premio 10
moxa

YOUR USER GUIDE
Must be kept with the appliance

English

Sedatelec®
YOUR WAY OF CARE,
OUR QUALITY DEVICES

Congratulations for choosing the Premio 10 moxa.

Heat stimulation is a valuable therapeutic aid.

Moxibustion, and its application to certain acupuncture points, is a major resource in the practitioner's arsenal.

Daily use of the Artemisia moxa in your practice poses a number of problems, with toxic fumes and the persistent odor being the most troublesome both for the therapist and the patient.
This has led some of you to avoid using a technique that provides a wealth of results.

Today, after many years of research, we have developed a device that reproduces the energy characteristics of Artemisia moxa as closely as possible, without the drawbacks.

Thanks to this high quality device, which complies with the up to date medical standards, you will have all of the applications, sensations and, of course, results that you expect. And you can rediscover ancient applications, or develop new ones...

Thierry GARABOUX,
Chairman

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<u>Warning</u>: Use carefully. May cause serious burns. Do not use over sensitive skin areas or in the presence of poor circulation. The unattended use of the PREMIO 10 moxa by children or incapacited persons may be dangerous. Do not heat the acupuncture needles – risk of serious burns.

To use your Premio 10 moxa as safely and comfortably as possible, we recommend that you read its user manual and the user manual for the power supply thoroughly before the first use.

We have designed this guide to help you in your daily practice, so please don't hesitate to consult it regularly... and to let us know what you think, so we can improve it and make it even more useful for you.

Please note that Sedatelec can only be held responsible for the safety, reliability and performance of the appliance if:

- the appliance is used in compliance with the description in the User Guide,
- the accessories used comply with the references cited in the User Guide,
- any assembly, adjustments, modifications and repairs of the appliance that should prove necessary have been carried out only by a person expressly authorized to do so by Sedatelec.

GENERAL INFORMATION

Your **Premio 10 moxa** is an appliance that emits **infrared radiation** at a spectrum that is particularly **close to that emitted by a burning roll of Artemisia**.

It therefore lets you provide efficient additional therapy for a number of pathologies, through application of very specific “heat” to acupuncture points, areas of pain or reflex points.

The total absence of harmful or bad-smelling fumes and ashes, and the ease of use and handling of the appliance with a single button provide general comfort when using for you and your patient.

Because of the identification of the heat with “traditional” moxa, you will immediately have all of the sensations you expect as well as the clinical results.

Moxibustion once again becomes a therapy providing great satisfaction for the happiness and health of your patients, now that it has been freed of the restrictions and inconveniences of combustion!

THE SPECTRAL CONCORDANCE OF THE PREMIO 10 MOXA AND BURNING ARTEMISIA

The **Premio 10 moxa** infrared emitter has been specially designed so its emission spectrum is as close as possible to that of the end of a roll of lit Artemisia, without the ash (moxa-like, see appendix 2).

The quality of the emission spectrum reproduces the exact stimulation obtained with a roll of Artemisia, in the same wavelength proportions.

This is important, as it means that you stimulate each group of cutaneous and deep receptors according to specific sensitivity, as with traditional Artemisia.

Other sources of heat can over- or under-stimulate some types of receptors, disturbing the patient's reaction, as there may be a sharp burning sensation before the energy can penetrate, or even no sensation of heat even though the deep tissue is being damaged.

INDICATIONS, SAFETY PRACTICES & CONTRAINDICATIONS

Indications
Your **Premio 10 moxa** is particularly efficient for heat therapy of a zone or point:

- in acupuncture (moxibustion)
- on reflex points
- in auricular therapy
- locally on areas of pain

Safety indications

As with every thermal appliance, it must be handled with care, in particular with respect to the hot metal parts.

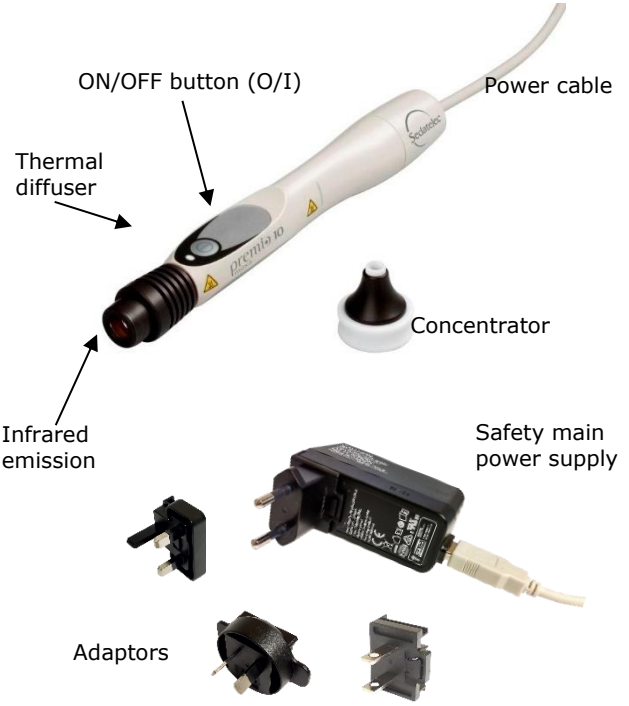
Its use as part of medical treatment requires skilled personnel with knowledge of the medical indications, contraindications and risks connected with use of localized heat. The practitioner must always remain attentive to how the patient feels during the treatment.

Contraindications
In particular use on people with diminished heat sensitivity or unable to communicate what they are feeling is not advised.

The sensitive zones (mucous membranes, eyes, damaged skin, abdomen of a pregnant woman, etc.) and those zones anatomically close to sensitive structures (major blood vessels) are to be avoided.

DESCRIPTION OF THE PREMIO 10 MOXA

The **Premio 10 moxa** is a blackbody thermal infrared emitter (see appendix 3) that is mains operated.



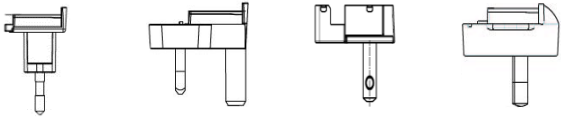
The **Premio 10 moxa** comes with an accessory, the Concentrator, 4 sector adaptors, an operating guide and a storage bag.

The bag contains a small pouch to hold the **Premio 10 moxa**, and a large one for the power supply, cord, operating guide, etc. This means you can store the appliance for transportation to your patients, if needed.
Once the **Premio 10 moxa** has been unplugged, it can be stored in its bag.

The **Premio 10 moxa** comes with an adaptor that clips beneath the power supply case. The 4 adaptors mean you can plug the appliance in, regardless of the country you happen to be in.

To change the adaptor,
1 – Press the middle of the power supply box where the adaptor is clipped on.
2 – While pressing, pull the adaptor up or down, depending on the models, to remove it from its housing.
3 – Replace the adaptor with the one you need. A "click" tells you the new adaptor is properly in place.

Europe *UK* *US* *Australia*



ELECTRICAL SAFETY INSTRUCTIONS

As the appliance is not sealed, never immerse it in liquid. Never use it in a flammable environment.
Never use the **Premio 10 moxa** during a thunderstorm. *Channeled electrical discharges are uncontrollable and dangerous for both the appliance and the users*.

Be sure to only use the 110V/240V, 50/60 Hz medical power supply box which supplies 5V between 1.5 and 3 A, or if not, a protected 5V external battery with an isolating cover, which is not connected to the mains whilst using Premio 10 moxa and does not supply more than 3 A.
Caution, it must be a medical power supply unit. Otherwise, you could be exposed to severe risks.
The power supply box must always be accessible so that the device can be disconnected from the mains.
Never leave the unconnected power cord outside of its box.

THERMAL SAFETY INSTRUCTIONS

When in use, some parts of the **Premio 10 moxa** become hot.
This means basic care is needed when handling:

- do not use the **Premio 10 moxa** in the presence of flammable gas (oxygen, alcohol or ether vapors, etc.)
- Stop the device before cold cleaning
- after cleaning, wait until the disinfectant has totally evaporated before turning the appliance on
- do not touch hot areas: metal parts of the diffuser and Concentrator.
- The temperature of the front part between the 2 symbols  can exceed 48°C, after 5 minutes of continuous operation. However, you can continue to use the device by holding it by the rear part.

The insulating end of the Concentrator significantly reduces the risk of burns, in case of accidental contact.

The Concentrator is safe to handle, thanks to the white insulating ring.

If the appliance is brought to a minimum of 2.5cm from the skin without the Concentrator in place, or to a minimum of 0.5cm with the Concentrator, the skin will not be exposed to temperatures exceeding 45°C, even in the case of prolonged exposure.

In general, make sure the patient is ready and able to inform you if the sensation of heat becomes too strong.

An electronic safety device shuts the appliance off in the event of accidental overheating of the emitter (confined emission).

REGULATORY AND STANDARD RELATED INFORMATION

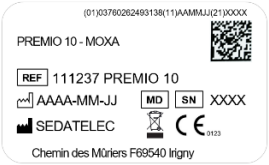
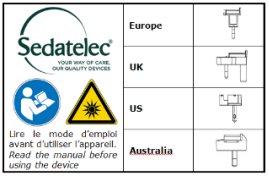
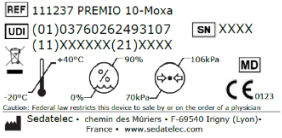
Classification :

The **Premio 10 moxa** is a IIa medical appliance according to directives 93 /42 EEC and 2007/47/EC.

Applicable standards:

- **ISO 14971 :2013**
- **EN 60601-1 :2012**
- **IEC 60601-1-2 :2014**
- **NF EN1041 :2008**
- **ISO 15223-1 :2017**

Labels used :

Position	**label :**
On USB plug	
On power supply unit (psu)	
In the product packaging	
On the cardboard packaging	

Symbols used

The appliance sales reference (on labelling)

Serial Number (on labelling)

" Obligation to refer to the manual / instruction booklet" (on labelling)

Dispose with electrical waste (directive WEEE) (on labelling)

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. (on labelling)

Warning: Hot Area (on handpiece)

Danger, optical radiation: Infra-red emission, avoid staring directly at the source. (on labelling)

Manufacturer (on labelling)

Manufacturing date (on labelling)

For indoor use (on power supply unit)

Electrical protection class 2, double insulation (on power supply unit)

Maximum and minimum limits of :

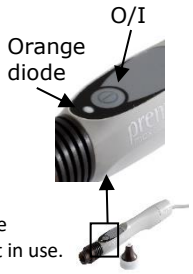
Atmospheric pressure

Hygrometry

Temperature

USE OF THE APPLIANCE

Connect the Premio 10 Moxa to a functional power source.



Press the **O/I** button (an orange diode lights up on the **Premio 10 moxa**). Wait about 5 seconds until the emitter reaches operating temperature. Pressing again stops emission.

You do not have to turn off the **Premio 10 moxa** to move from one zone to another. However, as heating does not take long, there is no point in leaving it on when it is not in use.

Turning the appliance on and off can be done with or without the Concentrator attached.

The Concentrator can be added or removed at any time, using basic care if it is very hot.

The **Premio 10 moxa** is programmed to automatically stop after 10 minutes of uninterrupted operation. The appliance can be turned back on immediately.

Thermal application

Operational in a few seconds,
the **Premio 10 moxa** lets you

- heat up an area of cm²,
- or, with the Concentrator, focusing the radiation on specific body or ear points: the "***thermal needle"*** effect.

To treat an area, sweeping the surface is apparently preferable to a point-by-point approach, to obtain a more homogenous effect and to avoid vascular reactions that could impede or attenuate the overall effect expected.
The time of application varies depending on the points being treated, the affliction, and the condition of the patient's health, etc.
It can be from a few seconds to several minutes while following the heat safety guidelines.
The number of treated points is generally low (from 1 to 5).

Your clinical experience with moxa is immediately applicable using the Premio 10 moxa.

Application without the concentrator

Just as you would with a roll of moxa, bring the appliance close to the skin while holding it perpendicular above the area or point to be stimulated, without bringing it into contact (risk of burns).

After a few seconds, and depending on the sensation of penetrating heat that your patient reports, move it away then bring it back, a few times; to extend this sensation and achieve your therapeutic objective depending on your usual clinical practice.

Application with the concentrator

The Concentrator focuses the energy on a reduced area, when you wish to stimulate a precise point.
This is useful with the ear in particular (**auricular therapy**), and with some parts of the body.

Your patient will describe a sharp feeling of deep heat penetration after a few seconds, and this is where the term "***thermal needle***" comes from.

DISINFECTION – MAINTENANCE

If the Concentrator comes accidentally in contact with the patient's skin, we recommend it be cleaned using a wipe and a traditional clinical cleaner before future use.

This must be done with the appliance off and reasonably cool, but does not require removal of the Concentrator. **Do not use ether or any flammable product**.

Reminder: make sure you let the disinfectant evaporate, if necessary, before turning the appliance back on.

The **Premio 10 moxa** does not require other specific maintenance.

Make sure no object comes in direct contact with the infrared emitter through the appliance's orifice.
There is no risk of electric shock for the user in this case, but the emitter's filament may be severely damaged.

To ensure all of the long infrared is emitted, which is an important part of the moxa effect, we cannot interpose a protective screen (*see Blackbody and infrared emission of the **Premio 10 moxa**, appendix 2*).

WARRANTY - BREAKDOWNS – RECYCLING PROCEDURES

The **Premio 10 moxa** is guaranteed 2 years in total (excluding the cord). If the appliance breaks down during this period, please return it to us for inspection. We will then either repair or replace your appliance.
This warranty does not cover deterioration or faults resulting from use, operation or handling that does not comply with normal use as defined in the operating guide.

If there should be a problem when using the **Premio 10 moxa**, please make sure the power supply is properly plugged in to a working socket.

If pressing the **O/I** button does not turn the emitter or orange diode on, talk to your retailer or return the appliance (in the box or sufficient protection for transport) to Sedatelec.

For safety reasons, never attempt to repair, or handle the infrared emitter, and never dismantle the appliance yourself.

When disposing of the **Premio 10 moxa**, as it includes electronic components, please respect the applicable regulations for your region.

APPENDIX 1: HEAT STIMULATION

Local application of heat has always been used both in medicine and "home remedies" to relieve pain and organic dysfunction.

Research has demonstrated the type of thermal receptors and stimulating action of heat.
The mobilized polymodal receptors transmit information by nerve channels, inducing

- *local effects* (vasodilatation, extravasation, inflammation and modification of the cellular metabolism, etc.)
- *central effects* (modification of the perception of the pain, adapted integration and reaction of the central nervous system, stimulation of the immune system...)

Energy must nonetheless be applied in as efficient a manner as possible. This means reaching the target in a sufficient quantity without causing collateral damage.
The type of heat source is crucial. It must be adapted to the cutaneous and deep thermal receptors.

Blackbody-type emission (with a continuous spectrum, see page 27) centered on the medium infrared (2 to 4μm) stimulates the superficial and deep receptors without saturating the thermal sensors by increasing the cutaneous temperature above 47°C, which is the physiological pain threshold.

If this threshold is exceeded, the pain triggers an immediate and reflexive withdrawal reaction, in addition to the unpleasant sensation felt by the patient.

The risk of burning is also significant.
This can come about through use of a halogen lamp source, for example, where the emission spectrum is centered on 1μm, which is far too much

energetic, but which gives a sensation of burning very quickly without penetrating the sub-cutaneous tissue.

Heat is then transmitted to adjacent tissue by conduction, not directly penetrating radiation, as occurs in the medium and long infrared.
The mobilization of the infrared receptors deep within the tissue is an important part of the physiological response to infrared stimulation.

Locally, heat can be used on trigger points or by sweeping a zone of pain, but where the skin is not damaged and the pathology justifies this application of heat stimulation.
The antalgic effect is rapid and observable, through the mobilization of the fine nerve channels (Adelta fibers, C fibers) and the centralized blocking of the pain (chronic impairment of a joint, for example).

Heat stimulation also markedly affects immunity by strongly increasing the production, diffusion and activity of leukocytes, neutrophil granulocytes and mastocytes, in particular.

Significant research on the indications and use of medium and long infrared in practical complementary medicine is currently being carried out.
For example, there is the use of the long infrared for arterio-veinous fistula in people with kidney disease and on dialysis, being studied in terms of vasoprotective effects.

It is also used as part of traditional medical practice.
Heat stimulation holds a particular place in Traditional Chinese Medicine.

APPENDIX 2: BLACKBODIES AND THE INFRARED EMISSION OF THE PREMIO 10 MOXA

A blackbody designates an ideal object whose electromagnetic spectrum – meaning the breakdown of the quantity of energy emitted according to wavelength – only depends on temperature.

This curve has a specific, continuous shape with a peak corresponding to the wavelength with the highest energy level, and a more or less straight slope for bigger or smaller wavelengths.
The area beneath the curve represents the total energy emitted.

When a blackbody is heated to 950°C, as with the **Premio 10 moxa** emitter, the emission is centered in the medium infrared (peak around 2.6μm), and a significant part of the energy is given off in the long infrared, up to wavelengths approaching 15μm.

The emission curve of the **Premio 10 moxa** is very near that of a blackbody (see fig. 2).

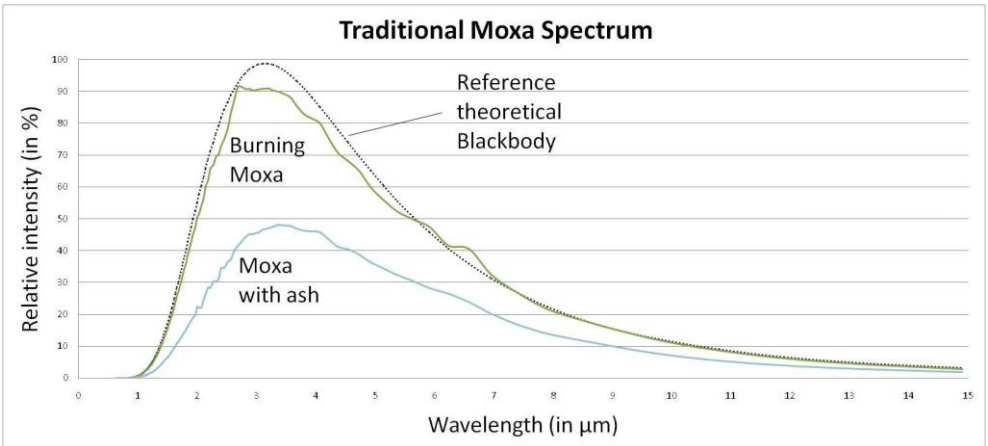

Traditional Moxa Spectrum
Relative intensity (in %)
Wavelength (in µm)
Reference
theoretical
Blackbody
Burning
Moxa
Moxa
with ash
0
10
20
30
40
50
60
70
80
90
100
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15

Fig. 1

Artemisia behaves like a blackbody during combustion.

Its emission peak is centered on the 2.7-3μm wavelength depending on the type of raw material and the combustion, always located in the medium infrared.
This curve also shows the strength of the emission in the long infrared, which penetrates deeply into tissue.

The energy imbued by the long infrared is fundamental, acting as stimulant of both the thermal receptors and the infrared receptors, for complex multimodal information.

The reaction to moxibustion with Artemisia is local, through the mobilization of local vascular, tissue and nervous resources, and general through the information and reaction of the central nervous structures.

Comparison of the Artemisia curve with that of the **Premio 10 moxa** shows a nearly identical spectrum, justifying the term “moxa-like” and above all ensuring identical results.

It also explains why the sensations experienced by the patient are similar, and thus lets you use the **Premio 10 moxa** in the same way as the roll of Artemisia you are used to (fig.1).

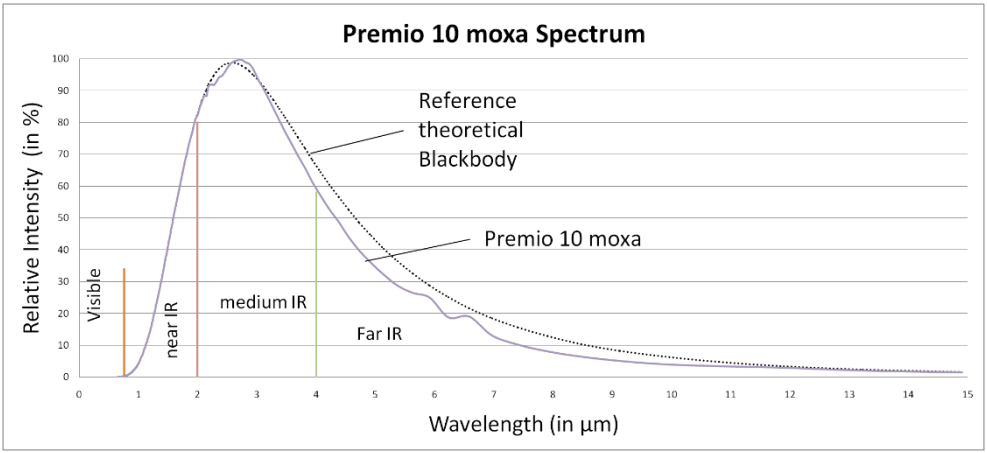

Premio 10 moxa Spectrum
Relative Intensity (in %)
Wavelength (in µm)
Reference
theoretical
Blackbody
Premio 10 moxa
Visible
near IR
medium IR
Far IR
0
10
20
30
40
50
60
70
80
90
100
0
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15

Fig. 2

An identical breakdown of the energy values by wavelength elicits an equivalent response from the different polymodal receptors involved: thermal receptors, near and medium infrared sensitive receptors, far infrared energy receptors…

The infrared radiation transports heat to the tissue through its capacity to penetrate the skin and subjacent structures (absorption windows).

The human body acts like a blackbody too, emitting a temperature with a spectrum centered on 10µm, in the far infrared. It can therefore legitimately be presumed that there are receptors specific to this wavelength in the body, and the radiation emitted by moxa or the **Premio 10 moxa** will resonate with these receptors.

Moxibustion, as you know, cannot be summarized as the simple intakel of a quantity of energy, but also adds energy capable of reaching deep tissue as well as specific information perceived by the physiological receptors.

APPENDIX 3: TECHNICAL SPECIFICATIONS

Manufacturer	SEDATELEC
Name	Premio 10 moxa
Type	Infrared emitter
Emission characteristics	
Spectrum	Infrared emission Blackbody type
Thermal protection (Thermistor)	Automatic shutdown in case of overheating
Automatic shutdown	After 10 minutes
Power supply	110-240V ~ 50-60Hz 5V= 2-2.5A Approved medical standards or if not, a protected 5V external battery with an isolating cover, which is not connected to the mains whilst using Premio 10 moxa and does not supply more than 3 A
Mechanics	
Handpiece	180mm x 25mm
Total weight	200g
Operating conditions	
Temperature	between 0°C and 25°C
Humidity	between 30 and 70 %
Atmospheric pressure	from 70.0 to 106.0 KPa
Storage and transport	
Temperature	between -20°C and 40°C
Humidity	< 90 %

Made in France

APPENDIX 4: ELECTROMAGNETIC COMPATIBILITY AND MANUFACTURER'S STATEMENT

Appropriate electromagnetic environment:

The **Premio 10 moxa** 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 10 moxa** 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	YES	IEC 61000-3-2 Classe A : P < 75W
Emission of voltage/clashing fluctuations	YES	IEC 61000-3-3

The **Premio 10 moxa** is designed for use in the electromagnetic environment specified below. The client or user of the **Premio 10 moxa** 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 undirect ± 8 kV direct ± 15 kV air	± 8 kV undirect ± 8 kV direct ± 15 kV air	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	± 2 kV	The quality of the power supply must be identical to a commercial or hospital environment.
Transitory power surge IEC 61000-4-5	± 1 kV différentiel ± 1 kV normal	± 1 kV différentiel Non applicable	The quality of the power supply must be identical to a commercial or hospital environment.
Voltage drop, power cut and power variations IEC 61000-4-11	0% Un / 10ms 0% Un / 20ms 70% Un / 20ms 0% Un / 5s	0% Un / 10ms 0% Un / 20ms 70% Un / 20ms 0% Un / 5s	The quality of the power supply must be identical to a commercial or hospital environment.
Network frequency (50/60 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 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_n : 230Vac / 50Hz			

Test of immunity	Compliance with IEC 60601	Level of compliance	Electromagnetic environment - recommendation
Conducted RF IEC 61000-4-6	3 V 150 kHz à 80 MHz 6 V 1.8->54MHz (15 bands)	3 V 6 V	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 10 moxa**, including the cables, otherwise the performance of these instruments may be reduced.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz -> 2.7 GHz (4 bands) 9, 27, 28 V/m 380MHz->5.8GHz (14 bands)	10 V/m 9, 27, 28 V/m	

APPENDIX 5: APPLIANCE LOG BOOK

Type of appliance: **Premio 10 Moxa**

Appliance number:

Manufacturer:

Sedatelec
Chemin des Mûriers
FR-69540 IRIGNY (France)

Distributor:

Date acquired:

Moxibustion made simple

An appliance for the local application of heat using infrared radiation at a "moxa-like" spectrum, the **Premio 10 moxa** lets you recreate the sensations and results of the traditional practice of moxa.
It frees you of all restrictions and inconveniences associated with the burning of artemisia, inspire trust in your patient and provides you with genuine ease of use, so you can safely apply your therapeutic skills.

For daily, efficient, pleasant and safe practice.

Your reseller:

Last update: May 2022 HME- PREMIO10-ENG

CE 0123

Sedatelec®
YOUR WAY OF CARE, OUR QUALITY DEVICES

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