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*English*

***Thank you for the trust you have shown in Sedatelec by acquiring this Premio 20.***

***Auriculotherapy, or Auricular Acupuncture is an effective, recognised and popular treatment method.***

***It requires accurate detection of each reaction point and correct assessment of the physiological state which it reflects.***

***Despite this, a thorough search for these points must be simple, quick and reliable, as your time is precious.***

***The technology can bring you true comfort in your work provided it guarantees absolute certainty of the quality of its uses.***

***Today, strengthened by over 40 years of skill, we are offering you a device which allows you to practice completely safely in every situation.***

***It also allows you to immediately and effectively stimulate points of the ear or body avoiding insertion of needles.***

***With this high technical quality, light, independently operating instrument which meets the latest medical standards, you can now dedicate yourself entirely to your passion: providing relief for your patient.***

***I hope you will enjoy your practice with it.***

***Thierry GARABOUX  
President of Sedatelec***

## General information

Your **Premio 20** is a device used to **assist with Diagnosis and Treatment<sup>1</sup>** in **Auriculotherapy** and in **Acupuncture**.

It allows you to find the points on the ear using **differential electrical detection**, and the points on the body using **direct electrical detection**. With the Premio 20DT you can do an electrical stimulation of the body and ear acupuncture points.

In order to guarantee the optimal safety and the best conditions of use of your device, we recommend that you read this user manual completely before you first use the device.

We have designed this booklet as an aide to your everyday practice so do not hesitate to refer to it regularly... and share your comments with us in order to improve it and make it even more useful.

Please note that Sedatelec will only be held responsible for the safety, reliability or performance of the device if:

- the device is used in accordance with the description described in this user manual,
- the accessories used are consistent with the part references described in the user manual,
- assembly, settings, modifications or any repairs to the device have been performed by a person approved by Sedatelec.

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<sup>1</sup> DT version only

We should remember that, both auricular and non-auricular acupuncture is an active treatment which must be carried out as part of an overall approach by practitioners trained in the discipline, capable of mastering both the technique and its methods.

Although electrical stimulation avoids insertion of a needle, it is nevertheless a stimulation procedure which causes a physiological reaction in the body.

We would invite users of the Premio 20 to train themselves regularly in the new advances of this medical practice.

## WARNINGS

- Any modification of the device is prohibited.
- Simultaneous connection of a patient to a high frequency EM surgical device may cause burns at the stimulator contact site and may possibly damage the stimulator.
- Operating in the immediate proximity (less than 1 m) of a short wavelength or microwave EM device may cause unstable stimulator output power.
- Application of electrodes close to the chest may increase the risk of cardiac fibrillation.
- Stimulation should not be applied from one side of the head to the other, to the eyes, mouth or front of the neck (and particularly to the carotid sinus) or from electrodes placed on the chest and upper part of the back or creating a current across the heart.
- Do not apply stimulation whilst the patient is asleep or is carrying out an activity in which stimulation may be hazardous to the patient.

## Contraindications

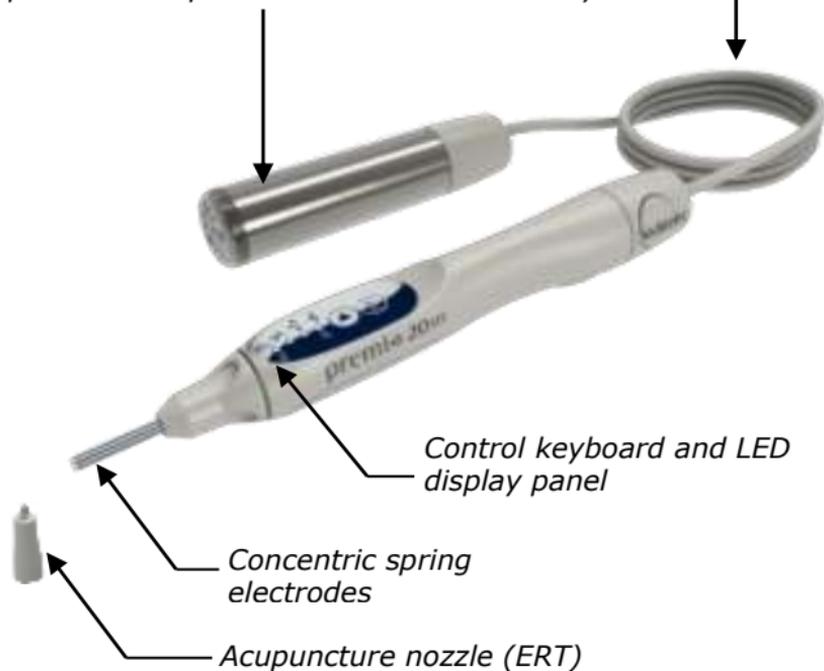
Applications to damaged skin, mucosal membranes or to patients with an implantable electric stimulation device (pacemaker, Parkinson's...) are contra-indicated.

Do not use this device on patients whose cause of pain has not been diagnosed.

## When you first open your Premio 20

Your Premio 20 is an electric detector/stimulator<sup>2</sup> (TENS) which is accurate, independent and battery-operated.

*Grounding handle to be held by the patient. Compartment for CR123A battery*



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<sup>2</sup> DT version only

## Quick start guide for the Premio 20

(Refer to the cover pages)

- 1- Place the battery** in its compartment in the direction shown.
- 2- Switch** your Premio 20 on by pressing on the **D or D/T** key. The LEDs located on the display panel will light up and the number of lights will show the charge status of the battery for a short period of time. The device stops automatically after three minutes of inactivity or can be stopped at will by a long press on the key (2s).
- 3- Give the grounding handle to your patient** so that he/she can hold it firmly in the palm of his/her hand.

### 4- To search for points on the ear

- Select the mode by pressing on the  key: **fall in impedance** (**G↓** indicator lights up) or **rise in impedance** (**S↑** indicator lights up)
- Apply the electrode perpendicularly to the ear, depressed to half way,
- Define the point by the status of the LEDs which light up (slow or fast flashing or fixed: 9 possible levels with audible signal from level 6 - also adjustable see §10).
- Move slowly over the area you are exploring point by point.



### 5- To identify a point on the body

- Place the ERT nozzle on the electrode.
- Apply the electrode close to the point perpendicularly, depressed to half way.

- c. Slowly move the electrode point by point to identify the point where most LEDs light up (representing the point with the minimum impedance).

## 6- To stimulate<sup>3</sup> a point on the body or ear

- a. Place the electrode in contact with the skin on the point being treated.
- b. Press on the **D/T** key. The **flashing** LED indicates the active stimulation programme (identical to the previous stimulation applied).
- c. To change the programme press on the  key.

A beep sounds every second and a long beep every 30 seconds. The average treatment time for a point is adjusted according to your practice:

	Auriculo	30 sec
	Harmonisation	30 sec to 1 min
	Dispersion	30 sec
	Tonification	2 to 3 min

- d. To return to detection mode, press on the **D/T** key.

## 7- Maintenance

- a. Daily: just clean the electrodes between each patient with a cloth soaked in 70% alcohol. This will keep the electrodes clean and operational and avoid any risk of contamination. Do not use liquid as the device is not waterproof.

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<sup>3</sup> DT version only

- b. remove the batteries if it is not going to be used for a long time,

## **8- Breakdowns**

- a. If nothing lights up when a button is pressed or if the device stops during use, check the batteries.
- b. The device does not detect any point: check that the patient is holding the ground handle correctly, and check the cleanliness of the electrode and check the Zero point.
- c. If the problem persists, the cord is damaged or the electrode is bent, return your instrument to our After-Sales Department.

## **9- Storing**

- a. On a daily basis, in its case to protect the electrodes
- b. Consider removing the batteries if it is not used for a long time.

## **10- Setting the audible threshold (level 1 to 9), if necessary**

When the device leaves the factory the signal is set to start at detection level 6. To change this level, proceed as follows:

In detection mode **G↓** or **S↑**, press on the  key and position the electrode on the calibration ear point (zero point). Stabilize the measure until the leds switch off (around 4s) and release the key. The device will now emit a detection bleep from this level onwards. It will re-initialise automatically as soon as the device is switched off.

## Precautions for use

- As the device is not waterproof it must never be immersed in a liquid. It must not be used in an explosive atmosphere or exposed to ionising irradiation (eg X rays etc.).
- Its use in a medical situation requires competent health personnel with sufficient knowledge of the indications, contraindications and medical risks of Auriculotherapy or Acupuncture practice.
- When used for the symptomatic treatment of pain, the Premio 20DT does not replace analgesics and other treatments for pain.
- It has no curative effect.
- The device is not effective on central pains such as headaches.
- Its efficacy depends greatly on patient selection by a practitioner who is qualified in pain management.
- Some patients may experience skin irritation or hypersensitivity due to the electric stimulation
- Patients suspected of having or who are diagnosed with epilepsy must follow the precautions recommended by their doctor.
- Take care if the patient has a tendency towards bleeding, for example, after an injury or fracture.

- Take care after surgical procedures if stimulation may interfere with a patient's recovery.
- Take care if stimulation is applied to areas of the skin which do not have normal sensitivity.
- The safety of electric stimulation during pregnancy has not been established. Also take care if stimulation is applied during menstruation.
- Keep this device out of reach of children.

## Use in Auriculotherapy

The work by Jacques Niboyet<sup>4</sup> has shown that acupuncture points have a different skin impedance, generally far lower, than the impedance of their environment.

For his part, Dr Paul Nogier<sup>5</sup> demonstrated that:

- on the ear, different impedance points are only detected when a disease is present in the body,
- the position of these points in the ear is specific to the dysfunctional organ, allowing what is now universal cartography to be performed,
- the electric change is proportional to the intensity of the organ dysfunction,
- the majority of reactive points show a fall in impedance, although points with high impedance which have a specific significance also exist.

The aim is therefore to identify the points with low (or high) impedance on the surface of the pinna of the ear. The Premio 20 is particularly simple to use and allows you to identify these points with the essential accuracy and reliability for your diagnosis.

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<sup>4</sup> Niboyet J.: University Doctor of Science thesis, Aix-Marseille 1963

<sup>5</sup> Nogier P.: Introduction à l'auriculotherapie. Ed. Maisonneuve 1978

## ***Positioning your patient comfortably...***

Firstly, as this is an electric measurement, it is essential that your patient holds the metallic ground handle in order to close the electric circuit.

The measurement current is extremely low and completely hazard free and is delivered by the electrode applied to the ear. It passes through your patient's body and then the ergonomic ground handle which is well suited to fit into the palm of the hand allows the current to return to the Premio 20. No current therefore passes through the practitioner.

For correct detection you are recommended to always clean and dry the skin in the area being investigated using for example a cloth soaked in medical-grade alcohol. You should also take care to avoid features which interfere with measurement, such as heavy sweating, small scars, hairs etc. which may lead to false detection. You should always avoid rapid repeated rubbing in order not to irritate the skin, otherwise its electric characteristics will change and detection becomes difficult.

## ***...Begin your investigation ....***

Once your patient has been given the ground handle, press on the **D/T** keyboard button to switch on the device. The **G↓** LED lights up showing that you are ready to investigate for low impedance points.

If you wish to search for high impedance points, press on the  key and the **S↑** LED will then light up.

Each further press on the  key will move you from one search mode to the other.

Holding the pinna of the ear in one hand between thumb and index finger, apply the electrode perpendicularly to the area being investigated, depressing it half way to exert constant pressure on the skin.

Impedance measurement is sensitive to pressing on the skin: pressing too lightly produces an approximate measurement and pressing too heavily changes the structure of the skin which is very thin on the ear. The calibrated spring in the Premio 20 prevents this risk and provides you with reliable measurements.

Move the electrode slowly to explore the pinna of the ear, at approximately 2 mm/second.

The electrode is made up of two parts, with a central axis and a cylindrical tube each free from the other.

In practice, your Premio 20 measures the impedance of the skin in the central axis and then performs a second measurement in the cylindrical tube, i.e. in the immediate environment of the central point.

A comparison between these 2 measures determines whether the central point has the same, lower or higher, impedance compared to that in the neighbouring skin: *this is the basis of Differential Detection, the only method which can accurately show you the reactive points on the ear.*

### ***...Analyse your results...***

In Auriculotherapy, the reactive points need to be both **identified** but also **qualified**, i.e. the magnitude of the fall (or rise) in impedance, which reflects the severity of the potential functional defect needs to be analysed.

During your investigations you will see the central LEDs:

- a single LED lit (G): no reactive point found
- two LEDs lit: the point exists although the difference in impedance with its environment is small and this point can generally be ignored.
- three LEDs lit: the point is considerable and significant for your diagnosis
- four LEDs lit: a highly reactive point which undoubtedly justifies treatment or at least to be carefully noted!

Progressive lighting (slow then faster flashing then constant lighting) enables fine detection with 9 status levels.

The audible signal starts from level 6.

### ***...Decide on your treatment...***

Once you have found a reactive point (three or four lit LEDs), you can decide:

- to record it on a diagram (the Romoli sectogram is particularly practical and accurate) and continue investigation.
- to apply a classical needle or an ASP® to it, or an alternative type of stimulation, Laser, infrared, etc. By fully depressing the electrode you can then mark the skin briefly in order to have an accurate visual landmark of the central point.
- to treat it<sup>6</sup> immediately with electric stimulation without moving the electrode. In this case all that needs to be

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<sup>6</sup> DT version only

done is press on the **D/T** button, moving your thumb or index finger slightly (this is the advantage of the Premio 20 of having fingertip controls) and you will begin electrical stimulation of the point.

Electrical stimulation is delivered by sending mini-impulses, the intensity of which is regulated automatically depending on your patient's skin, in order to remain painless.

The impulses are emitted in a specific frequency. In Auriculo (Ear position), the 7 Nogier frequency scan is offered– this is the stimulation which appears to be the most effective according to many practitioners.

In order to change the impulse rate, all that needs to be done is press on the  button. Each further depression changes the speed and the related LED starts flashing depending on what has been chosen.

As a general rule, 30 seconds are sufficient to invalidate the point.

Electric stimulation has many advantages:

- no needle
- little or no pain
- no risk of infection or local inflammation
- "gentle" but effective treatment
- frequential stimulation by scanning the 7 Nogier<sup>7</sup> frequencies, synergistic effects.
- fast

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<sup>7</sup> The Nogier frequencies are not recognised by Health Canada.

## The main indications for auriculotherapy

The contribution of auriculotherapy is now recognised as a complementary therapy for the treatment of:

- all forms of pain and all expressions of pain
- nausea and vomiting
- smoking
- assistance with motor recovery
- anxiety and depressive symptoms
- enuresis.

Its results on pain through TENS (Transcutaneous Electrical Nerve Stimulation) and returning functionality which reduces patient's suffering have contributed greatly to the worldwide expansion in this safe effective treatment.

It has been studied in many other domains and we would invite you to consult the publications, books, seminars and training courses in order to discover the many indications which benefit from the effects of auriculotherapy.

An Inserm report published in 2013 is available on <http://www.inserm.fr/thematiques/sante-publique/rapports-publies>.

## Use in Acupuncture

As you know, the acupuncture point is a very small area of skin in the region of  $\text{mm}^2$ . When a single skin impedance value is measured a dramatic reduction in the value measured is found at this point compared to the measurement value in the surrounding skin. This point can therefore be seen as an "electric well" facilitating circulation of current.

The aim of electric detection is to accurately determine a position of these wells by searching for the " $\text{mm}^2$ " of skin with the lowest single skin impedance measurement in the anatomical area in which the point is found.

One off measurement of skin impedance is performed between the point on the surface of the skin and the internal environment connected to the grounding electrode.

As a result, insert your ERT nozzle onto the electrode ensuring that it is sufficiently pressed in. You then have a mono-electrode, assembled on a spring to preserve constant force onto the skin, which avoids false detections (pressing too lightly with a risk of inadequate contact or too heavily changing the electric characteristics of the skin). When depressed mid-way the electrode should slide gently over the skin to investigate the whole area and not be applied point by point.

The "minima" marker (the last LED which lights up closest to the control **S↑**) indicates the lowest value found at each point as the electrode is moved over the area tested. Once you have gone beyond the acupuncture point the lit LEDs no longer reach this minimum in which case you need to go back over your

steps to relocate the single point corresponding to the minimum which has been found (see section 5 of the cover).

To restart the search just keep the electrodes in the air for over a second and the display will then set to zero. The device is then ready for a new search.

## Stimulation of acupuncture points

The Premio 20 DT can also provide electric stimulation of acupuncture points on the body.

To do this, with the device switched on and the patient holding the ground handle firmly in their hand, apply the electrode to which you have initially attached the ERT nozzle onto the point which you wish to stimulate and then press on the **D/T** button to begin treatment.

During use, the programme offered is the last stimulation delivered (see section 6 of the cover page).

To change the programme, press on the  button and move successively through all of the stimulations offered until the one desired is reached.

According to the majority of Acupuncturists who were consulted, to tonify a point, chose programme ().

2 to 3 minutes (4 to 6 long bleeps) of stimulation may be indicated for extensive tonification.

For dispersion, select () , and 30 seconds are generally sufficient

And to harmonise () for 30 sec to 1 minute.

You will only learn the time required for any stimulation through your own practice.

These programmes use the technique of frequency wobulation between 1 and 100Hz. This strategy, which is specific to SEDATELEC, provides the necessary expected dynamics and achieves excellent results according to practitioners who use the SEDATELEC "PREMIO 30 laser duo" laser.

Electric stimulation of acupuncture points is painless, avoids fear of needles and has no risk to health and has been proven in many studies.

## To be avoided - Adverse reactions

A few factors may compromise the quality of detection of the reactive point by the Premio 20:

- Irritation of the skin by
  - o Pressing for too long on the same point,
  - o Overly aggressive rubbing with the end of the electrode.
- Soiled electrodes: small amounts of dirt may enter between the central axis and the tube, which could reduce the freedom of movement of the parts against each other.
- The ground handle is not correctly held by the patient and contact at this level is intermittent.
- The electrode is not held perpendicularly to the surface of the skin, depressed half way.

The patients may experience skin irritation in response to the effect of stimulation.

They should inform their doctor if they experience adverse reactions.

## Maintenance and storage of the Premio 20

The Premio 20 has been designed to simplify your Auriculotherapy and Acupuncture practice, guaranteeing you reliable accurate results and tranquil use in all circumstances.

It is always ready to operate and does not require any specific maintenance although:

- consider cleaning the concentric electrode (tube and central stylet) and the ground handle with a cloth soaked in 70% alcohol, between each patient for obvious hygiene reasons, and also for the quality of electric contacts.
- if you are considering not using the device for a long period of time, remove the batteries from their compartment.
- choose high quality batteries and always keep a spare set
- keep the device in its case with the handpiece positioned in its compartment in order to protect the electrode.

### Recycling procedures

When you dispose of your Premio 20, it contains electric components. Please follow the instructions which apply in your region.



## Annex 1: Regulatory and standard-based information

### **Classification:**

**The Premio 20** is a class IIa medical device according to rule 9 of directive 93/42 EEC amended by directive 2007/47/EC. It belongs to class II according to the Canadian (DORS/98-282) and American regulations for medical devices.

### **Applicable standards:**

#### **- NF EN ISO 14971: 2013**

Medical devices - Application of risk management to medical devices.

#### **- IEC 60601-1: 2005-Ed.3.0/Cor.1:2006 and Cor.2: 2007**

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

#### **- IEC 60601-1-2: 2014-Ed.4.0**

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: Electromagnetic compatibility - Requirements and tests.

#### **IEC 60601-2-10: 2012-Ed.2.0**

Medical electrical equipment: Part 2-10: Particular requirements for the safety of nerve and muscle stimulators.

#### **ISO-10993-1:2010**

Biological evaluation of medical devices - Part 1: Evaluation and testing.

## Symbols used:



**Our manufacturing name**



**"Serial Number"**

Device serial number



Refer to the **device user guide**



Dispose with **electronic waste**  
(WEEE directive)



**EC Mark** ensuring compliance with directives 93/42/EEC and 2007/47/EC awarded by **TÜV SÜD Product Service**. Registered notified body, identification number 0123.



Type BF electrical device (according to standard IEC 60601-1)

## Annex 2: Periodic technical safety checks

Note : This device must undergo technical safety checks **at least every 60 months**.

### **Visual examination:**

- \* Of the device overall,
- \* Of labelling: identification and warning labels, description of commands and controls, the current user manual, etc.

### **Check on operation depending on user manual:**

- \* Switching on,
- \* Check on controls and displays,
- \* Check on emitted frequencies,
- \* Timing check.

### **Check on emitted energy:**

- \* Confirmation of the power crest emitted by each impulse.

We would strongly recommend you carry out these checks.

***☛ Sedatelec is here to help you do these!***

## Annex 3: Electrical characteristics of acupuncture points

Skin impedance is the measurement of resistance of the skin to an electrical current passing through it. It is expressed in Ohms ( $\Omega$ ) and ranges from 50 to 15,000 K $\Omega$  moving across the skin although this measurement falls very considerably when the search electrode is positioned exactly on an acupuncture point as described by Chinese medicine.

On the ear, Auriculotherapy points have the same electric features although the proximity of points to each other requires comparative measures of two areas very close to each other.

Furthermore, whilst the majority of points display a fall in impedance compared to their immediate environment some display higher impedance and need to be managed specifically.

In addition, the extent of the fall or rise in impedance is a key feature in determining the diagnosis and constructing a treatment programme.

All of these factors require irreproachable quality measurement avoiding artefacts at the same time maintaining maximum sensitivity.

The complexity of recording and analysing information which lies at the heart of the Premio 20 is your guarantee of reliable, accurate, correct information.

## Annex 4: Auriculotherapy

By Doctor P. Becu, DMV

*"The technique of reflexology often incorporated into Acupuncture and occasionally called Auricular acupuncture from which it differs through its origins and process.*

*It is a quite separate therapy and must be performed by trained competent health professionals.*

*It was born from the work conducted by Dr Paul Nogier, a Lyon physician in the 1950s and is now performed throughout the world both in the West and in China. Its efficacy and indications have been confirmed in published scientific works.*

*Auriculotherapy uses the rich innervation (Trigeminal nerve V, cervical nerves C1, C2, C3, Vagus nerve X, etc.) and vascularisation of the ear to communicate with the Central Nervous System (CNS), the supreme organiser of the body's physiology and homeostasis.*

*This communication occurs in two directions:*

- *By identifying reactive points the pinna of the ear can be used to identify functional disorders of the body following a somatotopism which is now validated and represented on Auriculotherapy charts.*
- *By stimulating some points, the same pinna can be used to trigger a reaction initiated by the CNS remotely changing the physiology of dysfunctional structures or organs towards more appropriate functional balance.*

*The communication between the ear and the CNS appears to mobilise the neuronal and vascular pathways.*

*Transmission of central information to organs uses neuronal, immune and humeral pathways.*

*Localisation of a reactive point on the ear corresponding to an organ is not fixed but lies within an area which ranges between a few millimetres between individual people and depending on the physiological state of the organ. A full stomach or pregnant uterus occupies more place than the same empty organs.... as do their representations on the ear.*

*In general the reactive points display greater sensitivity to pressure. Searching for pain points which trigger a pathognomic grimace is one of the localisation methods used for these reactive points.*

*It is useful to confirm the exact position of these points by measuring the fall in local impedance, the value of which provides important diagnostic information about disturbance of the structure or organ which it reflects.*

*Stimulation of reactive points either by manipulation, needle or electric, light or laser impulses can by mobilising the body's resources correct numerous problems and in particular effectively and sustainably relieve acute or chronic pain.*

*Reference books, scientific publications, training and seminars will enable you to supplement your knowledge and continue to improve your mastering of this remarkable technique in terms of its results".*

**Please contact your distributor!**

## Annex 5: Technical specifications

**Manufacturer** SEDATELEC

**Name** Premio 20 D / DT

**Type** Premio 20 DT: Acupuncture point detector and stimulator

Premio 20 D: Acupuncture point detector

### Characteristics

#### DETECTION

Type	Differential detection by dual skin impedance measurement
Max current	5 $\mu$ A

#### STIMULATION

Wave shape	Positive and negative exponential pulses		
Frequencies	Auriculo	1.14, 2.28, 4.56, 9.12, 18.25, 36.5, 73 Hz	
	Harmonisation	1.14 – 100 – 1.14 Hz	
	Dispersion	100 – 1.14 Hz	
	Tonification	1.14 – 100 Hz	
Offset	Nil		

\* Values for frequencies of 1.14Hz to 100Hz

Imp. (M $\Omega$ )	Max voltage* (V)	Duration/pulse* (ms)	Energy/pulse* ( $\mu$ J)
1	5.0 ... 2.5	50 ... 5	1.25 ... 31 $\times 10^{-3}$
3	6.6 ... 4.2	250 ... 5	2.06 ... 29 $\times 10^{-3}$
9	7.6 ... 6.0	440 ... 5	1.74 ... 20 $\times 10^{-3}$
20	9.0 ... 7.4	440 ... 5	1.47 ... 14 $\times 10^{-3}$

**Power supply** 1 x 3V CR123A battery, 1600 mAh.

A rechargeable commercial ICR123A battery, voltage 3.0-3.7 V, 800-1600 mAh, may be used.

Regardless of your choice, choose high quality parts from recognised brand names.

### **Mechanics**

Handpiece	190mm x 25mm
Ground handle	4 110 x 25 mm
Total weight	197 g

### **Operating conditions**

Temperature	between 10°C and 35°C
Relative humidity	< 70 %
Atmospheric pressure	70.0 KPa to 106.0 KPa

### **Storage conditions**

Temperature	between -20°C and 50°C
Relative humidity	< 90%
Atmospheric pressure	70.0 KPa to 106.0 KPa

**Sound level** < 80 dB

**MANUFACTURED IN FRANCE**

## Annex 6: Electromagnetic compatibility

Appropriate electromagnetic environment.

The **Premio 20 D/DT** is suitable for use in all facilities including domestic premises and those directly connected to the public low voltage mains supply supplying buildings for domestic use.

The **Premio 20 D/DT** uses RF energy only for its internal operation. As a result its RF emissions are extremely low and are not liable to cause interference with a neighbouring electronic device.

**WARNING:** Avoid simultaneous use of the PREMIO 20 D/DT with other devices which may cause interference with cables connecting the ground to the main instrument: short wave length generators, high frequency surgical equipment and more generally in an environment polluted by electromagnetic emissions outside of standard levels.

Protection of the public mains electricity supply:

Emission tests	Compliance	Comments
Emission of conducted disturbances	NA	Battery operated
Emission of irradiating disturbances	Yes	Class B/Group 1
Emissions of harmonics	NA	Battery operated
Emission of voltage fluctuations/flashings	NA	Battery operated
Electromagnetic emission	Yes	1GHZ to 18GHZ

The **Premio 20 D/DT** is intended to be used in the electromagnetic environment described below. The client or user of the **Premio 20 D/DT** should ensure that it is used in such an environment.

Immunity test	Compliance with IEC 60601	Compliance level	Electromagnetic environment – recommendation
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV in contact  ± 15 kV in air	± 8 kV in contact Stop the device during direct discharges on the electrodes ± 15 kV in air Stop the device during direct discharges above the keyboard	Floors should be made of wood, concrete or ceramic tiles. If the floors are covered with synthetic materials the relative humidity should be at least 30%

Immunity test	Compliance with IEC 60601	Compliance level	Electromagnetic environment – recommendation
Conducted RF IEC 61000-4-6	3 Veff 150 kHz to 80 MHz	3 Veff	<i>WARNING: Portable RF communication devices (including peripherals such as aerial cables and external aeriels) should not be used closer than 30 cm (12 inches) from any part of the <b>Premio 20 D/DT</b>, including cables. Otherwise the performance of these devices may be adversely affected.</i>
Irradiating RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz Discrete frequencies 9, 27 or 28 V/m	3 V/m  Discrete frequencies 9, 27 or 28 V/m	

## Annex 7: Delivery of the instrument

Type of instrument: **Premio 20**

Instrument no:

Date of manufacture:

Manufacturer: **Sedatelec** Chemin des Mûriers F-69540  
IRIGNY

Supplier/Distributor:

Year of acquisition:

Manufacturing authorisation number:  
**CE 0123 - TÜV product service**

## VISUAL EXAMINATION

Date	Performed by	Comments

## OPERATION CHECK

Date	Performed by	Comments

**EMITTED ENERGY CHECK**

Date	Performed by	Result	Comments

**TECHNICAL SAFETY CHECK**

Date	Performed by	Comments

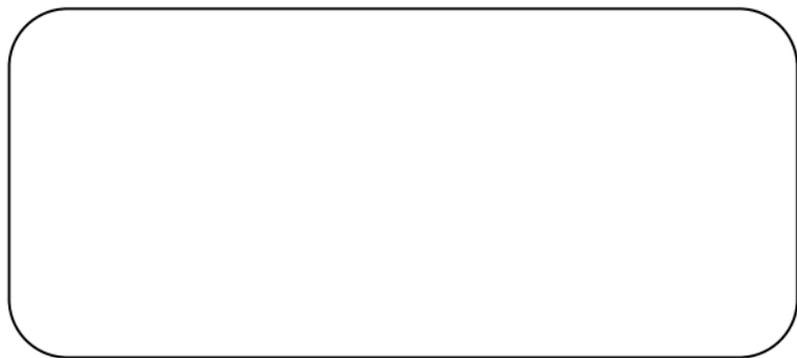
## Auriculotherapy is becoming easy

The **Premio 20** DT is a TENS device dedicated to Auriculotherapy practice and enables you to find and treat reactive points accurately and effectively.

It operates independently, is easy and simple to use and releases you from all restrictions guaranteeing reliable information, inspiring confidence in your patient and providing you with considerable comfort at work, entirely safely mastering the therapeutic procedure.

For effective comfortable safe everyday practice.

Your distributor:



Last version: January 2017

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