UVA Collagen Cross-linking Instrument

User Manual

Version: 2.2

EMC Declaration of Conformity

We, the Manufacturer

NanoSigma Biotech. Co.,Ltd.

12F., No.27-6, Sec. 2, Jhongjheng E. Rd., Danshuei Dist., New Taipei City 25170, Taiwan

declare that the product

UVA Collagen Crosslinking Instrument

Product Model: Intacs XL

Is in conformity with

(in accordance with Medical devices Directive(MDD) 93/42/EEC)

☑ EN 60601-1-2:2007/AC:2010

☑ CISPR 11:2009+A1:2010 Group 2 Class B

IEC61000-3-2:2005+A1:2008+A2:2009

IEC61000-3-3:2008

☑ EN 60601-1-2:2007/AC:2010

IEC 61000-4-2:2008	IEC61000-4-3:2006+A1:2007+A2:2010
IEC 61000-4-4:2004+A1:2010	IEC 61000-4-5:2005
IEC61000-4-6:2008	IEC 61000-4-8:2009
IEC61000-4-11:2004	

EMC test report No.:U11051103E-A01
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This certificate is issued by: Nonosigma Biotech Co.,Ltd
Dated: 01 May 2014

Signed: Ming-Yuan Shao

Ming-Yuan Shao
General Manager
NanoSigma Biotech. Co., Ltd.

Recommended separation distances between portable and mobile RF communications equipment and the UVA collagen cross linking instrument.

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (m)		
	150kHz to 80 MHz $d=\left[\frac{3.5}{V1}\right]\sqrt{P}$	80MHz to 800 MHz $d=\left[\frac{3.5}{E1}\right]\sqrt{P}$	150kHz to 80 MHz $d=\left[\frac{3.5}{E1}\right]\sqrt{P}$
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 transmitter 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.

NOTE1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's Declaration - Electromagnetic Immunity

The UVA collagen cross linking instrument is intended for use in the electromagnetic environment specified below. The customer or the user of the UVA collagen cross linking instrument should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±6 kV contact	±6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±8 kV air	±8 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for input / output lines	N/A	
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV line(s) to earth	N/A	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the UVA collagen cross linking instrument requires continued operation during power mains interruptions, it is recommended that the UVA collagen cross linking instrument be powered from an uninterruptible power supply or a battery.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	<5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 5 sec	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Manufacturer's Declaration - Electromagnetic Immunity – for non-life-supporting EUT

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the UVA collagen cross linking instrument, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d=1.167\sqrt{P}$ $d=1.167\sqrt{P}$ 80 MHz to 800 MHz $d=2.333\sqrt{P}$ 800 M Hz to 2.5 GHz Where 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 in meters(m) 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 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply 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 RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the UVA collagen cross linking instrument is used exceeds the applicable RF compliance level above, the UVA collagen cross linking instrument should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the UVA collagen cross linking instrument.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than (*V*1) V/m.

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0.01	0.12	0.12	0.23
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NOTE1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

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Table of Contents

1. Product Description

Intacs XL is a UVA collagen cross-linking instrument designed with special focus on an intuitive usage, effective performance and above all, safety. Intacs XL is a UV irradiating device for performing a corneal cross-linking procedure at a wavelength at 365 nm and designed with an illumination intensity of 3.0 mW/cm^2 with a working distance of 50 mm.

Background

Cross-linking of the cornea is a new approach to increase the biochemical stability of the stromal tissue. Thus far, the clinical indication for cross-linking is limited to the degradative processes of the cornea and corneal thinning disorders such as keratoconus, pellucid marginal degeneration, and iatrogenic keratectasia after laser in situ keratomileusis (LASIK). The aim of this treatment is to create additional chemical bonds inside the corneal stroma by means of a photopolymerization in the anterior stroma while minimizing exposure to the surrounding structures of the eye.

Surgical Technique

The treatment procedure should be performed under sterile conditions in an operating theater. The currently accepted treatment protocol includes deepithelialization for efficient penetration of riboflavin due to the incomplete absorption of riboflavin by the epithelium because of tight junctions. This method has been successfully used for the treatment of progressive keratoconus and pellucid marginal degeneration since 1999 and for iatrogenic keratectasia since 2003. Published and peer-reviewed data on the safety and efficacy of these parameters for cross-linking are available from numerous research groups, with long-term results out to 6 years. In the standard technique, removal of the epithelium is required in order to expose the underlying stroma for a complete absorption of riboflavin.

Cross-linking with Removal of the Epithelium

Abrasion of the corneal epithelium out to 7 mm is performed under topical anesthesia. Prior to the treatment itself, ultrasound pachymetry should be performed at the thinnest point of the deepithelialized cornea, to ensure a minimal corneal thickness of 400 µm. Riboflavin solution, is then applied to the cornea every 3 min for 30 min. The saturation of the cornea with riboflavin and its presence in the anterior chamber is monitored closely by slit-lamp inspection prior to treatment. Riboflavin shielding ensures the protection of deeper ocular structures such as the corneal endothelium. UVA irradiation is performed using an UVA diode instrument. Prior to treatment, the intended irradiance of 3 mW/cm^2 surface irradiance (5.4 J/cm^2 surface dose) is calibrated using a UVA meter at a working distance of 50 mm. Irradiance is performed for 30 min using 3 mW/cm^2, corresponding to a surface dose of 5.4 J/cm^2. During the procedure, riboflavin solution and topical anesthetic (oxybuprocaine 0.4%) is applied every 2-3 min to saturate the cornea with riboflavin and for corneal hydration.

2. Intended Use

The indications for use of the Intacs XL for cornea collagen cross-linking are:
1. Progressive keratectasia of any form
2. Iatrogenic keratectasia after LASIK
3. Pellucid marginal degeneration
4. Corneal melting

This procedure may only be performed by a trained ophthalmologist for the treatment of this condition.

This device must be combined with 0.1% Riboflavin eye solution to protect the cornea from damage.

CAUTION: Before performing the corneal collagen cross-linking treatment, an ultrasonic pachymetry must be done to ensure a minimum of 400 µm thickness. The hypotonic 0.1% riboflavin eye drops may be used to to swell the stroma. Do not perform the procedure unless the deepithelialized cornea has a thickness greater than 400 µm.

3. Parts of the Intacs XL

ITEM	Parts/Function description	Picture
1.	LED UVA Light Source Generation of LED UVA light	
2.	Control Panel Contains the command center for all Intacs XL functions	
3.	Bracket Secures the LED UVA Light Source to a stable support surface (Table shake limited: below 0.5G)	

ITEM	Parts/Function description	Picture
4.	AC Power Cable	
5.	USB 3.0 cable Connects the LED UVA Light Source to the Control Panel	

4. Intacs XL Accessories

The following accessories and supplies are furnished with the Intacs XL:

Intacs XL User's Manual	x 1
UVA Safety Glasses	x 1
Optional Extension Arm	x 1
Fixed Wrench	x 1
Carrying Case	x 1

UVA Safety Glasses

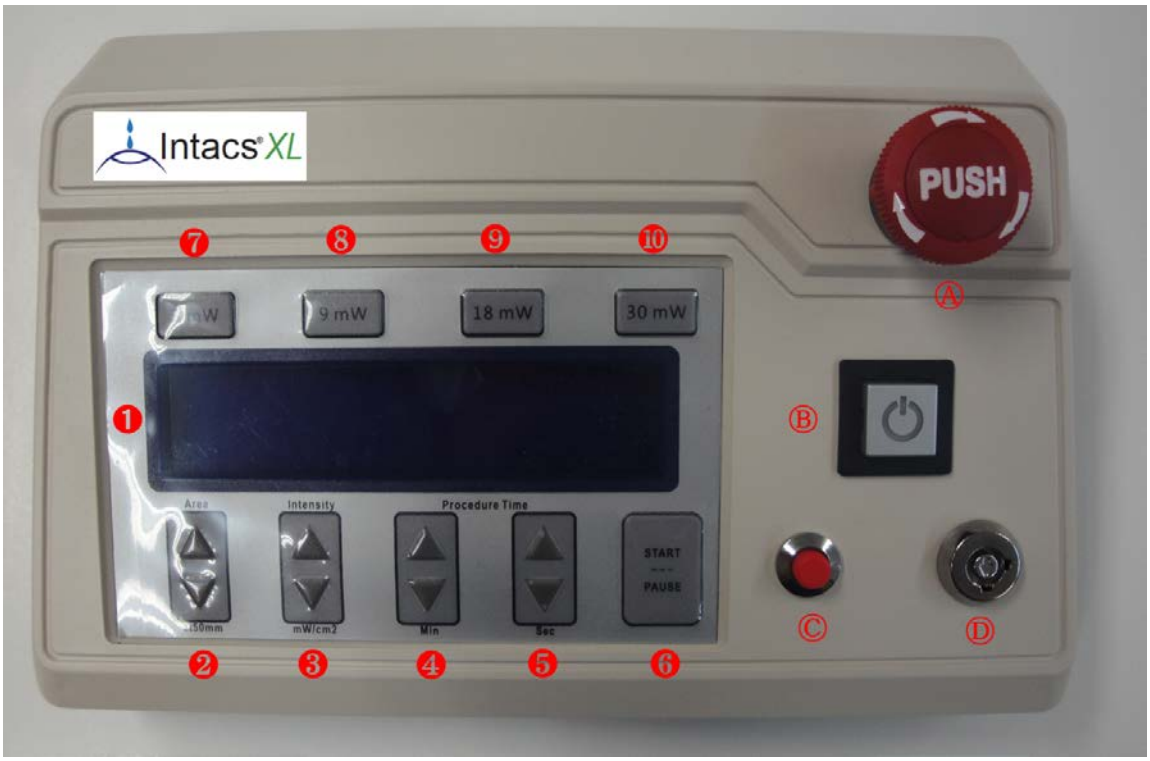
Optional Extension Arm

Fixed Wrench

Carrying Case

5. Control Panel Description

5.1 Button Description



❶ LCD Display

❷ Spot size adjustment button (▼/▲ 6 ~ 9 mm)

❸ UVA intensity adjustment button (▼/▲3~30 mW/cm^2)

❹ Time setting button (▼/▲1~30 Min)

❺ Time setting button (▼/▲1~59 Sec)

❻ Irradiated START/PAUSE button (365 nm LED UVA light start/pause button)

※ When LED UVA light is already on, push and hold for about 5 seconds. The program can be re-setting.

❼ Preset button 1 (UVA intensity = 3 mW/cm^2,Spot size=7mm, Time=30 min)

❽ Preset button 2 (UVA intensity = 9 mW/cm^2,Spot size=7mm, Time=10 min)

❾ Preset button 3 (UVA intensity = 18 mW/cm^2,Spot size=7mm, Time=5 min)

❿ Preset button 4 (UVA intensity = 30 mW/cm^2,Spot size=7mm, Time=3 min)

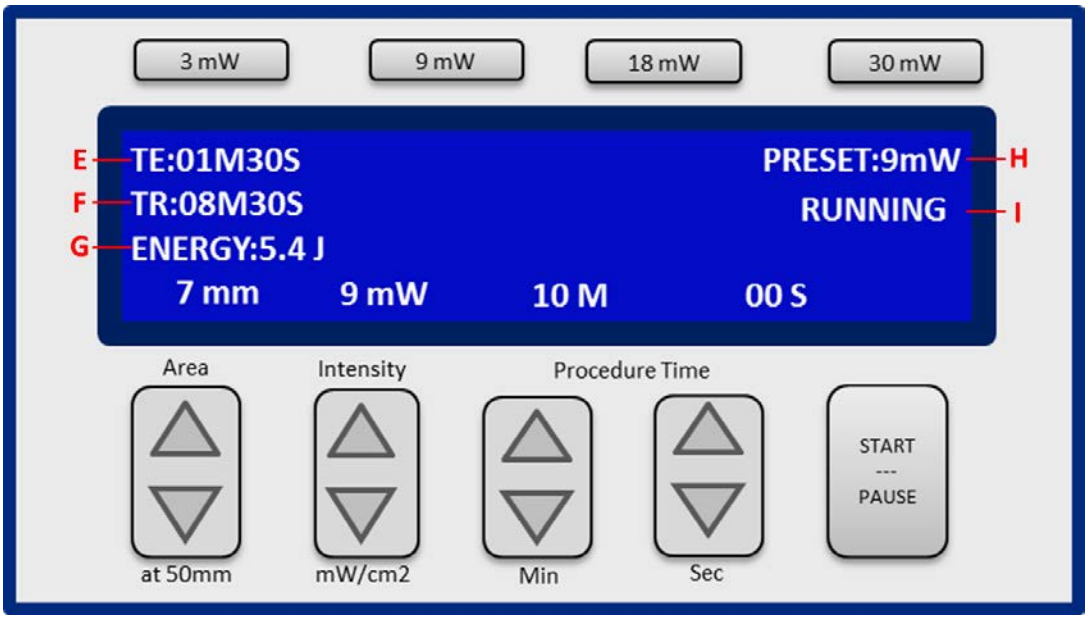
Ⓐ Emergency shut off button

Ⓑ Main Power On/Off button

Ⓒ 630nm LED On/Off button (For the dual spot infrared alignment system)

Ⓓ Power lock Key

5.2 LCD Display Descriptions



E TE=Time Elapsed

F TR=Time Remaining

G ENERGY=Total Energy Deliverable

H PRESET Mode/User Defined Mode

I Status of UVA light (Running/Pause)

6. Instrument Labels

Model Number description label

The Model Number description label is located on the back panel of the instrument. The label describes the UVA Collagen Cross-linking Instrument model name or number, its manufacturer and other regulatory information.

Intacs® XL CORNEAL CROSS-LINKING				
CE 0120		2011 Sep		
NanoSigma Biotech. Co., Ltd. 12F., No.27-6, Sec. 2, Jhongjheng E. Rd., Danshuei Dist., New Taipei City 25170, Taiwan (R.O.C.) Tel: +886-2-2809-3961 Fax: +886-2-2809-1504		EC REP AJL Ophthalmic, S.A. Ferdinand Zeppelin, 1, Parque Tecnológico de Alava, 01510 Miñano(Alava), Spain Tel: (+34) 945298256 / 945298289 Fax: (+34) 945298209		

Information Label

The information label is located on the back panel of the instrument and provides additional data about the instrument including its serial number and the voltage-input requirements.

SN Serial No	**2011-0003**
Voltage-input	**AC 100 to 240 V, 50 to 60 Hz, 0.15A**

7. Environmental Requirements

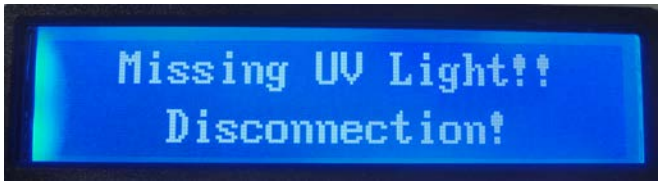
Temperature: 0 - 55℃/32~131℉
Atmospheric Pressure: 700 kpa~1060 kpa
Humidity: below 85% RH
Power Source: AC 100 to 240 V, 50 to 60 Hz, 0.15A
Table shake limited: below 0.5G
Avoid keeping in direct sunlight
Avoid organic solvents or contact with strong acid or alkaline solutions.
Do not store or maintain near any radio-active substances and/or flammable materials
Keep in a dry area

Caution: If the Intacs XL is damaged during operation, turn off power immediately by pressing the Emergency shutoff button or move out the lamp from the top of treatment eye.
If the Intacs XL is dropped and impacts the floor or other hard surfaces, it will probably cause damage to the electronic components. If unit does not start up or have a correctly verified intensity, contact distributor.

8. Installation

1. Place the control panel on a fixed base (table, tray)
2. Install the LED UVA Light Source and secure with a bracket.
3. Connect LED UVA Light Source and Control Panel with USB 3.0 cable.
4. Plug in the power (100 to 240 V, 50 to 60 Hz)
5. Push down the Ⓑ Power On/Off button

Caution: If the LED UVA Light Source and Control Panel disconnect, the LCD display will show the warning message.



9. Operation

- This procedure should be performed under strict supervision of an Ophthalmologist at all times

- Make sure the lamp is placed in a sturdy surface allowing for very limited in advert movement to minimize misalignment and improper irradiation
- The dual spot infrared alignment system allows you to accurately adjust the proper distance of 50mm from the corneal apex for a more precise and complete irradiation process. Please check randomly during the procedure to assure its proper alignment

- When the user turn on the instrument in the beginning. The instrument will run the Self-Checking program to make sure that the motor of lens go back to the home position.
- The version will change to the operating version automatically after 30 sec.

Corneal Collagen Cross-linking Treatment

1. Adjust the height of bracket and focus the red light spot on the cornea of patients.
2. Make sure the riboflavin eye drops should be applied for at least 30 minutes before the UVA exposure.
3. Set the mode or user define and push the start key (6). The UVA light will turn on automatically.
4. The dual spot infrared alignment system will turn off during the UVA treatment
5. When the set time is finished The UVA light will turn off automatically.
6. If the setting procedure needs to restart. Push the start key 6 for 5 seconds and the setting program can be reset.

Safe clinical application of Intacs XL must respect the following criteria: (1) to facilitate diffusion of riboflavin throughout the corneal stroma, the epithelium should be removed; (2) a 0.1% riboflavin eye solution should be applied for at least 30 minutes before the UV exposure (during the UV exposure, the riboflavin serves as UVA blocker); (3) the cornea to be cross-linked must have a minimal thickness of 400 µm to protect the endothelium.

Preset Mode

The Intacs XL includes 4 preset mode for treatment. The default settings are shown as below.

1. Preset button 1 (UVA intensity = 3 mW/cm^2,Spot size=7mm, Time=30 min)
2. Preset button 2 (UVA intensity = 9 mW/cm^2,Spot size=7mm, Time=10 min)

3. Preset button 3 (UVA intensity = 18 mW/cm^2,Spot size=7mm, Time=5 min)
4. Preset button 4 (UVA intensity = 30 mW/cm^2,Spot size=7mm, Time=3 min)

In the preset mode, the system allows users to adjust the spot size by press the spot size adjustment button and the UVA intensity still keeps in the preset value.

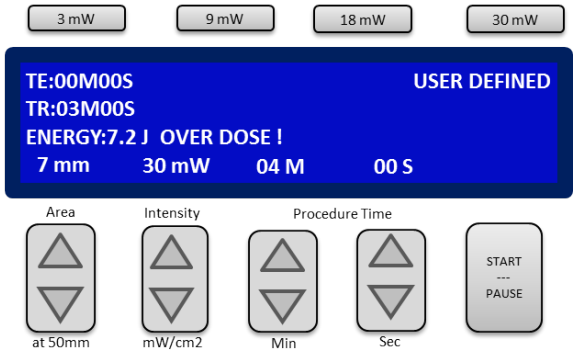
User Define Mode

The Intacs XL allows users to setting the spot size, UVA intensity and treatment time. The acceptable range is shown as below.

1. Spot Size: 6~9 mm
2. UVA intensity: 3~30 mW/cm^2
3. Treatment time: 1 Sec~30 Min

For the safety issue, the user can not do the UVA cross-linking treatment, if the total energy was more than 5.4J.

The warning message will be shown on the LCD display and the button of START/PAUSE will not be function, if the total energy was more than 5.4J.



Bracket Extension

For the special situation, the user can extend the length of bracket by the extension arm insertion. Total length of bracket extends from 30 cm into 54 cm. Detail installation procedure please see as below.

1.Standard Bracket

2.loosen the screws

3.Remove the screws

4.Extension Arm

5. Insert the Extension Arm

6.Tighten the first screw

7.Tighten the second screw

8. Extension finished

10. Maintenance and Cleaning

Intacs XL requires minimal preventive maintenance. It should be kept clean and away from dusty environments or environments with temperature and humidity extremes.

Regularly remove any dirt or dust from shell of control panel or UVA light source with a dry soft brush

The output energy of UVA lamp will decay after using over 1000 hours. The warning message will be shown on the LCD screen after using 800 hours. Please note and contact with your local supplier.

11. Instrument Specifications

Specification	
Wavelength range:	365 nm ± 5 nm
Illumination intensity:	3~30 mW/cm2
Maximum error	±10%
Working distance:	50 mm
Mode Type	4 PERSET Modes and USER DEFINED Mode
Light emission:	Continuous wave (CW)
Spot sizes:	6 - 9 mm (4 sizes Adjustable)
Timer:	1 Sec ~30 Min
Operating Temperature	15° to 37° C (Ambient)
Power source	AC 100 to 240 V, 50 to 60 Hz, 0.15A
SIZE:	
Control Panel	H x W x D 133 x 189 x 58 (mm)
LED UVA light	H x W x D 60 x 37 x 100 (mm)
Bracket	Height x Arm 390 x 230 (mm)
WEIGHT:	
Control Panel	430 g
LED UVA light	120 g
Bracket	800 g

12. Customer Service

NanoSigma Biotech, through its operating relationship with Addition Technology, is ready to resolve any difficulties that may arise with the operation or performance of the Intacs XL UV lamp. If a problem cannot be solved using the procedures in this manual, please contact us.

Contact NanoSigma Biotech by email, mail, telephone, or fax at the address and numbers listed.

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EC REP
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Tel: (+34) 945298256 / 945298289
Fax: (+34) 945298209

13. Explanation of Symbols

	Manufacturer
	Date of Manufacture
CE 0120	CE Certificate with Notify Body Number
EC REP	Authorized Representative in the European Community
	Please Read Instruction for Use Before Operating Device
	Caution, Consult Accompanying Documents (Attention, See Instruction for Use)
SN	Serial Number

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