s, "SCAN OFF" mode is enabled.
  See *Micromanipulator Operator's Manual*.

"Curving" parameter
If the "arc of circle" shape has been selected, the "Curving" parameter is enabled in the User menu.
The two arrows in this area allow to change this parameter, that is the extension of the selected arc.

Fig.30 - Curving parameter

Its value is expressed as ratio between the subtended arc and the maximum available extension - that is the circumference -.
The pictures below show, for example, the arcs resulting from some values of the "Curving" parameter.

Curving: *2/10* *5/10* *10/10*

The "Curving" parameter is NOT available for the other scanning shapes.

Rotation of the scanning patterns
The selected scanning shape can be rotated in one of the following ways:
- by the two yellow keys located on the scanning head - see Fig. 28 -;
- by the rotation of the key of the remote command on the micromanipulator joystick. See *Micromanipulator Operator's Manual.*

Emission mode
The area "**Emission mode**" alternately selects and displays either **CW** or **UP** emission mode.
Please refer to par. 8.3.1 for details on these two emission modes.

Exposure
The selected exposure mode is displayed on the screen in the "**Exposure mode**" area; touch this area to enter the screen which allows to change the exposure mode.

Three exposure modes can be selected by touching the relevant area:
- continuous - "Contin." on the screen -;
- timed single exposure - "Single" on the screen -;
- timed repeated exposures - "Repeat. " on the screen -.

Fig.31 - Selection of the exposure mode

Note that the emission mode - CW/UP - can be changed regardless of the selected exposure mode.

In **continuous exposure mode**, the exposure time is fully controlled by the operator acting on the footswitch: as long as the footswitch is kept pressed, the shutter is open, the laser emission occurs and the scanning unit repeats the selected pattern.
When this mode is selected, it is also possible to select a finite number of scannings ("**Pass**" parameter on the screen, see Fig. 31): in this case, laser emission is stopped as soon as the selected number is reached.
It is possible to change the "**Pass**" parameter acting on the two arrows.
The User menu displays the depth of ablated tissue for each scanning and the total depth once completed all the selected scannings.

When the **single exposure mode** is enabled and the footswitch is pressed, the system opens the shutter and keeps it open only for the time of one complete scanning. Once this time is exhausted, the shutter is automatically closed regardless if footswitch is still pressed.
If the operator wants to perform a new exposure, he has to release and then press again footswitch.

When **timed repeated exposures mode** is enabled and the footswitch is pressed, the system opens the shutter and performs scanning sequences until footswitch is kept pressed.
Once a single scanning is completed, the shutter is automatically closed then, if footswitch is still pressed, the system waits the selected "Delay" time; after this time the shutter is open again and a new scanning is performed. This sequence is continuously repeated as long as footswitch is kept pressed.
Use the arrow keys (Fig. 31) to change the "**Delay**" time between two scans from 0.1s to 3s.

Scanning modes

The HiScan Surgical system allows the operator to use two different working modes available in the "**MODE**" area of the User menu: the "Depth mode" and the "Power mode".

Using the "**Depth mode**", the operator can act directly on two parameters: the **emission power** and the **cutting depth**. According to the selected

values for these two parameters and according to the selected focal length, the system automatically calculates the required energy density (fluence).
The "Depth" parameter can be changed from 0.2mm to 2mm acting on the two arrows.

Using the "**Power mode**" (*please refer to the User menu shown in Fig. 29 where this mode is selected*), the operator can act directly on two parameters: the **emission power** and the **dwell time** of the laser beam on a scanning point; according to the selected values for these two parameters and according to the selected focal length, the system automatically calculates the required energy density (fluence) and therefore the cutting depth on tissue: this last parameter is displayed on the User menu.
The "Dwell time" can be changed from 100µs to 45ms acting on the two arrows.

NOTE
If, according to the selected dwell time and power value, the resulting depth is higher than 2mm, the system does not declare this value and shows a warning icon next to the dwell time.

The tissue ablation depth is strictly connected to the type and characteristics of treated tissue, therefore the "Depth" parameter shown on the screen is purely as an indication.

CAUTION
Possible risk for patient/operator

Power selection
The "**Power**" selection keys allow to change the power value from 0.5W up to 60W.

Disabling the scanning
If an area is to be treated without scanning, select the "point" shape in the "SHAPES" area of the User menu (without unscrewing the scanning head).
The "point" becomes red highlighted and the selection of the scanning parameters is disabled: the operator can change only the power value, the emission mode and the focal length.

The scanning can be disabled also by keeping pressed for a few seconds the red key on the scanning head (or the central key of the remote command on the micromanipulator joystick) until the red aiming beam stops at the center of the area given by the spacer of the scanning head. The laser pulse will be performed on this point.
As the "**No Scan**" mode is set, the system displays a warning message to remind the operator that it is necessary to manually move the laser beam in order to avoid dangerous overexposures. For this reason the operator can enable an acoustic signal to warn that the "No Scan" status is set: this acoustic warning keeps on until the scanning mode is enabled again.

Fig.32 - "No Scan" mode

CAUTION

Possible risk for patient/operator

When the "No Scan" mode is selected, footswitch works in continuous way.

Aiming source

The intensity of the aiming beam from OFF to 100% (step: 2% between OFF and 10%, step: 10% for the other values).
It is also possible to switch off the aiming beam while lasing: press the "Aiming" area and select the "Dowl" ("Diode Off while Lasing") option.
Set the "Dowl" option on to have a clear view of the operating field and well distinguish the ablated tissues during treatment.

CAUTION

Possible risk for patient/operator

CO_2 aiming beam intensities higher than 60% require an optical protection as indicated in par. 5.2.1.The system displays a warning icon next to the selected value (if higher than 60%).

Scanning Info

The system displays further info about scanning, that is the total scanning time and energy according to the selected parameters.

"Free hand" mode

It is always possible to go back to the "Free Hand" mode by pressing the "**Free Hand**" area: the systems displays a message to warn the operator that the delivery system selection has been changed.
Press the "Confirm" key to go back to the User menu.

Settings

The "**Settings**" option allows to access two other options: the "Focal" and the "Centering correction" options.

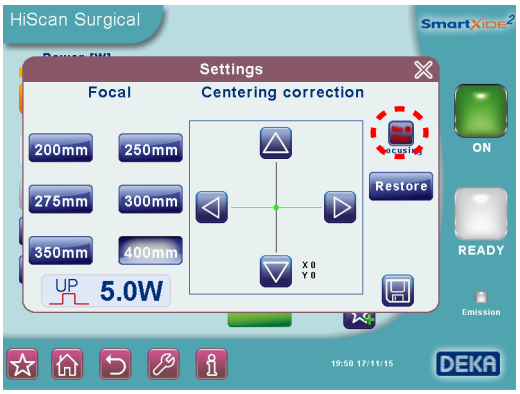


Fig.33 - "Settings" option

The "**Focal**" option allows the operator to "inform" the system about the focal length set on the micromanipulator. Select the same focal length set on the micromanipulator and press "" area to confirm the choice.

Be careful to correctly select the focal length because this parameter is used by the system to calculate the scanning area and the cutting depth.
The selected focal length must be the same of the working focal length set on the microscope on which the focus of the micromanipulator was adjusted.

CAUTION
Possible risk for patient/operator

The "**Centering correction**" option allows to adjust the laser beam centering, if necessary.
This adjustment doesn't take the place of the alignment procedure of the articulated arm but it just helps when little adjustments are needed before treatment, in order to enter peectly the most critical accessories like micromanipulators or laparoscopes.
Before starting the surgical procedure the operator has the responsibility to check the coaxiality between the red aiming and CO_2 beams.
In microsurgery procedures this check has to be performed through the microscope and the micromanipulator at the system's working setup; the operator has not to change it after this operation during the surgical procedure.
For further information, please refer to *Micromanipulator Operator's Manual.*
The arrow keys manage the horizontal and vertical motions of the laser beam along the two axes;
the "**Restore**" key allows to center the laser beam in the same position set by factory;
the "" icon confirms the selected centering.

NOTE
Assuming that the laser arm is correctly aligned, the "**Restore**" option is very important in order to come back to the initial position. It may be useful if the operator "loses" the beam during the centering procedures.

ATTENTION!
If you perform the centering correction procedure without saving the new settings (that is, if you switch off the system before exiting the "Centering correction" menu), at the next system start-up a warning message is displayed: the user has to perform again the centering procedure before using the scanning unit.

In order to check the accuracy of centering, the system allows to switch on the laser source and perform a laser emission on a target surface using preset parameters (UP, 5W). This operation can be done with the steady point or with the full circle pattern. To switch between the two modes, press the area highlighted in Fig. 33.

NOTE
It is possible to control the horizontal and vertical motion of the laser beam along the two axes also in the following ways:

- press the red key on the scanning head or the central key of the remote control on top of the micromanipulator joystick to select the horizontal or the vertical axes;
- press the two yellow keys on the scanning head or the right-left keys of the remote control on top of the micromanipulator joystick to move the beam.

9.2.1. HiScan Surgical alarms

Hi-Scan
This fault condition concerns troubles with the HiScan Surgical unit.
Try to reset the fault condition. Call the technical assistance service if it persists.

HS KEYB
On the scanning head there are three keys. The system states a fault condition if one of these keys is pressed when the HiScan Surgical unit is activated. Try to reset the fault condition. If it persists call the technical assistance service.

HS galvo driver
The system states a fault condition if the mirrors inside the HiScan Surgical unit are not properly working. If this fault is stated on HiScan Surgical activation, check all the connections with the scanning unit.
Try to reset the fault condition. If it persists call the technical assistance service.

HS points maker
This fault condition concerns troubles with the software of the HiScan Surgical unit. Try to reset the fault condition. If it persists call the technical assistance service.

EEPROM Factory Centering/EEPROM User Centering
These fault conditions concern problems with the centering procedure data storing. In the first case, call the technical assistance service; in the second case, perform again the centering procedure and, if the problem is not solved, call the technical assistance service.

9.3. Use of the EndoScan unit

Another external scanning unit called EndoScan is available among system accessories - optional - and shown in Fig. 34.
EndoScan can be used either via long focal handpieces (4" or longer), or via DEKA micromanipulator, or via laparoscope.

Fig.34 - EndoScan unit

NOTE
If present, screw the micromanipulator on the connector of the EndoScan unit shown as **(A)** and connect the remote control, if available, to the connector **(B)**.

To activate the unit, if properly installed, press the area with the name of the scanner in the CO_2 user menu. The screen changes as shown in Figure:

Fig.35 - User menu when the EndoScan unit is activated

Shapes
The scanning unit can generate two types of patterns:

Surface mode (red highlighted in Fig. 35)
A circular surface is covered, with a composed ellipsoid mode.
In this scanning modality, using the UP mode, more delicate ablations are obtained.

Perimeter mode
The focused laser beam moves in a circular mode. In this scanning modality the laser becomes a sort of "milling cutter" that ablates each passage a layer of tissue.

In any moment it is possible to stop the scanning movement to pass to the steady spot, just by pressing the dedicated button on the centre of the touch screen.

NOTE
The EndoScan unit moves the red aiming beam on the selected scanning figure. This function allows to immediately check the characteristics - shape and dimensions - of the scanning area.

Size of the scanning pattern
The "**Dimen.**" option allows to change the dimension of the scanning area (shown as percentage of the maximum available scanning area).

CAUTION

Possible risk for patient/operator

Once the power level has been set, the tissue ablation rate is higher for smaller scanning patterns.

Emission mode
The area "**Emission mode**" alternately selects and displays either CW or UP emission mode.
Please refer to par. 8.3.1 for details on these two emission modes.

Scan mode
The system allows to control the exposure time during a laser treatment.
The selected exposure mode is displayed on the screen in the "Exposure" area; touch this area to enter the screen which allows to change the exposure mode.

Three exposure modes can be selected by touching the relevant area:
- continuous - "Contin." on the screen -;
- timed single exposure - "Single" on the screen -;
- timed repeated exposures - "Repeat. " on the screen -.

Note that the emission mode - CW/UP - can be changed regardless of the selected exposure mode.

In **continuous exposure mode**, the exposure time is fully controlled by the operator acting on footswitch: as long as footswitch is kept pressed, the shutter is open, the laser emission occurs and the scanning unit repeats the selected pattern.
When the **single exposure mode** is enabled and footswitch is pressed, the system opens the shutter and keeps it open only for the time of one complete scanning. Once this time is exhausted, the shutter is automatically closed regardless if footswitch is still pressed.
If the operator wants to perform a new exposure, he has to released and then pressed again footswitch.
When **timed repeated exposures mode** is enabled and footswitch is pressed, the system opens the shutter and performs scanning sequences until footswitch is kept pressed.
Once a single scanning is completed, the shutter is automatically closed then, if footswitch is still pressed, the system waits the selected "Delay" time; after this time the shutter is opened again and a new scanning is performed. This sequence is continuously repeated as long as footswitch

is kept pressed. Use the arrow keys to change the "delay" time between two scans from 0.1s to 3s.

Power
The "**Power**" selection keys allow to change the power value from 0.5W up to 60W.

Dwell Time
Only if the circular scanning pattern is selected, the "Dwell Time" parameter, that is length of time that the laser beam stays on a scanning point, can be selected from 100µs to 1000µs.

"No Scan" scanning mode
Touch the "**No Scan**" option in the "Shapes" area to select this scanning mode: this area becomes red highlighted while all the scanning parameters are disabled except the emission mode.
The scanning can be disabled also by keeping pressed for a few seconds the central key on the scanning head (or the central key of the remote command on the micromanipulator joystick) until the red aiming beam stops at the center of the scanning area. The laser pulse will be performed on this point.
If the "No Scan" scanning mode is selected, the system emits a fixed laser beam, without scanning.

Aiming source
The intensity of the aiming beam from OFF to 100% (step: 2% between OFF and 10%, step: 10% for the other values).
It is also possible to switch off the aiming beam while lasing: press the "Aiming" area and select the "Dowl" ("Diode off while lasing") option.
Set the "Dowl" option on to have a clear view of the operating field and well distinguish the ablated tissues while operating.

CO_2 aiming beam intensities higher than 60% require an optical protection as indicated in par. 5.2.1. The system displays a warning icon next to the selected value (if higher than 60%).

CAUTION
Possible risk for patient/operator

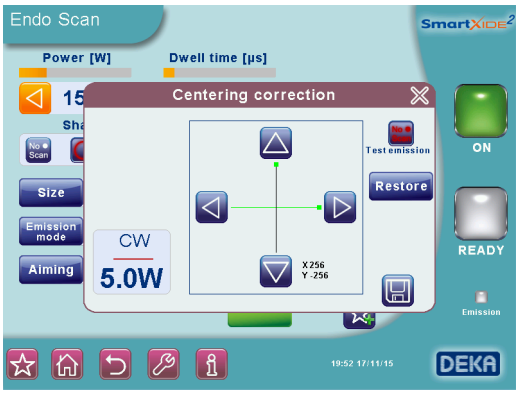
"Free hand" mode
It is always possible to go back to the "Free Hand" mode by pressing the "**Free Hand**" area: the systems displays a message to warn the operator that the delivery system selection has been changed.
Press the "Confirm" key to go back to the User menu.

Adjusting of the laser beam centering

The "**Centering correction**" option allows to adjust the laser beam centering, if necessary.
This adjustment doesn't take the place of the alignment procedure of the articulated arm but it just helps when little adjustments are needed before treatment, in order to enter peectly the most critical accessories like micromanipulators or laparoscopes.
Before starting the surgical procedure the operator has the responsibility to check the coaxiality between the red aiming beam and CO_2 beam.
In microsurgery procedures this check has to be performed through the microscope and the micromanipulator at the system's working setup; the operator has not to change it after this operation during the surgical procedure. For further information, please refer also to *Micromanipulator Operator's Manual.*

The arrow keys manage the horizontal and vertical motion of the laser beam along the two axes;
the "**Restore**" key allows to center the laser beam in the same position set by factory;
the "  " icon confirms the selected centering.

Fig.36 - EndoScan centering correction



NOTE
Assuming that the laser arm is correctly aligned, the "**Restore**" option is very important in order to come back to the initial position. It may be useful if the operator "loses" the beam during the centering procedures.

ATTENTION!
If you perform the centering correction procedure without saving the new settings (that is, if you switch off the system before exiting the "Centering correction" menu), at the next system start-up a warning message is displayed: the user has to perform again the centering procedure before using the scanning unit.

NOTE
It is possible to control the horizontal and vertical motion of the laser beam along the two axes also in the following ways:

- press the central key on the scanning head or the central key of the remote control on top of the micromanipulator joystick to select the horizontal or the vertical axes;

- move right-left the central key on the scanning head or the right-left keys of the remote control on top of the micromanipulator the joystick to move the beam.

In order to check the accuracy of centering, the system allows to switch on the laser source and perform a laser emission on a target surface using preset parameters (UP, 5W).
This operation can be done with the steady point or with the full circle pattern. To switch between the two modes, press the area highlighted in Fig. 36.

ATTENTION!
If you are performing the centering procedure with the scanning unit connected to a laparoscope, use the circle pattern: the laser beam is correctly centered only if you see the full circle (not an arc of circle) through the laparoscope (projecting the aiming beam on a perpendicular plane suface).The correct centering has to be verified every time the laparoscope is connected to the EndoScan unit.

Scanning Info
The system displays further info about scanning, that is the total scanning time and energy according to the selected parameters.

9.3.1. EndoScan alarm

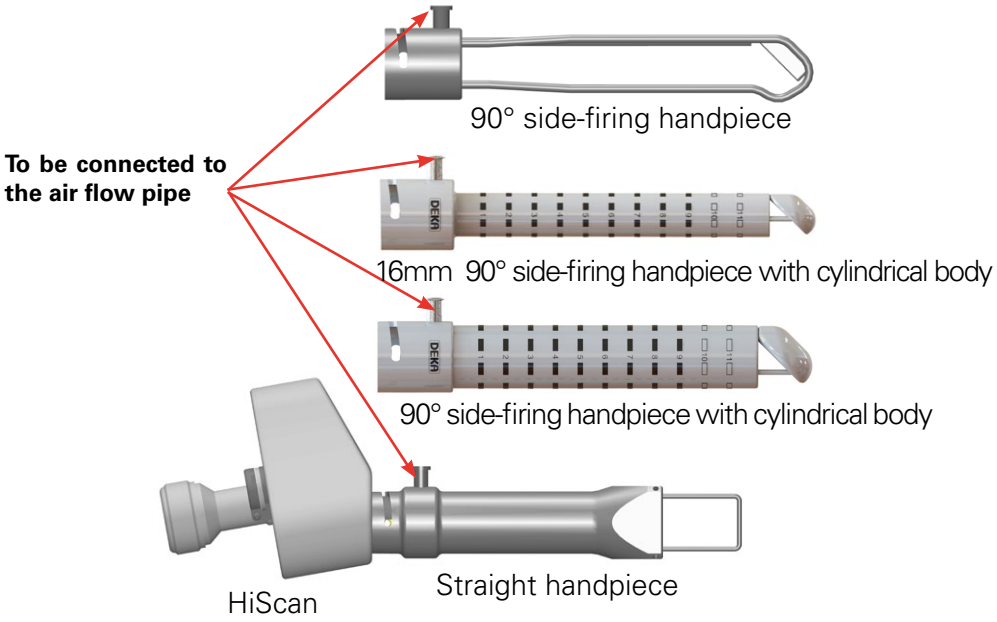
EndoScan
This fault condition is displayed by the "SYSTEM FAULT" menu if the SmartXide² system detects troubles about the EndoScan unit.
Make sure that the scanning unit is properly connected. Try to reset the fault condition; call the technical assistance service if the fault persists.

EEPROM Factory Centering/EEPROM User Centering
These fault conditions concern problems with the centering procedure data storing.
In the first case, call the technical assistance service; in the second case, perform again the centering procedure and, if the problem is not solved, call the technical assistance service.

9.4. Use of the HiScan DOT

Another optional scanning unit for the SmartXide² system is the HiScan DOT unit which allows to achieve high performance in ablative skin resurfacing and gynaecological treatments.
Three handpiece are available for this HiScan unit:

Fig.37 - HiScan DOT unit



The 90° side-firing handpieces with cylindrical body must be used with the inserter, as shown in the figure below. The inserter must be positioned at the height of one of the black marks, depending on the vulvo-vaginal depth to be treated.

Fig.38 - Handpiece with inserter

To treat the introitus use the above mentioned handpieces without the inserter. Said handpieces must be inserted into the vaginal canal using as reference the gray marks at the distal end of the handpiece, taking care not completely remove the handpiece from the vaginal canal during the emission of the laser beam.

NOTE
Due to the reduced size of the 16mm 90° side-firing handpiece with cylindrical body, before connecting it to the scanning head, first plug the air tubing then connect the handpiece to the scanning unit by acting on the air connector.

To turn the external HiScan DOT unit on, when installed correctly, press "HiScan DOT" on the CO_2 user menu. The screen will appear as below:

Fig.39 - User menu with HiScan DOT unit on

Power

The "**Power**" selection keys allow the user to change the power value up to 60W (40W in HP emission mode).

Dwell time

The scanning "**dwell time**", i.e. the length of HiScan emission, can be selected between 100µs and 2,000µs (at increments of 100µs).

Spacing

The "**Spacing**" parameter, i.e. the "distance" between scanning dots, can be selected between 0 and 2,000µm (at increments of 50µm).

Shape and size of the scanning area

The **Shape** key allows the user to change the shape of the scanning area, depending on the probe (handpiece) to be used.

The following pop-up is displayed:

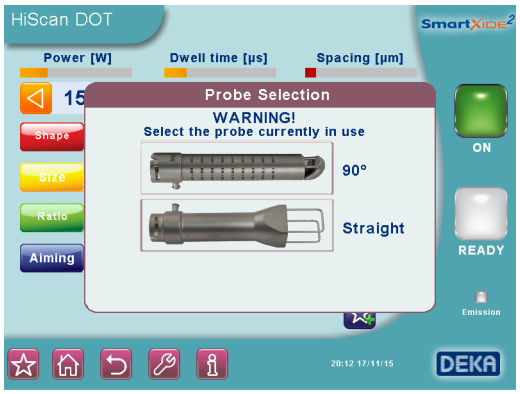


Fig.40 - Probe selection pop-up

Select the probe in use by pressing the relevant icon.
This pop-up is displayed again every time the user sets the READY status.

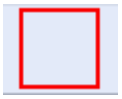
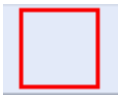
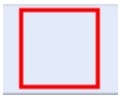
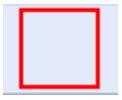
The user menu displays the selected probe in the top left corner of the screen (highlighted in Fig.41).

Fig.41 - User menu with selected probe

CAUTION

Possible risk for patient/operator

Always make sure to select the correct handpiece that is currently connected to the scanner.
Selecting a different handpiece from the one currently in use could result in the application of scanning area shapes that might not be suitable for the current handpiece, which may cause uncontrolled, inefficient and/or potentially dangerous treatments.

Probe	Shape of scanning area
	
	
	
	

The **Size** area allows the user to change the size of the scanning area (shown as a percentage of the maximum available scanning area, i.e. 8mm x 8mm);
the **Ratio** area allows the user to change the height-width ratio of the scanning area.

NOTE

The HiScan DOT unit moves the red aiming beam along the outline of the selected scanning area. This function allows the user to immediately check the characteristics - shape and size - of the scanning area.

Aiming beam intensity
The intensity of the aiming beam can be set between OFF and 100% (increments of 2% between OFF and 10%, increments of 10% for the remaining values).
It is also possible to switch the aiming beam off during laser treatment: press "Aiming" and select the "Dowl" ("Diode off while lasing") option.
Set the "Dowl" option to ON to have a clear view of the treatment area and to clearly distinguish the treated tissues during the procedure.

Smart Stack
It is possible to select and edit the "**Smart Stack**" parameter which manages the number of pulses delivered consecutively by the system on the same "dot".
This value can be set between 1 to 5 by pressing "Smart Stack" by the number of pulses the user wishes to set.
For example, if value "1" is set, the system will perform only one pulse on every single dot, while a value of "3" will provide three pulses on a single dot, before moving onto another spot/dot. In theory, this scanning mode (i.e. Stack 3) should have the same effect on tissue as three consecutive scanning applications, however it has the advantage to ensuring greater overlapping by emitting three pulses over the same dot.

CO_2 aiming beam intensities higher than 60% require an optical protection as indicated in par. 5.2.1. The system displays a warning icon next to the selected value (if higher than 60%).

CAUTION
Possible risk for patient/operator

Scan mode
It is possible to select a scan mode from Normal, Interlaced or SmartTrack, by simply touching the "**Scan mode**" area.

- **"Normal" scan mode**
  When this scan mode is selected, the area is treated by scanning lines from left to right and from right to left, starting from the first line at the top, to the last line on the bottom.

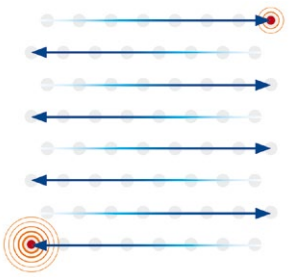
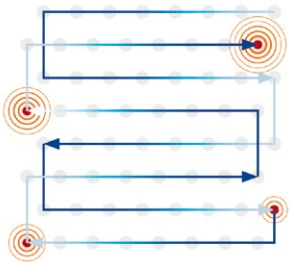


Fig.42 - Example of "Normal" scan mode

- **"Interlaced" scan mode**

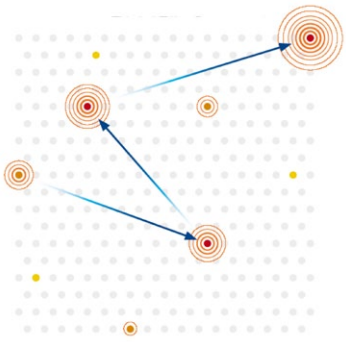
Fig.43 - Example of "Interlaced" scan mode



When this scan mode is selected, the area is treated by scanning the odd numbered lines first, followed by the even numbered lines. Once the odd numbered lines have been scanned from the top to the bottom, the even lines are scanned from the bottom to the top. Use of the interlaced scan mode is advisable for reducing thermal effects during treatment.

- **"SmartTrack" scan mode**

Fig.44 - Example of "SmartTrack" scan mode



When this scan mode is selected, the area is treated by scanning dots in random order: this minimizes the risk of tissue overheating, and therefore thermal damage.

Exposure mode

The system allows the user to control scanning exposure time.
Touch the "**Exposure mode**" area to open the screen where the exposure mode can be changed.

Two exposure modes are available by touching the relevant areas:

- single scanning ("Single" on the screen);
- timed repeated scannings ("Repeat." on the screen).

- **Single scanning**
  When the single exposure mode is enabled and footswitch is pressed, the system opens the shutter and keeps it open only for the time of one complete scanning. Once this time is over, the shutter closes automatically, whether the footswitch is still down or not. If the operator wants to perform a new exposure he/she must release the footswitch and then press it down again.
- **Timed repeated scanning mode**
  When this mode is enabled and the footswitch is pressed down, the system opens the shutter and performs scanning sequences as long as the footswitch is held down. Once a single scanning is complete, the shutter closes automatically and then, if the footswitch is still down, the system waits out the selected "Delay" time; after this time the shutter opens again and a new scanning is performed. This sequence is repeated continuously as long as the footswitch is held down. Use the arrow keys to change the "**Delay**" time between scannings from 0.1s to 3s.

Emission mode
An emission mode can be selected from **DP**, **HP** and **SP** modes: please refer to par. 8.3.1 for details on these emission modes.

For the same amount of time selected for pulse length, the amount of energy released by the system in DP mode is greater than the energy released in SP mode, because of a different pulse shape. Moreover, having equal power values, the energy released in HP mode is different (and can be much higher) from the other modes. *Always check the value of the released energy as it is the indicator of the thermal effect on the tissue.*

CAUTION
Possible risk for patient/operator

Scanning info
The system displays additional information about the scanning: the value, according to the selected parameters, of the energy released on each scanning point ("Pulse Energy"), the fluence (energy density) and the percentage of treated surface ("Density").

"Free hand" mode
It is always possible to go back to the "Free Hand" mode by pressing the "**Free Hand**" area: the systems will ask the operator to confirm this choice.

9.4.1. HiScan DOT alarms

Hi-Scan
This fault is related to problems with the HiScan DOT unit.
Try to reset the fault display.
Call the technical assistance service if the fault persists.

HS galvo driver
The system reports a fault if the mirrors inside the HiScan DOT unit are not working properly.
If this fault is reported when the HiScan DOT is switched on, check all the connections with the scanning unit.
Try to reset the fault display. If it persists call the technical assistance service.

HS points maker
This fault is related to problems with the software of the HiScan DOT unit.
Try to reset the fault display. If it persists call the technical assistance service.

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10. CLINICAL APPLICATION

This section discusses the clinical application of the system in general terms; it is not intended to be an exhaustive clinical manual.

10.1. CO_2 laser clinical application

Laser applications and interventions evolved rapidly in the last three decades. Laser systems are nowadays being used extensively in all fields of surgery, and in particular of otorhinolaryngology, gynaecology and dermatology. Current developments are focused on modes of emission and intelligent laser power control as well as the application of laser energy with scanning technology.
The CO_2 is the election laser in most medical fields, thanks to its optical property of being absorbed mostly by water it has excellent tissue cutting properties with very little lateral tissue damage (about 50µm, with superpulsed systems and scanners).
The carbon dioxide (CO_2) emits at 10.6 µm, in the far invisible infrared region. As CO_2 radiation is invisible, a visible (typically red) aiming beam laser is accurately superimposed on to the path of the CO_2 beam.
The CO_2 radiation arrives to the accessory passing through an articulated arm with mirrors inside of it, better if 7.
The accessories for the CO_2 laser are always optical devices, single lens, groups of lenses (like zooms). This devices serve to focalize the beam on little spots. The more the spot is little, the more energy density (fluence) can be achieved even using low power, thus permitting a tissue ablation with minimal charring. The attachment with micromanipulators allows coaxial delivery of the energy for laser surgery with operating microscopes, thus extending its range of clinical application considerably, making its use more and more refined. With the zoom of the micromanipulator the focal point can change and be set on the surgical working plane. Thus the operator has to know how to focalize and work with it, specially with an electronic scanner that produces his best effects if working with a peectly focalized laser, in regime of photoablation.
Please refer also to *Micromanipulator Operator's Manual*.

10.1.1. Contraindications

There are no known contraindications for the use of the system, apart general contraindications as in standard surgery.
Generally, contraindications to using the carbon dioxide laser include an inability to visualize the area to be treated because of anatomic considerations (e.g., prolapsing lateral vaginal sidewall, larynx anatomic conformation) and inadequate physician training or experience.

10.1.2. Side effects

Complications, though rare, can occur according to the anatomic district or the surgical procedure.
Generally speaking, they can be: blood spill, swelling, discomfort or moderate pain, abnormanl cicatrization, adhesions.
The patient must understand the importance of pre-treatment and post-treatment instructions, and that failure to comply with these instructions may increase the probability of complications.
Both bacterial and viral infections are potential side effects if proper clinical precautions are not observed; these precautions are related to the kind of surgical procedure.

10.1.3. Precautions

CAUTION ***Possible risk for patient/operator***	• **Beam alignment and focalization checks are extremely important for safe and correct operation: carefully check if the CO_2 laser beam is properly focused at the microscope's operative working distance and check the coaxiality between the red aiming beam and CO_2 beam.** **Do not use the laser if aiming and treatment beams are not coincident.**
CAUTION ***Possible risk for patient/operator***	• **Spot size and laser energy are independently controlled. If a smaller spot size is used, as in excision procedures, the operator must remember that the energy density is higher.** **Laser parameters should be employed with extreme caution until you understand the biological interaction between the laser energy and tissue.**

The beam should be moved manually or through the scanning system, if present, to control the ablation depth.

- Plastic instruments such as speculums or eye shields can melt when impacted by the laser beam. Use only stainless steel surgical instruments designed specifically for laser use.
- If necessary, the area around the target site can be protected with wet towels or gauze sponges or laser beam backstops. Ensure that sponges do not dry!
- Be especially careful with the use of oxygen. Oxygen accelerates both the severity and the extent of fire. Always refer to the protocols related to anaesthesia, in force in the hospital where the laser system is used.
- Use non-flammable substances for uses as anesthesia, preparing soft tissue for treatment, and cleaning or disinfecting instruments.
- The solvents of adhesives and flammable solutions used for cleaning and disinfecting should be allowed to evaporate before the laser equipment is used.
- Keep a minimum of combustible materials in the treatment room. If treatment requires the use of a combustible material, such as gauze, first soak it in water.

- **Prevent singeing or burning when treating an area with hair by wetting the area with water or saline before beginning treatment.**
- **Attention should also be drawn to the danger of ignition of endogenous gases. When procedures are performed in the perianal area, moistened sponges should be inserted into the rectum.**

CAUTION
Possible risk for patient/operator

Always use laser-resistant, cuffed, and flexible stainless steel endotracheal tube. The endotracheal tube cuff can be inflated with saline to protect it from inadvertent penetration. The saline can be dyed with methylene blue so that evidence of cuff-penetration by the laser will readily appear on surrounding gauze sponge.

CAUTION
Possible risk for patient/operator

10.1.4. Pretreatment Recommendations

At the time of the initial visit, the physician should determine the suitability of the laser treatment and inform patients about the treatment.

If using the laser with micromanipulator, before starting starting the surgical procedure the physician has the responsibility to check if the CO_2 laser beam is properly focused at the microscope's operative working distance and to check the coaxiality between the red aiming beam and CO_2 beam.
The physician has not to change the microscope's working distance after the focusing operation and/or during the surgical procedure.

CAUTION
Possible risk for patient/operator

10.1.5. Treatment Recommendations

Adjust the appropriate maximum joystick's operating field using the dedicate adjustment screw before starting the procedure, in a way that the beam does not exceed the microscope's operating view.

CAUTION
Possible risk for patient/operator

This guarantees the laser beam will never get out of the visual field eventually being "lost" by the operator.

10.1.6. Posttreatment Recommendations

After each treatment session, physicians should advise their patients on proper care of the treated area according to the surgical discipline or procedure.

CAUTION
Possible risk for patient/operator

Patient has to contact the physician if there is any indication of infection (redness, tenderness or pus).

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11. TREATMENT GUIDELINES

As with any dermatosurgical modality, the doctor must have a complete understanding of the indication and limitation of a given laser procedure.

11.1. Pre-Treatment Care

11.1.1. Patient Examination

First of all it is important to proceed with the visit and the anamnesis of the patient. During the initial consultation, the doctor should evaluate the patient's expectation of the treatment. A person's history should be compiled by establishing the following:

- Sun and UV lamp exposure: avoid them before (at least 1 month), during and after treatment. Apply SPF50 sunblock before and after the treatment.
- Be careful in case the patient is taking following types of drugs (suspend the administration according to the specific drug so that its effect is expired before the treatment):
  - Anticoagulants (as acetylsalicylic acid, heparin, etc),
  - Retinoids – these drugs can cause problems in the healing process with possible scar results - (as isotretinoin, etc),
  - Photo-sensitizers (as tetracycline [antibiotic], naproxen [NSAD], auranofin [antirheumatic], estrogens and progestins [oral contraceptive], cloroquine [antimalarial], etc.)
- Recent exfoliation treatment (peels, scrubs, retin-A, previous laser resurfacing or dermabrasion) and surgical treatment (as lifting, etc.), because the procedure could potentially delay the wound healing response due to the presence of inflammation or fibrosis.
- Past skin disorders and keloid formation.
- History of herpes virus infection.

In order to ensure a positive outcome with laser treatment, the patient must strictly follow a pre-operative protocol to help prevent the two main possible complications: Post-Inflammatory Hyperpigmentation (PIH) and infection.

11.1.2. PIH prevention

Especially with darker phototypes (III, IV, V and VI) and Asian phototypes, it is recommended to apply a topical cream every day for four weeks before the treatment for inhibiting melanin production. It is possible to use cream containing hydroquinone or, as alternative lighteners, arbutin, azelaic acid, kojic acid or stabilized vitamin C. This procedure is highly recommended with darker and Asian skin types, while for photo type I and II it is just a suggestion.

11.1.3. Infection prevention

The drugs used fall into two main categories:

- **Antiviral drugs** (aciclovir, valaciclovir, etc). It is suggested to start the antiviral prophylaxis 6 days before the treatment in subjects with a positive anamnesis of herpes virus infections history. The antiviral treatment can start 2 days before the treatment in subjects without previous experience of herpes infections. It is recommended to continue the antiviral drugs at routine doses for 5-15 days after the intervention.
- **Antibiotic drugs** (macrolides, cephalosporins, etc). The doctor may consider prescribing antibiotic drugs for 7-8 days after the procedure. Remark: It is not necessary to prescribe antibiotic drugs in all cases. It is often enough the application of a topical antibiotic cream or ointment (like gentamicin) after the procedure.

11.1.4. Cleaning the Skin

Before treatment clean the relevant area, removing all impurities that could interact with the light radiation (make-up, lotions, deodorants, ointments etc.). Use a mild soap and rinse well with water. As a precaution the patient should be advised not to use cosmetics for 48 hours prior to treatment.

11.1.5. Classification of the Phototypes

Before starting treatment it will be necessary to evaluate the patient's phototype.

Type	Hair colour	Skin colour	Eye colour	Reaction to the Sun
I	Red	Fair	Blue-grey	Goes red, does not tan
II	Blonde	Fair	Blue	Goes red, does not tan
III	Brown	Medium	Brown	Goes red, then tans
IV	Dark Brown	Light Brown	Dark Brown	Tans
V	Black	Dark Brown	Black	Tans
VI	Black	Black	Black	Tans

11.1.6. Photographic Monitoring

Taking pictures that document the patient during the various treatment phases helps to monitor the effectiveness of the treatment. For ensuring the best photographic quality it is necessary to standardise the shots in order to reproduce the same position of the patient and the same lighting conditions.

11.1.7. Anaesthesia

Dermal treatments with laser may give rise to a painful sensation described as similar to an elastic band being pinged against the skin, or the pain caused by burns.
The anaesthetic protection for CO_2 laser skin therapies becomes necessary in specific cases, such as:

- Traditional CO_2 laser skin resurfacing;
- The treatment of extensive skin areas;
- The treatment of deep lesions;
- Patients with a low pain threshold;
- Non-compliant patients;
- Paediatric patients.

11.1.8. Suggested Treatment Parameters

Treatment parameters are for reference only. Many variables exists which may dictate higher or lower settings. There is no substitute for training and consultation.

USE OF SCANNER FOR ABLATIVE SKIN RESURFACING

Treated area		Pulse Shape	Power	Spot Pitch	Dwell Time
Rhytides: Forehead and Cheek	Moderate	DP	10-20W	500-700µm	500-800µs
	Severe	DP	20-30W	600-800µm	800-1000µs
Rhytides: Perioral	--	DP	15W	500-600µm	500-800µs
Rhytides: Neck and Hands	--	DP	15W	500-700µm	500-700µs
Rhytides: eyelids **NOTE:** one pass only	--	DP	10-15W	500-800µm	500µs
Acne scars: Forehead and Cheek	Moderate	SP	10-20W	500-700µm	500-800µs
	Severe	SP	20-30W	600-800µm	800-1000µs
Soft tissue vaporization	--	HP	5-10W	0 µm	--

NOTES:
1) Based on the speed of treatment and the tissue targeted for treatment, power can be adjusted.
2) Test spots should be done prior to treatment.

11.2. Post Treatment care

Operations carried out with CO_2 laser devices generate thermal injury, abrasion or ablation of the skin which makes daily care of the wound essential. Therefore, side effect are expected and must be differentiated from complication.
The aim is to achieve healing, preventing the formation of scabs in the middle and on the inner edges of the area treated, and thus guaranteeing an adequate cleanliness and softness.
Nearly all patient encounter minor side effects ranging from postoperative pain and edema to pruritis and tighteness. In order to reduce the swelling and the inflammation that may occur after the procedure of skin resurfacing, we recommend applying on the skin, just after the treatment, cool compression or wet gauzes cooled using the Cryo6 air jet. A mild serous (watery) discharge could be seen, which subsides spontaneously after 2/3 days.

For post-treatment care, apply skin cleansing, cold packs compression which must always be carried out with sterile gauze and saline solution. Patient must re-applies every time emollient and/or antibiotic and enzymatic ointments, especially after cleaning and showers. This procedure has to be performed 3-4 times per day until the clinical healing is observed (4-7 days typically). After this time, apply a normal skin-care moisturizer and a sunblock protection (for 2-5 months according to the skin phototype and the environmental conditions).
It is suggested to wait for 1 day before having a shower (avoid hot water on the treated area until healing is complete). Avoid sun exposure for at least 2-4 weeks.
The use of moisturizing and emolient lotions is suggested without time limitation: it helps in maintaining the uniform and compact aspect of the new skin.

NOTE: The patient must immediately call the physician in the event of any side effects such as excessive reddening, infections or blistering. The physician will judge whether it is necessary to use antibiotic creams.

12. TROUBLESHOOTING

This sections describes the faults detected by the system and provides a troubleshooting of some problems that can be identified and solved by the operator.

12.1. Faults management

The SmartXide2 system is able to detect fault conditions that may be dangerous for the subject under treatment and for the system itself.
As soon as one of these conditions is detected, the system automatically switches to safety mode: shutter closed, source turned off (STAND BY), footswitch disabled.
The SYSTEM FAULT menu is immediately displayed on the screen.

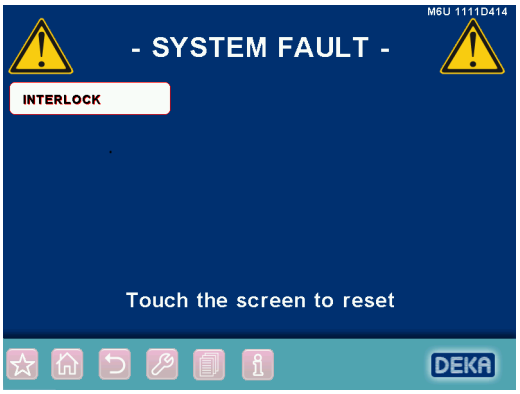

Fig.45 - "SYSTEM FAULT" menu

The SmartXide2 system displays only the currently detected fault conditions - i.e. in figure an INTERLOCK fault was detected -.
Moreover, once a fault is detected, the system keeps on displaying the label even if the fault is solved: this allows the operator to record the detected faults to eventually inform the technical assistance service.

12.2. Descriptions of Faults

The possible faults and the appropriate actions to take are detailed below.

12.2.1. Interlock

This fault is displayed if the INTERLOCK system detects an open circuit.
If the INTERLOCK feature is attached to an external interlock device, check that the door is closed, that the external interlock device is functioning and that the cable from the external interlock device is properly attached to the INTERLOCK socket on the system.
If an external interlock device is not used, check that the INTERLOCK connector (provided with the system accessories) is properly attached to the INTERLOCK socket.
Reset the fault display. Call Technical Service if this fault persists.

12.2.2. Temperature

This fault is displayed if the temperature of the cooling fluid inside the CO_2 laser source or the temperature of the high voltage power supply unit gets too high.
Do not turn off the system in order to let the cooling fluid cool down.
Wait approximately 2 minutes, and then press any key to reset the fault display. Call Technical Service if this fault persists.

12.2.3. Shutter

This fault condition is displayed if the shutter's detected position is not the same as the shutter's expected position. Press any key to reset the fault display.
Call Technical Service if this fault persists.

12.2.4. High voltage

This fault condition is displayed if the internal high voltage power supply unit is not properly working.
Press any key to reset this fault display, then switch on the laser source again. Call Technical Service if this fault persists.

12.2.5. Flow

This fault condition is displayed if low flow in the cooling circuit is detected.
Press any key to reset the fault display.
Call Technical Service if this fault persists.
Only Deka technical assistance service or skilled personnel authorized by Deka may service the cooling circuit.

12.2.6. High power/Low power

These two fault conditions are stated if the power evaluation procedure detects a wrong output power level.
The "High power"/"Low power" label is displayed in the SYSTEM FAULT menu in the same location of "High current" alarm.
Carefully read par. 8.3..
Reset the fault condition, then try to switch on the laser source in order to perform once again the power evaluation procedure.
Call the technical assistance service if the fault persists.

12.2.7. EEPROM/Data Memory

These fault conditions are stated if an internal memory component does not work properly.
It can be stated at the start up of the system or when the CO_2 laser source is switched off - STAND BY key pressed -.
These faults are not critical as concerns the performances of the system but there might be problems with the management of the treatment programs that is the system might forget the changes made by the

operator to the treatment programs.
Try to reset the fault condition, if it persists call the technical assistance service.

12.2.8. CO_2 PS TEMP

This fault condition is stated if overheating of the CO_2 power supply temperature is out of the operating range.
Try to reset the fault condition.If the fault persists, call the technical assistance service.

12.2.9. CO_2 Power Supply

This fault condition is stated if the system detects problem with the CO_2 power supply.
Try to reset the fault condition, if it persists call the technical assistance service.

12.2.10. CO_2 DUTY

This fault condition is stated if the system detects an internal fault generated by the CO_2 power source.
Try to reset the fault condition, if it persists call the technical assistance service.

12.3. Warnings

If the system detects power fluctuations, the power level on the screen may be displayed with yellow characters instead of red characters once calibration is completed. If laser treatment is in progress when this occurs, the warning tone rate increases. These two conditions are warnings, not fault conditions. The system does not go into standby and the operator can continue with the laser treatment.

12.4. Troubleshooting

Following is a brief troubleshooting of some problems that can be identified and solved by the operator.

System does not turn on
- Make sure the mains cable is properly connected and the mains voltage/current values match with the specifications of the system.
- Check if the key switch, the emergency switch and the circuit breaker are correctly positioned.

Nothing happens as footswitch is pressed
- Make sure the system is in the OPERATE state - see the Section "System description" -.
- Make sure footswitch is properly connected to the suitable connector - see the Section "System description" -.

Poor laser emission or no laser emission from the handpiece
- Call for Technical Assistance Service.

Aiming beam and CO_2 beam not coaxial
- Make sure the articulated arm was properly installed.
- The problem may be due to a misalignment of the articulated arm: call Technical Assistance Service.

Power displayed after calibration is different from power selected.
- System cannot provide the selected power.
  Read carefully par. 8.7..

System does not detect the scanning unit presence
- Make sure the scanning unit is properly connected.
  Read carefully the relevant Sections.

For any further problem contact your agent or contact:

DEKA M.E.L.A. s.r.l.
Via Baldanzese 17
50041 Calenzano (Firenze) - Italy
Tel. (+39) 055 8874942
Fax (+39) 055 8832884
Email: info@dekalaser.com

13. MAINTENANCE

13.1. Ordinary maintenance

13.1.1. Laser Care and Handling

Deka suggests that the operator periodically clean and disinfect the exterior of the laser system in the following manner:

- Clean the exterior of the laser with a mild soap and water.
- Use a soft cloth for both cleaning and disinfecting.
- When necessary, disinfect the exterior parts of the equipment with a hospital-grade disinfectant.
- Periodically, remove and vacuum the air filter located on the back of the unit (please refer to par. 12.1.7).

Precautions

- Take care that detergent does not penetrate cavities or apertures of the device;
- do not use chemical solvents and/or abrasive detergents;
- do not use alcohol to clean the surface of the display.

13.1.2. CO_2 reusable parts reprocessing

CO_2 handpieces and HiScan DOT handpieces have to be reprocessed after use. Proper handling and reprocessing of reusable parts for next patient has to be done by carefully adhering to reprocessing steps described below:

NOTE

Start cleaning of reusable parts as soon as possible after use.

NOTE

Immediately after each treatment, clean the HiScan DOT handpieces according to the entire procedure outlined in the Operator's Manual.
Pay strictly attention to clean the terminal end mirror by using the cleaning brush provided with the accessories.
Then, be sure that no residual dirtiness remains on the handpieces.

A) Wear heavy-duty rubber gloves, a plastic apron, eye protection, and mask during reprocessing.

B) Precleaning at the point of use

Prior to thoroughly cleaning, remove visible soil.
A deep container, e.g. a bucket, containing a wire-mesh basket can be filled with tap water at 22°C to 43°C (72°F to 110°F) and enzymatic detergent (protease formula that dissolves proteins), such as Endozime® AW Triple Plus with APA. This detergent has to be used in accordance with the detergent manufacturer's directions (e.g., dilution/concentration, temperature, water quality, soak time).
The parts are placed in the wire basket, agitated for 3-5 minutes, and then lifted out. The basket is overturned onto a table or tray in order to separate the items prior to cleaning, packing and autoclaving.

C) Disassembling the reusable parts

HiScan DOT handpiece:

1. Switch off the system and disconnect the HiScan DOT unit and the laser system from the electrical mains;
2. Disconnect the HiScan cable, the air pipe from the scanner and unscrew the scanner unit from the articulated arm
3. Remove the handpiece from the scanning head by rotating counterclockwise the bayonet coupling.

Disassembling the CO_2 handpieces

1. disconnect the air pipes from the handpiece body
2. If connected, unscrew the handpiece from the articulated arm
3. Extract the lens assembly currently connected unscrewing it
4. Pull the spacer out

To reassemble the handpiece, reverse the steps.

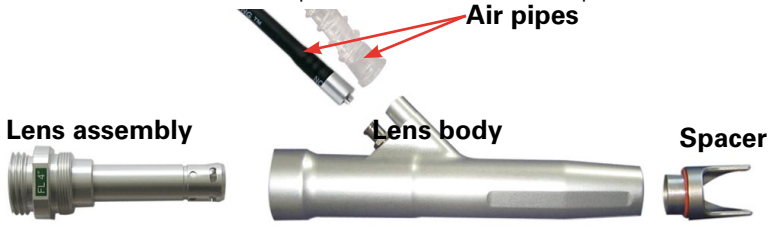

Fig.46 - Disassembling the CO_2 handpieces

Disassembling the CO_2 4" dental handpiece

1. Disconnect the air pipe from the handpiece
2. If connected, unscrew the handpiece from the articulated arm
3. Unscrew the aperture currently connected
4. If present, remove the tip
5. Unscrew the central body, the lens holder and the rear body

To reassemble the handpiece, reverse the steps.

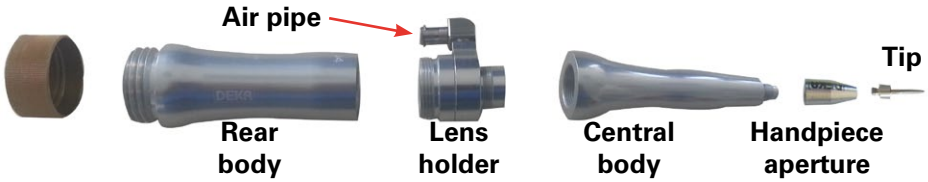

Fig.48 - Disassembling the CO_2 4" dental handpiece

Disassembling the CO_2 2" dental handpiece

1. Disconnect the air pipe from the handpiece
2. If connected, unscrew the handpiece from the articulated arm
3. Unscrew the aperture currently connected

To reassemble the handpiece, reverse the steps.

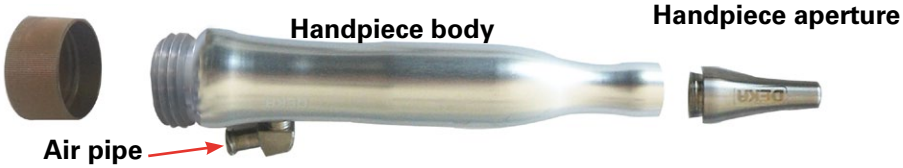

Fig.49 - Disassembling the CO_2 4" dental handpiece

D) Thorough cleaning

Thorough cleaning allows the removal of all foreign material (dirt and organic matter) from the parts being reprocessed and must always precede sterilization procedures.
If instruments and other items have not been cleaned, sterilization may not be effective because microorganisms trapped in organic material may survive sterilization.

Steps for thorough cleaning

1. Soak the instruments in a container deep enough for the number of items, filled with a solution of tap water at 22°C to 43°C (72°F to 110°F) and the same enzymatic detergent used for precleaning (**step C**).
2. Scrub items vigorously to completely remove all foreign material using the brushes provided with the accessories. Hold items under the surface of the water while scrubbing and cleaning to avoid splashing.
3. Be sure to brush in the grooves and joints where organic material can collect and stick.
4. Rinse items 2-3 minutes thoroughly with tap water to remove all detergent. Please adhere to the suggested rinse time as it ensures that residues remaining on the item do not exceed safe levels.
5. Inspect items visually to confirm that they are clean. If any visible debris remains, repeat steps 2-4.

E) Sterilization

For steam sterilization the following protocol is recommended:

1. Package each component with self sealing pouches suitable for steam sterilisation made of medical paper (heavyweight 70 gsm) and transparent 2-ply laminate. Pouches are available in the following dimensions (they have to be large enough hold items without stressing the pouch seals):
   – 2¼" x 4" / 60mm x 100mm
   – 3½" x 8" / 90mm x 200mm
   – 5¼" x 14" / 135mm x 360mm
   – 7½" x 13" / 190mm x 330mm.
2. Arrange all wrapped items in the chamber of the autoclave in a way that allows the steam to circulate freely. DO NOT STACK.
3. Follow the manufacturer instruction for operating the autoclave. Set the autoclave parameters as follows, according to the autoclave type:
   1) Pre-vacuum cycle: 132°C, 4 minutes, minimum drying time: 5 minutes.
   2) Gravity cycle: 132°C, 10 minutes, minimum drying time: 5 minutes.

ATTENTION:

The autoclave should be checked each time it is used in order to make sure that it is functioning properly. Follow the manufacturer's instructions

whenever possible since autoclave maintenance varies depending on the type of autoclave.

F) Post-processing handling

1. Do not store packs items until they cool to room temperature.
2. Store items using the following guidelines:
   - Store items in a closed, dry, cabinet with moderate temperature and low humidity in an area that is not heavily trafficked.
   - A wrapped pack can be considered sterile as long as it remains intact and dry. When in doubt about the sterility of a pack, consider it contaminated and re-sterilize the items.
3. Reassemble the items before use, reversing the steps previously described (phase **C**).

13.1.3. Inspect, clean and disinfect the scanning units

Before and after each use, inspect the scanning unit (HiScan Surgical, EndoScan) for dirt or damages. Failure to clean or improperly cleaning can alter the efficiency of the system.
Proceed as follows:

- **Switch the system off and disconnect the scanning unit from the laser system before inspection/cleaning/disinfecting.**
- To clean and disinfect the external surface of the scanning unit, use a cloth dampened with a hospital grade disinfectant.
- Dry with a clean cloth. Do not use the scanning unit until its surface is completely dry, that is the disinfectant solution is fully evaporated.
- Do not use disinfectants containing peracetic acid or chlorine.

13.1.4. Emergency switch and interlock

Check the correct working of the emergency switch and of the interlock network once a month.

13.1.5. Air filters cleaning

This operation has to be performed once requested by the system.

Always disconnect the system from the mains before cleaning.

CAUTION

Possible risk for patient/operator

The filters are located in a proper housing in the bottom rear side of the system: pull out the housing as shown in Fig. 47 and remove the protection grid.
Blow away the dust on the filter, then put it back. These filters are washable: **be sure they are completely dry before putting them back**. Replace the filters, if necessary.

Fig.47 - Air filters replacing

13.2. Disposal of system

To comply with European Commission Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and other country and state regulations, please do not dispose of this equipment in any location other than designated locations.
You can also contact your local DEKA M.E.L.A. s.r.l. dealer to arrange the return of the equipment to the manufacturer.

NOTE
The fiber optic has a plastic sheath. The damaged fiber optics should be disposed according to national and local regulations.

13.3. Maintenance to be carried out by skilled personnel

The following maintenance procedures should be performed in order to assure system reliability:

- laser source inspection;
- footswitch/shutter check;
- internal power meter inspection and calibration;
- check of the electric insulation.
- check of the cooling circuit.
  The cooling fluid of the SmartXide^2 system is bidistilled water.

All these maintenance procedures should be carried out at least once per year by qualified personnel authorized by DEKA M.E.L.A. s.r.l..

14. ACCESSORIES

SmartXide² is provided with the accessories listed in the following table:

Table 13 - Accessories

Name	Code	Quantity
Interlock connector	N21901	1
Footswitch	E094B1 E06301 (optional)	1
System key	041400050	2
Mains cable	021300052	1
Door safety labels	079101200	2
Operator's Manual	See code on the cover	1
CO_2 safety glasses	070100077	3
Aiming beam protection eyewear	070100078	2
Air filters	020601021	2
5mm Allen wrench	041100082	1
Cleaning brush	031001153	3
Accessories case	070400043	1
1.5" handpiece *including* 1.5" focal assembly Handpiece body Spacer Handpiece case	F26301 N76601 N77101 04370010A 070400108	optional
2" handpiece *including* 2" focal assembly Handpiece body Spacer Handpiece case	F26401 N76701 N77101 04370010A 070400108	optional
4" handpiece *including* 4" focal assembly Handpiece body Spacer Handpiece case	F26501 N76801 N77101 04370012A 070400108	optional
5" handpiece *including* 5" focal assembly Handpiece body Straight spacer Spacer with backstop 90° spacer 120° spacer	F28001 N77801 N78001 04370017A 04370018A 04370019A 04370020A	optional

7" handpiece *including* 7" focal assembly Handpiece body Spacer Handpiece case	F26601 N76901 N77101 04370012A 070400108	optional
8" handpiece *including* 8" focal assembly Handpiece body Straight spacer Spacer with backstop	F28101 N77901 N78401 04370022A 04370023A	optional
Collimated handpiece *including* Collimated focal assembly Handpiece body Spacer Handpiece case	F26701 N77001 N77101 04370012A 070400108	optional
HiScan Surgical unit *including* HiScan Surgical head HiScan cable	F27001 E165A1 N74801	optional
EndoScan unit *including* EndoScan Cable	F26801 N77501 N74901	optional
HiScan DOT unit *including* HiScan DOT head HiScan DOT cable 90° Side-firing handpiece with cylindrical body Straight handpiece 90° Side-firing handpiece (*optional*) 16mm 90° Side-firing handpiece (*optional*)	F34601 E109J1 N77601 N94601 N76001 N94701 N97701	optional
Micromanipulator EasySpot Hybrid	N183F1	optional

Table 14 - Optional accessories

Name	Code	Quantity
2" dental handpiece for CO_2 source	N81601	
including		
120° aperture	N81901	optional
straight aperture	04375015A	
straight aperture with spacer	04375014A	
4" dental handpiece for CO_2 source	N81501	
including		
straight aperture	04375011A	
105° terminal	N81701	optional
120° terminal	N81801	
tapered removable tip	04255044A	
straight removable tip	04255049A	
Endonasal probes kit 80mm	F27901	optional
including		
Handpiece for endonasal probes	N34601	1
Hollow flexible waveguide 80mm	N76501	2
Straight endonasal probe 80mm	04283016A	2
90° endonasal probe 80mm	04283018B	2
Brush for internal probe cleaning	031001152	1
Brush for external probe cleaning	031001153	1
Accessories for laparoscopy:		
400mm focal for laparoscope	N759A1	
300mm focal for laparoscope	N75901	optional
Direct coupler	04366003A	
Connection for STORZ laparoscope*	04366004A	

*For other laparoscope models, please ask to the laparoscope's Manufacturer or to DEKA.

For other accessories, please contact your DEKA dealer or DEKA directly.

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15. APPENDIX A

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSION		
The system SmartXide² is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartXide² system should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic enviroment**
RF Emissions CISPR 11	Group 1	The SmartXide² system uses RF energy only for its internal function. Therefore, its RF emission are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The SmartXide² system is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supply buildings used for domestic purposes.
Harmonic Emissions CEI EN 61000-3-2	Class A	
Voltage fluctuation/ flicker emissions CEI EN 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The SmartXide² system is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartXide² system should assure that it is used in such an environment.			
Immunity test	**Test level CEI EN 6001-1-2**	**Compliance level**	**Electromagnetic enviroment**
Electrostatic discharge (ESD) CEI EN 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst CEI EN 61000-4-4	±2kV for power supply lines ±1kV for input/ output lines	±2kV for power supply lines ±1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge CEI EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines CEI EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	<5% U_T (>95% dip in U_T) for 0,5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SmartXide² system requires continued operation during power mains interruptions, it is recommended that the SmartXide² system be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field CEI EN 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY			
The SmartXide² system is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartXide² system should assure that it is used in such an environment.			
Immunity test	**Test level CEI EN 6001-1-2**	**Compliance level**	**Electromagnetic environment - recommended separation distance -**
Conducted RF CEI EN 61000-4-6	$3V_{RMS}$ 150kHz÷80MHz	$3V_{RMS}$	d=1,2√P
Radiated RF CEI EN 61000-4-3	3V/m 80MHz÷2.5GHz	3V/m	d=1,2√P from 80MHz to 800MHz
			d=2,3√P from 80MHz to 2.5GHz
Portable and mobile RF communications equipment should be used no closer to any part of the system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 			
Note: (1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies. (2) The guidelines may not applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. to assess the electromagnetic environment due to fixed R transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartXide² system is used exceeds the applicable RF compliance level above, the SmartXide² system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the SmartXide² system. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE SmartXide²

The SmartXide² system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SmartXide² can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SmartXide² as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150kHz÷80MHz $d=1,2\sqrt{P}$	80MHz÷800MHz $d=1,2\sqrt{P}$	800MHz÷2,5 GHz $d=1,2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note:
(1) At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
(2) The guidelines may not applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CABLES AND ACCESSORIES WITH WHICH COMPLIANCE TO EN 60601-1-2 EMC REQUIREMENTS IS CLAIMED	
Interlock connector	N21901
Foot switch	E094B1
Mains cable	021300052
1.5" handpiece	F26301
2" handpiece	F26401
4" handpiece	F26501
5" handpiece	F28001
7" handpiece	F26601
8" handpiece	F28101
Collimated handpiece	F26701
HiScan Surgical cable	N74801
EndoScan cable	N74901
HiScan DOT	F34601
Micromanipulator	N183F1

NOTE
The use of accessories, transducers and cable other that those above specified may increase electromagnetic emission and decrease electromagnetic immunity.

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16. APPENDIX B

CAUTION!
The following procedures should only be done by trained personnel authorized by DEKA M.E.L.A. s.r.l..
When the system enclosure is removed, hazardous voltages and/or laser radiation levels are exposed.

16.1. Internal power meter calibration

The SmartXide^2 system is equipped with an internal power meter that allows the microprocessor to detect the real output power level generated by the CO_2 laser source. The signal from this power meter is first processed by the hardware on the CPU board before being read and converted by the A/C converter located inside the microcontroller.
Please contact the Manufacturer to arrange for an annual calibration.

The calibrating procedure is here described just for information:

1. Enter the SERVICE menu, set "calib OFF" and check that the offset value between TP1 (GND) and N10-7 ≤13mV
2. Set 30W CW and measure the output power from the articulated arm: if needed, act on the Ton value in order to obtain the requested power level 24W<P_{meter}<36W
3. Regulate RP1 (GAIN) up to make the internal power meter read the same power of the external one ±0.2W
4. Preregulate RV1 (SPEED UP) up to make the internal power meter read the right power in 3s, without overshot.
5. Set 0.5W CW and measure the output power from the handpiece: if needed act on the DAC value in order to obtain the requested power level 0.4W<Pmeter<0.6W
6. Regulate RP3 (GAIN) up to make the internal power meter read the same power of the external one ±0.02W
7. Check the power meter calibration in the following sets:
   P_{ext} =CW 4.5W
   P_{ext} =CW 10W
   P_{ext} =UP 60W

   and verify respectively that:

   4.05W<P_{int} <4.95W
   9.5W<P_{int} <10.5W
   54W<P_{int}<66W

   If the measured values are out of the requested range, repeat the operations from step 3.

8. Set Calib On and check in UP mode that the Ton value to have the output power in the range indicated below:
   P_{ext} =40W
   Ton_{40W} ≤750µs
9. Perform reset.

The Code of Excellence

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