premio 32 evo

Laser A-G program

User manual

Carefully read this manual before you use your device, and make sure you keep it at all times

English

Sedatelec®

YOUR WAY OF CARE, OUR QUALITY DEVICES

Thank you for choosing the PREMIO 32 EVO laser A-G program !

Since it was formed, Sedatelec has based its work on studies carried out in complementary medicine; particularly those conducted by Dr P. Nogier, the father of auriculotherapy and auriculomedecine, to offer practitioners novel, highly reliable, high performance instruments.

Nowadays we are developing and incorporating the values of respecting patient, practitioner and the environment into our products, consistent with the highest level medical standards, so that you can practice comfortably and effectively.

We are pleased to work with our excellent permanent research partners and are also proud of our increasing participation in sharing medical information between the different people who work in the field. Please do not hesitate to contact us for any further information by email at infomed@sedatelec.com.

I hope you will be fully satisfied with your use of PREMIO 32 EVO laser A-G program . I am happy to hear from you and am open to any ideas to advance your practice in this novel medical approach.

Best wishes,

Thierry Garaboux, Chairman.

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INTENDED USE

PREMIO lasers are low power light radiation (low level LASER) equipment that act by stimulating natural biological properties of cells. Their applications are:

- local stimulation of tissues
- Stimulation of reflex points (acupuncture or auriculotherapy points, "trigger points", "gate control" points, etc.).

They are intended for use by competent medical personnel.

SAFETY INSTRUCTIONS, RESIDUAL RISKS AND PRECAUTIONS FOR USE

The **PREMIO 32 EVO laser A-G program** is an infrared laser which emits a laser beam at a wavelength 905 nm.
The Maximum Permitted Emissions (MPE) are 0.269 J/m^2 for the skin and $2.47*10^{-4}$ J/m^2 for the cornea.
The "Laser danger" symbol, placed on the end of your device, represents the "opening indicator plate" designating an **"opening for laser radiation"**

Safety for the skin
The laser emission from the PREMIO 32 EVO laser A-G program is under this MPE and the beam can be directed onto the skin entirely safely without causing harm.

Safety for the eyes
Important note: The instrument must **never be used to treat the globe of the eye**.
The Nominal Ocular Danger Distance (NODD) is the distance from which the light applied to the eye must be less than the MPE for the cornea.
The NODD for the PREMIO 32 EVO laser A-G program is 75 cm.

Thus, any time the laser is handled within 75 cm of the eyes, it is recommended that the patients, practitioner, and any other person who may be watching or whose eyes may accidentally be affected by the direct or laser beam wear protective goggles specifically designed for the purpose. (See the section on specific additional protective goggles in the chapter on Maintenance /Accessories).

Precautions for use of the PREMIO 32 EVO laser A-G program

You are recommended:

- Not charge it in stormy weather,
- Not to use it in an environment containing by electromagnetic emissions outside of standard levels (eg: close to a CT scanner or MRI),
- Not to use it if the casing is not intact,
- do not use the device if the laser nozzle is broken, chipped or has shifted,
- Not use in an explosive or inflammable environment,
- Not to subject it to ionising irradiation (eg: X-rays),
- Not expose or use outside the conditions of use and storage defined in the chapter: Technical specifications,
- Never to immerse it in a liquid.

The PREMIO 32 EVO laser A-G program contains a Li-Ion technology battery which must only be replaced by the Sedatelec staff or instructed by Sedatelec.

It is essential that only the charger designed for the **PREMIO 32 EVO laser A-G program** is used. Use of any other charging system could damage the instrument and may cause a high **electrical discharge** to the user or a **risk of explosion**. **The charger must remain accessible to**

be disconnected from the power supply. (See the section on replacing accessories in the chapter on Maintenance / Accessories).

For safety reasons, the instrument is provided with a **laser key**, which can restrict its use to authorised personnel.

The PREMIO 32 EVO laser A-G program requires **technical safety checks** at least every **24 months**. These must be carried out by people who have knowledge, equipment and experience to carry out these checks (cf. appendix 2).

☞ Sedatelec's technical department or a service authorised by Sedatelec carries out all of the appropriate technical tests on the PREMIO 32 EVO laser A-G program.
Contact us…

Where applicable, PREMIO 32 EVO laser A-G program should be installed and used in accordance with the standard CAN/CSA-Z386-08: Safe Use of Lasers in Health Care Facilities

INDICATION & CONTRAINDICATIONS

Indications

The **PREMIO 32 EVO laser A-G program** is used for laser biostimulation (coherent light) locally on painful or pathological areas.

Its use requires **skilled staff** who have sufficient knowledge of the indications, contraindications and medical risks of laser biostimulation, in a medical situation.

Contraindications

- Direct contact with mucosal membranes or broken skin.
- Treatment of endocrine areas (particularly in children).
- Treatment of the globe of the eye.
- Treatment of abdomen in pregnant women.
- Treatment of the chest region in a patient with a cardiac pacemaker.
- Previous use of anticoagulants and aspirin.
- Past history of cheloid or hypertrophic scarring.
- Active infection/compromised immune system.
- Past history of herpes.

And more specifically, for people with a history of photo sensitivity:

- Exposure to sunlight or artificial UV light for 3 to 4 weeks before treatment.
- Hypersensitivity to light at 905 nm.
- Receipt of medicines when exposure to sunlight is contraindicated.
- Receipt of oral isotretinoin medicines or anticoagulants.

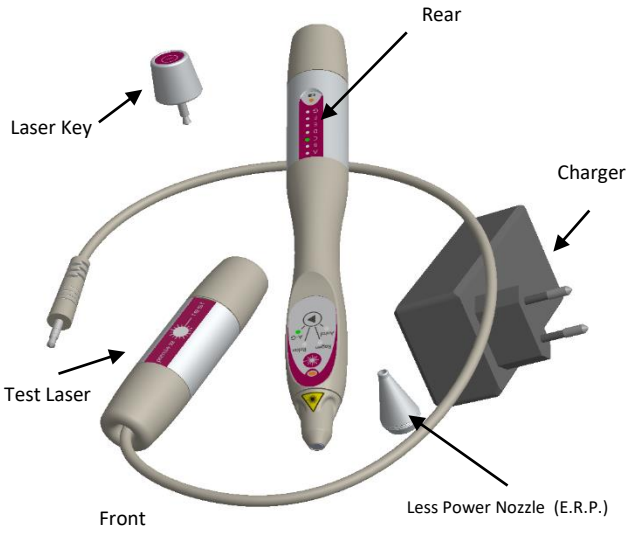
ADVERSE EVENT REPORT

In the event of any adverse event associated with the device, SEDATELEC and the relevant body of the user's and/or patient's member State must be notified.

DESCRIPTION OF THE PREMIO 32 EVO LASER A-G PROGRAM

The **PREMIO 32 EVO laser A-G program** is supplied in a bag containing:

- A handpiece PREMIO 32 EVO laser A-G program ,
- A specific laser key,
- A test laser box,
- A battery charger,
- A less Power Nozzle
- A pair of protective glasses with its manual,
- An instruction for use manual.



Front panel

Laser beam output: invisible laser radiation

"Laser Danger" and "laser aperture" indicator

Laser emission indicator

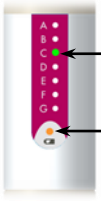
Laser emission operating key

Laser stimulation programme indicator:

Antal	E & G frequencies
Regen	A, B & F frequencies
Relax	C, D & G frequencies
A-G	Nogier frequency* scanning

Type of laser stimulation selection key

Rear panel



Indicator for frequency (IF) used

Battery charge indicator

Laser key

ON/OFF and individual frequency selection key.

**The application of Nogier frequencies with this device has not been authorised by Health Canada for lack of sufficient clinical studies*

HOW TO USE THE PREMIO 32 EVO LASER A-G PROGRAM

Use of commands or settings or carrying out procedures other than those described in this manual may result in exposure to dangerous radiation.

Before starting

a. To recharge the **PREMIO 32 EVO laser A-G program :**

The **PREMIO 32 EVO laser A-G program** cannot be used during charging

- Remove the laser key,
- Insert the charger plug into the instrument,
- Connect the charger to the power supply.

Power indicator: (extract from the documentation *)

- **Yellow: Charging** (steady then flashing at the end of charging)
- **Solid Green or charging time >3H: Fully charged the battery.**
- **Flashing green:** The PREMIO is not connected.

See charger manual * for:

- LED off or blinking red: Battery / charger fault
- Solid yellow + Flashing red: Temperature fault

*: See the attached manufacturer's manual or on https://www.mascot.no/downloads/user-manuals/battery-chargers/ “chargers_li-ion”)

In the event of a **Battery fault**: See chapter Troubleshooting.

b. To check correct operation of the **PREMIO 32 EVO laser A-G program :**

- Remove the laser key,
- Introduce the test laser plug into the instrument,
- Connect the laser key to the test laser,
- Press on the key.

- Press on the emission key => continuous audible signal (if no signal, contact your distributor or Sedatelec),
- Apply the laser beam contact with the test laser unit.

If the audible signal remains unchanged, this means that the energy emitted is not within the -20%/+20% of nominal value band. You should then contact your distributor or Sedatelec to have your instrument adjusted.

Note: After using, disconnect the **PREMIO 32 EVO laser A-G program** test laser in order that the battery does not discharge.

Starting and operating information

a. **Insert the key** into its socket on the rear of the instrument. Press on the ON/OFF key

Important comment: when switching on, the **PREMIO 32 EVO laser A-G program** returns to the configuration of last use.

b. **Checking the battery charge indicator:**

- Slow flashing: recharge recommended
- Fast flashing: the instrument may stop at any time; the battery is in urgent need of recharging.

c. Select the stimulation mode: press on the ▶ key to select the desired programme: Antal / Regen / Relax / A-G

Each programme represents a combination of Nogier frequencies* which are shown on the rear panel by the corresponding LEDs lighting up.

d. Press on the ✳ key**:** the light indicator and a continuous audible signal inform the user that the laser is being emitted. A beep is emitted every 30 seconds A targeting LED enables you to position the beam on the zone to be stimulated. This emits continuous light with no therapeutic effect.

e. To stop the beam being emitted, press on the ✳ key again.

f. You can select an individual frequency to personalise your therapy time. To do this, make a short press on the key ⓘ and then select the frequency by pressing on the key. ▶ Pressing once on the ⓘ key will return you to the previously selected programme mode.

Stopping the instrument

a. Long press on the ⓘ key.

Note: The instrument also stops automatically after 2 minutes without use.

b. Remove the key.

**The application of Nogier frequencies with this device has not been authorised by Health Canada for lack of sufficient clinical studies*

Less Power Nozzle

The **Less Power Nozzle** (ERP) is a device which has been designed to reduce the power of the laser beam by a factor of ~ 2.5.
To adjust the laser penetration depth for superficial points.
It is easily placed on your **PREMIO 32 Evo laser A-G program** thanks to its elastic internal fixation and is easily removed (by pulling and/or a slight rotation) for cleaning (autoclave possible) or replacement.

FREQUENCIES & PROGRAMMES

Antal	E & G frequencies
Regen	A, B & F frequencies
Relax	C, D & G frequencies
A-G	Nogier frequency* scanning

	Frequency of laser pulse frames (Hz)						
carrier frequency	A	B	C	D	E	F	G
18 688Hz	2.28	4.56	9.12	18.25	36.5	73	146

TROUBLESHOOTING - RECYCLING

If the instrument does not function correctly, return it completely in its original bag to your distributor or to Sedatelec with your comments.

When disposing of your **PREMIO 32 EVO laser A-G program** , note that it contains electronic components and you should observe the current instructions for your country.

TECHNICAL SPECIFICATIONS

Manufacturer	**Sedatelec**
Name	**PREMIO 32 EVO laser A-G program**
Type	Infrared laser (3B class IEC60825)

Emission features

Type of laser diode	InGaAs/GaAs
Wavelength	905 nm (±10 nm)
Energy per pulse(±20%)	8.9 µJ
Pulse duration (±20%)	80ns
Equivalent energy for 30s	2.5 J
Output frequency	Carrier modulated by Nogier frequency

A	B	C	D	E	F	G
2.28Hz	4.56 Hz	9.12Hz	18.25 Hz	36.5 Hz	73 Hz	146 Hz

Beam divergence	10° x 25°

Electrical supply

Internal battery	Li-Ion 3.6V 850 mAh
Li-Ion charger	90-264V ~/ 47-63Hz

Mechanics

Handpiece	213mm x 25mm
Weight of handpiece	111g

Operating conditions

Temperature	between 10°C and 35°C
Relative humidity	>30% and < 70 %
Atmospheric pressure	between 70 kPa and 106 kPa

Storage and transport

Temperature	between -20° and 50°C
Relative humidity	< 90 %
Atmospheric pressure	between 70 kPa and 106 kPa

Eye protection

In compliance with European standards	EN 207
Required optical density	>=2 (at 905 +/-10 nm)
Energy/pulse lighting	$2.3*10^{-2}$ J/ m^2 to 10cm

MADE IN FRANCE

We recommend routine disinfection of parts which may come into contact with patients.
Your **PREMIO 32 EVO laser A-G program** does not require specific maintenance and can be cleaned with a cloth soaked in soapy water, 70°C alcohol or with a cold disinfectant.

The instrument is not watertight and must **not be sprayed or immersed** in a fluid.

When **not used for long periods of time**, it is recommended that the instrument is stored with the battery charged and that at least 1 charge/discharge cycle is carried out every 6 months.

The **laser protective glasses** can be cleaned with a soft cloth soaked in soapy water.
If the lenses are perforated, scratched, damaged or change in colour, or if the frame is damaged, the protective glasses must no longer be used and must be replaced.

You must not attempt to modify or repair any part of the device or its accessories. All such work must be performed by persons duly authorised to do so by Sedatelec

Any work on or use of the device that is not described in this manual shall cancel the warranty and may represent a significant safety risk for you, those around you and your patients, and may adversely affect the reliability and performance of the device

Accessories :

Please contact your authorised Sedatelec distributor if you need anything else or if you need to replace the accessories provided with the device (charger, laser protective goggles, etc.)

APPENDIX 1: REGULATORY AND STANDARD RELATED INFORMATION

Classification:

The PREMIO 32 EVO laser A-G program is a class IIa medical device according to directives 93 /42 EEC and 2007/47/EC.

Applicable standards:

- **ISO 14971 : 2019**
- **EN 60601-1 : 2012**
- **IEC 60601-1-2 : 2014**
- **IEC 60601-2-22 : 2012**
- **IEC 60825-1 : 2014**
- **NF EN1041 : 2008**
- **ISO 15223-1 : 2017**

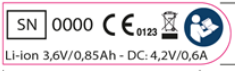
SYMBOLS USED

Sedatelec	**Manufacturer**
Color : blue	" Obligation to refer to the manual / instruction booklet"
	Dispose with **electrical waste** (directive DEEE)
CE 0123	**EC Mark** ensuring compliance with directives 93/42/EEC and 2007/47/EC awarded by **TÜV SÜD Product Service**. The notified body, registration number 0123.

Maximum and minimum limits of :

Atmospheric pressure	Hygrometry	Temperature

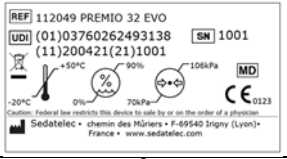
LABELS USED :



Positioning: *on the device*:

SN Serial number of the device
Battery: Li-ion 3.6V 0.85Ah
Charger: DC 4.2V 0.6A

Positioning: *On the charger*
Product designation
QR code + digits: UDI identifier *
REF : Device reference
: Name and address of manufacturer
: Date of manufacture



Positioning: *On the box*

UDI: UDI identifier *
MD : Medical Device

Color : yellow

Color : yellow

Positioning: *Towards the laser output of the device*
Laser danger (+ indication by the tip of the warning "laser opening")

Positioning: *In this manual*
Warning: "laser opening"
Laser radiation is emitted by the diode located at the end of the tip

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Color : yellow

Positionnement : *in the case*
Warning: "invisible laser radiation. Dangerous beam exposure. Class 3B laser device" according to IEC 60825-1.

Positioning: *On the "laser test" box*

LOT : batch number of the "laser test"

* UDI: Unique identifier of the product

APPENDIX 2: PERIODIC TECHNICAL SAFETY CHECKS

Reminder: This laser device must have technical safety checks **every 24 months.**

Visual examination:

- Of the overall device,
- Of the labelling: identification and warning labels, commands and control markings, current method of use etc.

Operating control depending on method of use:

- Starting,
- Setting commands and indicators,
- Confirming the frequencies emitted,
- Checking timer.

Checking emitted energy:

- Check crest energy emitted by each pulse

Technical safety check:

- Laser Test check
- Examination of the laser safety key

We would thoroughly recommend that you perform these checks and that you fill in the corresponding monitoring table at the end of the booklet.

☞ ***Sedatelec is at your service to do these!***

APPENDIX 3: ELECTROMAGNETIC COMPATIBILITY

Appropriate electromagnetic environment.

The **PREMIO 32 EVO laser A-G program** is suitable for use in all facilities including domestic and those directly connected to a low voltage public electrical supply network and domestic building supplies.
The **PREMIO 32 EVO laser A-G program** uses RF energy only for its internal operation. As a result its RF emissions are therefore very low and are not liable to cause interference with a neighbouring electrical instrument.

WARNING: Avoid using this instrument next to other machines which might induce disturbances in the cables connecting the test box to the main device: short wave generators, high-frequency surgical devices, and more generally in an environment contaminated by non-standard electromagnetic emissions.

Emissions and immunity test according to IEC 60601-1-2:

Emissions tests	Compliance	Comments
Emission of conducted disturbance	YES	CISPR 11 Class B, Group 1
Emission of irradiation disturbance	YES	CISPR 11 Class B, Group 1
Emission of harmonics	NA	Classe A : P elec < 75W
Emission of voltage/clashing fluctuations	NA	Test not required as the instrument does not produce significant voltages

The **PREMIO 32 EVO laser A-G program** is designed for use in the electromagnetic environment specified below.The client or user of the **PREMIO 32 EVO laser A-G program** should ensure it is used in such an environment.

Test of immunity	**Compliance with IEC 60601**	**Level of compliance**	**Electromagnetic environment - recommendation**
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV on contact ± 15 kV in air	± 8 kV on contact ± 15 kV in air Direct pressure on the keys can stop the laser emission.	Floors should be wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity should be at least 30 %.
Rapid transitory bursts IEC 61000-4-4	± 2 kV for power supply cables ± 1 kV for input/ output cables	± 2 kV for power supply cables Not applicable	The quality of the power supply must be identical to a commercial or hospital environment.
Transitory power surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV normal mode	± 1 kV differential mode Not applicable	The quality of the power supply must be identical to a commercial or hospital environment.

Test of immunity	Compliance with IEC 60601	Level of compliance	Electromagnetic environment - recommendation
Voltage drop, power cut and power variations IEC 61000-4-11	< 5% U_T (>95% drop of U_T) for 0.5 cycle 40% U_T (60% drop of U_T) for 5 cycles 70% U_T (30% drop of U_T) for 25 cycles <5% U_T (95% drop of U_T) for 5 sec.	< 5% U_T (>95% drop of U_T) for 0.5 cycle 40% U_T (60% drop of U_T) for 5 cycles 70% U_T (30% drop of U_T) for 25 cycles	The quality of the power supply must be identical to a commercial or hospital environment. As the instrument is battery-operated, only charging is impacted by the quality of the electrical supply.
Network frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	The quality of the magnetic field at the frequency of the electricity network must be identical to a commercial or hospital environment.
NOTE U_T is the alternating network voltage before application during trials			

Test of immunity	Compliance with IEC 60601	Level of compliance	Electromagnetic environment - recommendation
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Veff 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz Discrete 9, 27 or 28 V/m frequencies	3 Veff 3 V/m Discrete 9, 27 or 28 V/m frequencies	WARNING: RF portable communication devices should not be used (including peripherals such as aerial cables and external aerials) closer than 30 cm (12 inches) from any part of the PREMIO 32 EVO laser A-G program , including the cables, otherwise the performance of these instruments may be reduced.

APPENDIX 4: INSTRUMENT BOOKLET

VISUAL EXAMINATION

Date	Performed by	Comments

OPERATING CHECK

Date	Performed by	Comments

ENERGY EMISSION CHECK

Date	Performed by	Result	Comments

TECHNICAL SAFETY CHECK

Date	Performed by	Comments

The effective Laser Biostimulator

The **PREMIO 32 EVO laser A-G program** is an instrument dedicated to local application of laser biostimulation. It applies, to the cells, the energy and beneficial frequency information to restore harmonious physiological function.

It is wireless operated and of sufficient power to entirely safely penetrate to the core of tissues. It is pre-programmed and light, frees you from any constraints, inspires confidence in your patient and allows you to work comfortably in entire safety and master the treatment procedure.

For effective, comfortable, safe, everyday practice.

Your distributor:

Last revision: Dec 2022

Sedatelec®
YOUR WAY OF CARE, OUR QUALITY DEVICES
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Tel +33 (0)472 663 322 • Fax +33 (0)478 508 903

Type of instrument:

PREMIO 32 EVO laser A-G program

Serial number:

Manufacturer :

Sedatelec
Chemin des Mûriers
69540 IRIGNY FRANCE

Distributor :

Acquisition date:

CE 0123