AGISTIM DUO

Your User Guide & Maintenance booklet

This must be kept
with your **AGISTIM DUO**

Sedatelec®
YOUR WAY OF CARE,
OUR QUALITY DEVICES

ENGLISH

Thank you for having chosen an **AGISTIM DUO***!*

For more than 30 years, Sedatelec has worked from complementary medicine studies particularly those carried out by Dr. P. Nogier, the father of auriculotherapy to offer practitioners new, high performance, extremely reliable, appliances.

Nowadays we are developing and incorporating the values of respecting the patient, the practitioner and the environment into our products using the most demanding medical standards to make your practice relaxed and effective.

We are pleased to work with people who are always striving for excellence and we are also proud to be increasingly involved in sharing medical information between the different workers in the field. Please do not hesitate to contact us for any further information, by e-mail at infomed@sedatelec.com.

We hope you will be completely satisfied with this **AGISTIM DUO***, and we are always open to any ideas which could improve your practice in this novel medical approach*

Kind regards,
Thierry GARABOUX, President.

Table of contents

List of illustrations

List of tables

Foreword…

Thank you for the trust you have shown us in acquiring this **AGISTIM DUO**.
In order to discover all of its functionalities and use it under the best conditions of safety and comfort we recommend that you read this user guide completely before you use the device.

We have designed this booklet as an aide to your everyday practice so please do not hesitate to refer to it regularly … and please send us your comments at infomed@sedatelec.com to improve it and make it even more useful for you.

This user guide includes maintenance and troubleshooting information and it is essential that it remains accessible: you may be asked for it in an official inspection.

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

- the assembly, adjustment and modifications and any repairs to the device have been carried out by a person approved by **Sedatelec**,
- the accessories used are the part numbers shown in the user guide,
- the device is used as described in the user guide.

Technical safety instructions

Your **AGISTIM DUO** is powered by a safety mains supply which is insulated according to standard IEC 60601-1. **For your safety and the safety of your patients it is essential that you always use this specific adaptor. It must remain accessible so it can be disconnected from the mains.**

The treatment current is delivered as positive and negative pulses with no continuous offset. The maximum pulse current is limited to 12 mA, which is equivalent to a current RMS value of less than **3.4 mA** at maximum frequency (99 Hz) and on a load impedance of 1,000 Ohms.

It carries no specific electrical hazard provided the following points are followed:

- As the device is not waterproof it must never be immersed in liquid or used in an explosive atmosphere.
- Avoid using the **AGISTIM DUO** simultaneously with other appliances which may cause interference in the cables connecting the needles or electrodes: short wave generators, high frequency surgical instruments … and more generally in an environment contaminated by electromagnetic emissions outside of recommended Standards.
- Only use the recommended accessories.

Never use the **AGISTIM DUO** and disconnect it from the main supply in stormy weather. Although the **AGISTIM DUO** is protected against voltage surges in keeping according to up to date standards, lightening is an unpredictable electrical effect which can damage electrical appliances and cause serious injuries to users.

Standards

NF EN ISO 14971: 2013
Medical devices - Application of risk management to medical devices

IEC 60601-1: 2006 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012)
Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

IEC 60601-2-10: 2012
Medical electrical equipment – Part 2-10: Particular requirements for the safety of nerve and muscle stimulators

IEC 60601-1-2: 2014
Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

NF EN 1041: 2008
Information supplied by the manufacturer of medical devices

ISO 15223-1:2017
Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.

Classifications

AGISTIM *DUO* is a **class IIa** medical device (according to European Directive DDM 2007/47/EC) and a **class II** device (according to the Canadian regulations on medical devices of 7 May 1998).

AGISTIM DUO is approved by Santé Canada under licence no. 3137.

AGISTIM DUO is not approved by the FDA (United States).

Technical medical devices must only be used by people who can be ensured to operate them correctly as a result of their training or knowledge and their practical experience. You are strongly recommended to use the provided accessories in order to guarantee reliable use of the device. Practitioners must ensure that the **AGISTIM DUO** *is safe and operating correctly before using it.*

Technical safety tests must be performed on this instrument at least every 24 months. These tests must be carried out by people who are able to conduct them to the state of the art through their training, knowledge and experience without the need for specific recommendations before testing.

Sedatelec has always been proud that it strictly follows safety standards and recommendations to keep your own mind and that of your patients completely at rest. Our products are amongst the safest on the market, operate completely reliably, are innovative in design and offer you the multitude of applications you can think of.

Explanation of symbols used on the labels


Name of manufacturer


Manufacturing date

Product number

Serial Number

UDI identification

Medical Device


You must refer to the User's Guide for the device.


Type BF applied part (IEC 60601-1 regulation)


Attention, danger warning symbol, the user must consult the operating instructions for important information related to safety


Dispose with electronic waste (WEEE Directive)

EC mark ensuring compliance with Directives 93/42/EEC and 2007/47/EC

Direct current


Alternative current


Double insulation power supply

Maximum and minimum limits for:


Atmospheric pressure


Humidity


Temperature

General information

Indications

Your **AGISTIM DUO** is an **electric stimulation** device for acupuncture points and skin reflex areas.

It has 4 independent output channels, divided into **two groups** identified by the colours **green** and **pink.**
The output intensities can be adjusted independently on each channel and the frequency and output mode values can be selected **independently for each of the two groups**. From this standpoint, your **AGISTIM DUO** can be thought of as **two stimulators in one.**

Stimulation is provided by **rectangular, asymmetrical shape pulses, positive and negative with no offset.**

The pulses can be generated at:
- **any frequency between 1 and 99 Hz**
- **one of the 7 NOGIER Frequencies**
  (these frequencies between 1.14 and 73 Hz are memorised in the device).

They can be emitted in **4 different modes:**
- **continuously,**
- **with short rest periods,**
- **with long rest periods,**
- **with frequency scanning**.

These emission modes can be the same or different for each of the groups.

Possible options:

Your **AGISTIM DUO** enables you to connect up to 8 needles or 8 electrodes in 2 groups, each of 2 channels with 2 needles or electrodes per channel.

To increase this number, a "**4 Needle Module"** device can be used which allows 4 needles to be connected to each of the **AGISTIM DUO** channels.
In this way up to 16 needles can be stimulated simultaneously.

A "**Lipolysis kit"** containing 4 "4 Needle Module" devices and a specific user guide is also available for practitioners wishing to use electrolipolysis techniques. Sixteen electrolipolysis needles can therefore be connected. Different cable colours allow easy identification.

The "**Styl Module**" is a probe used for electrical stimulation treatment of one site or small areas of skin. It is entirely suitable for stimulating acupuncture points, auricular points and trigger points.

Indications, contra-indications & precautions

Indications

- Stimulation of acupuncture and auriculotherapy points,
- Stimulation of triggers points,
- Pain treatment by increase of endorphins and TENS applications.

Contra-indications

- Disorders in which acupuncture is not indicated,
- Do not use to treat pregnant women,
- Do not use on injured skin,
- Do not use on mucous membranes,
- Do not use on patients who have an active implanted electronic device (pacemaker or other device).
- 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.

Precautions

- Take precautions when treating haemophilia patients or patients on anticoagulants,
- Always disinfect the skin before positioning the needles or using the Styl Module. Only use sterile disposable needles. Position the electrodes on healthy skin,

- Only keep electrodes used on a patient for subsequent use on the same patient. Never re-use them on another patient, even after disinfection.

Description of the **AGISTIM** ***DUO***

The **AGISTIM** **DUO** set is supplied to you in a case with protective foam.
If the external packaging is damaged on delivery, however, we would recommend that you report this to the carrier.

The package contains:

- the **AGISTIM** **DUO** main box
- the mains power supply
- the output current test box
- a bag of 4 electrodes
- a set of 4 needle cables
- a set of 2 electrode cables
- this User Guide /Maintenance booklet

The **AGISTIM** **DUO** consists of a base box (1) and a safety mains supply (2) to connect it to the power supply (see FIGURE 1).

On the upper part of the front you will see:

- Top right, a display (1a) which displays all of the information required to set the instrument: frequencies, emission mode, timer, alarm messages. Different languages are available (see Selecting display language chapter) to display the messages.

- Top right, knob (1b) to switch the device on and off and to set the timer. A green LED (1c) shows that the device is switched on.

- Immediately beneath, a knob (1d) used to select emission mode, which can either be the same or different for each of the two channel groups.

- In the centre, two sets each with one knob (1e) and one knob (1f) allowing the frequency of each of the two channel groups to be set precisely.

- On the left, four knobs (1g) to individually set the intensity of each channel. An orange LED next to each knob either lights *continuously* (setting or rest time) or *flashes* (stimulation) to show that the knob is not set at zero.

The left side has 4 double sockets (1i) to contact the electrode (3) or needle (4) connecting cables.

(3)

(4)

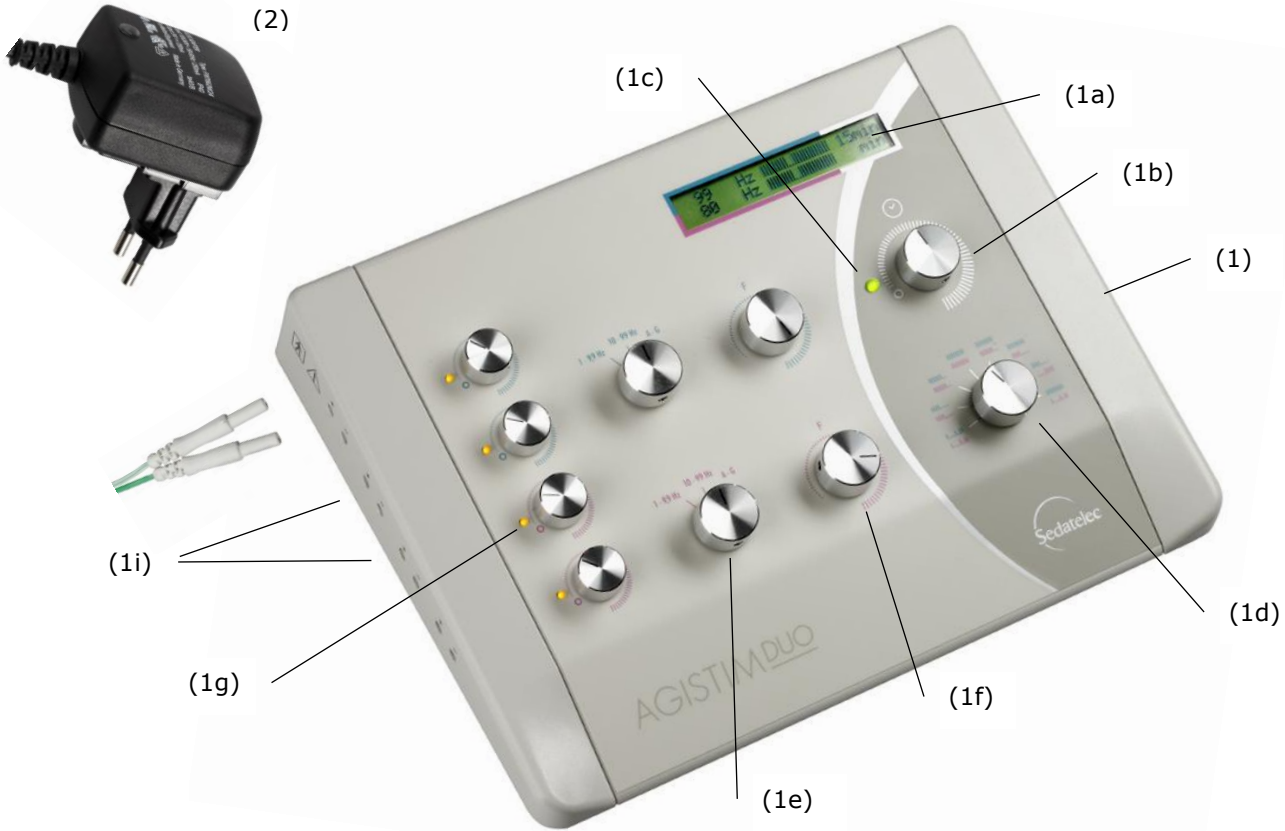


Figure 1: DESCRIPTION OF THE **AGISTIM DUO**

Electrical connections

MAINS CONNECTION

Your **AGISTIM DUO** is mains powered (100-240 Volts / 50-60 Hz) via a safety supply. This supply must be connected to the back of the case and delivers a voltage of 24 Volts.

For obvious safety reasons it is essential that the safety supply supplied with the device is always used and that the cable is checked to ensure it is in good condition.

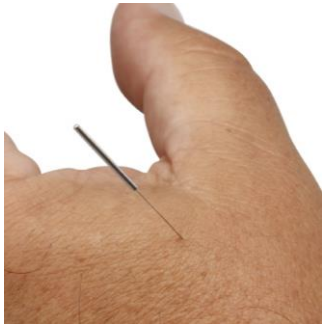
CONNECTION OF NEEDLE OR ELECTRODE CABLES

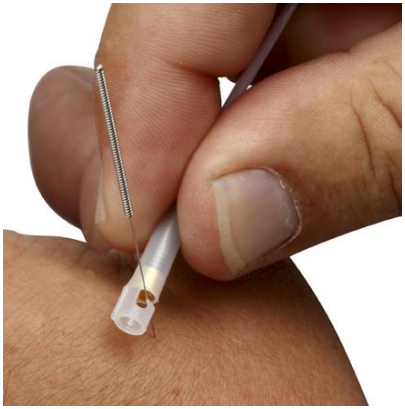
Before starting stimulation and after implanting the needles or positioning the electrodes they must be connected to main the box using the cables provided for this purpose.

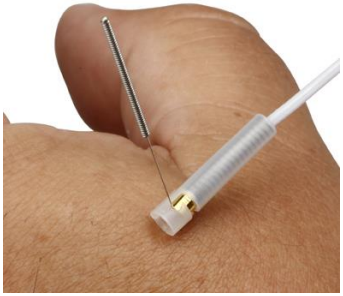
- Connecting the needles

For needles use the cables with special clips.

To use the clip, hold it at its base between thumb and index finger and then clamp the wire in the palm of your hand with your other fingers, keeping your thumb and index finger slightly bent. To open it, simply extend your thumb and index fingers to separate the clip, with the wire clamped. Then introduce the needle into the gap perpendicularly to the clip and release the clip. The spring will maintain contact. To disconnect the needle follow the procedure in reverse.







- Connecting the electrodes using the cable with the banana pin.

- Connecting to the main box

If the signal is not symmetrical, it is sometimes useful to be able to identify the current direction. To do this, the conductors for each needle or electrode pair are identified and connected to each polarity (+) and (-) of each channel. Appendix B shows how to interpret these identifiers.

Figure 2: CONNECTING THE NEEDLES OR ELECTRODES

Note: Unused devices (needles or electrodes) must be disconnected from the box before switching it on or if they are removed during treatment.

Selecting display language

There is a small arrow in the middle of a number circle from 0 to 9 at the back of your **AGISTIM DUO**, on the product label.

Before switching on, you can select the display language from any of the following by turning the arrow with the tip of a small screwdriver:

Number	***Display language***
0	*French (Français)*
1	*English*
2	*German (Deutsch)*
3	*Spanish (Español)*
4	*Italian (Italiano)*
5	*Portuguese (Português)*
6	*Dutch (Nederlander)*

Table 1: DISPLAY LANGUAGES

Note: If you change the language after switching on, the change will only be effected when the instrument is next switched on. For the change to be effected immediately, switch your **AGISTIM DUO** off and then switch it on again.

Switching on and setting the timer

The device is switched on by turning the knob (1b) on the front (top right) clockwise. The LED (1c) lights up continuously green to show that the device is switched on**.**

After approximately one second, the maximum desired programmed treatment time appears at the top right of the display. This value can easily be set to be between 1 and 60 minutes by turning the knob (1b).

The figure located immediately below is the actual treatment time. This counts up as soon as treatment is started and the treatment stops automatically once the programmed time is complete.

The programmed time can be increased or reduced at any time, even during treatment. The treatment time can therefore be increased even if treatment has already started, or stimulation can be stopped manually by reducing the programmed time to a value at or below the treatment time which has actually passed.

Note: Your **AGISTIM DUO** does not have an automatic mains shut-down and the device must always therefore be manually switched off after use.

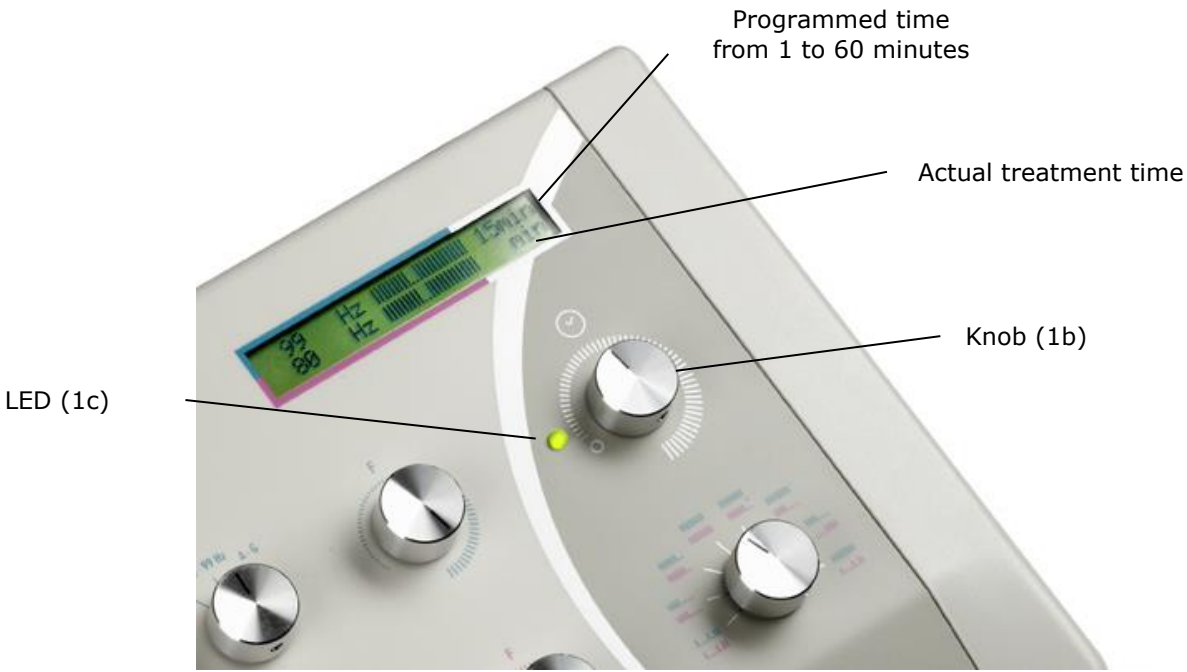


Figure 3: SWITCHING ON AND SETTING THE TIMER

Selecting emission mode

Your **AGISTIM *DUO*** allows you to select between 4 different emission modes:

Continuous mode: in this pulse mode a current is emitted at the selected frequency continuously throughout treatment.

Short stop time mode: in this mode pulse emission is stopped intermittently for 1 second rest periods, representing approximately 12.5% of the total treatment time.

Long stop mode: in this mode the rest times are 4 seconds, representing 50% of the total treatment time.

Frequency scanning mode: this mode enables the pulse emission frequency to change permanently. The frequency selected (knobs 1e and 1f) then become the **maximum frequency**. The actual emission frequency oscillates intermittently between 1 Hz and the selected frequency.

The same or different modes can be used for the two groups of channels**.** Knob (1d) at the bottom right is used to select the desired combination.

Moving from left to right, the **first 4 positions** select the same emission mode on both groups of green and pink channels. They are selected in the following order: scanning mode (1), long rest time (2), short rest time (3) and continuous mode (4).

(1) (2) (3) (4)

Positions 5 and 6 are used to select a continuous emission mode for the green channels when the pink channels have short (5) or long (6) rest times.

(5) (6)

Position 7 is similar to position 2 (50% rest time on all channels) although in this position the rest times alternate between the green and pink channels instead of being simultaneous.

(7) 

Position 8 is used to obtain a continuous emission mode on the green channels when the pink channels are in frequency scanning emission mode.

(8) 

The selected mode pictogram is displayed permanently on the display: on the top line for the green group and the bottom line for the pink group.

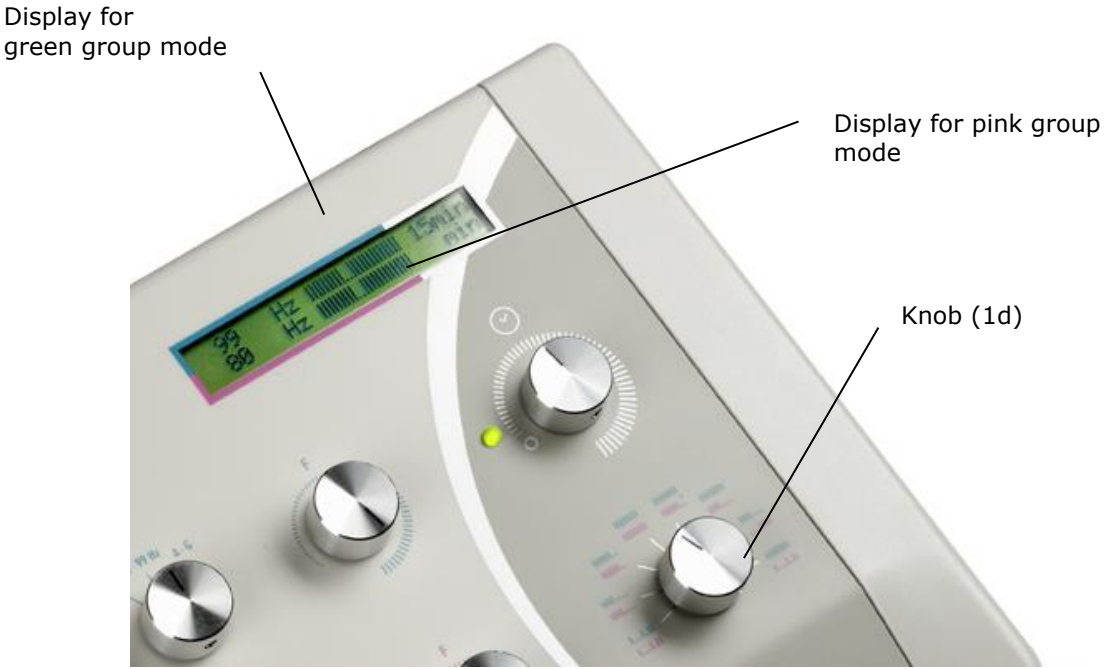


Figure 4: SELECTING EMISSION MODE

Selecting frequency

Frequency is selected by group. For each group, a 3 position switch (1e) and an adjustment potentiometer (1f) are used to select the pulse emission frequency between 1 and 100 Hz.

The value selected is permanently shown on the display: on the top line for the green group and on the bottom line for the pink group.

Selecting your own frequency
To select your own frequency, select the range with knob (1e).

- 1 to 9.9 Hz
- or 10 to 99 Hz

then select the exact value using knob (1f). Selection is in 0.1 Hz steps in the first range and 1 Hz in the second.

Selecting a programmed Nogier frequency.

To do this, select:

- range A – G with knob (1e),
- then the desired frequency using knob (1f).

The available frequencies are: frequencies A (2.28 Hz), B (4.56 Hz), C (9.12 Hz), D (18.25 Hz), E (36.5 Hz), F (73 Hz), G (1.14 Hz). The 1.14 Hz frequency is also called the Universal frequency (U) and can be accessed by turning the knob fully to the right or left.

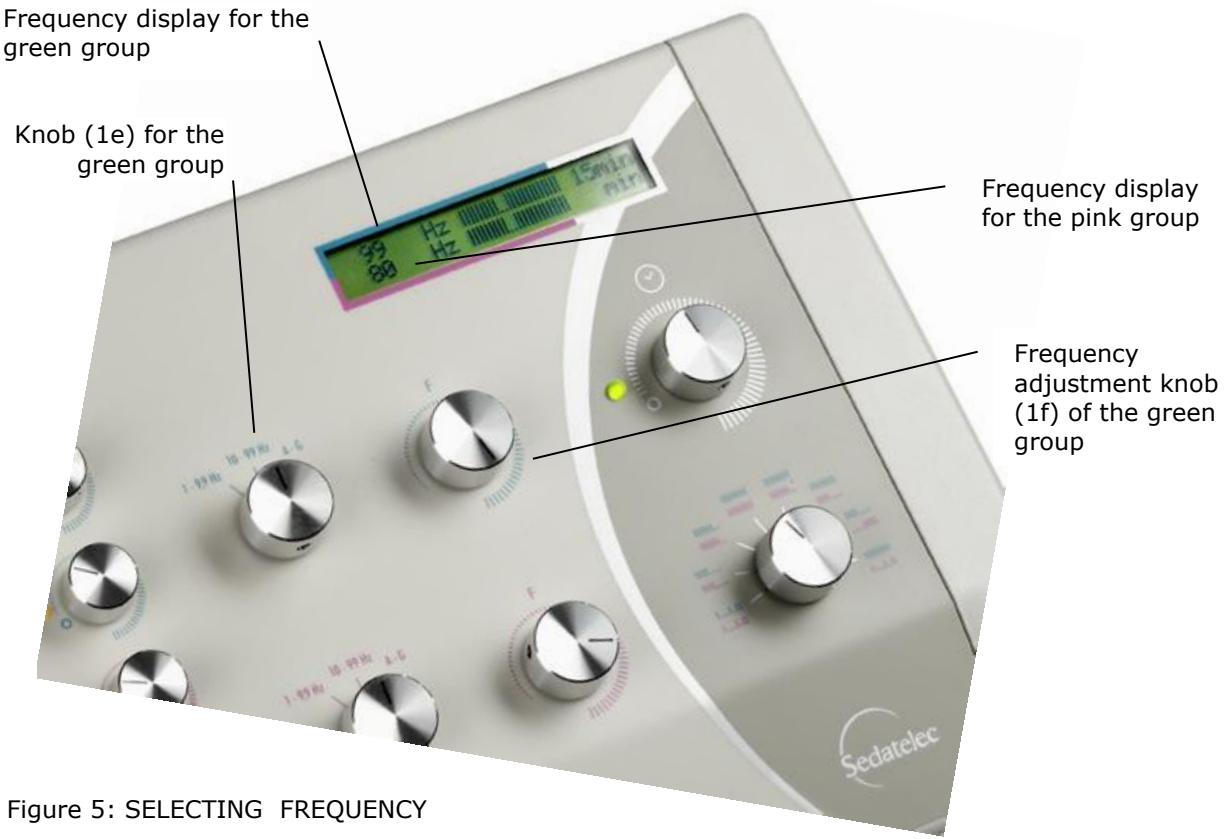


Figure 5: SELECTING FREQUENCY

Starting treatment

Once the needles or electrodes which are to be stimulated have been connected to one or more channels, the channel frequency and emission mode settings have been adjusted and the treatment time has been selected, the treatment can be started.

To do this you simply **turn the intensity knobs** for the channels being used **very slightly** (these are located on the left). As soon as one of the knobs is no longer at zero the corresponding LED will light up. The treatment time will then begin to count up.

Setting the intensity on each channel

To maintain patient comfort, **intensity should always be increased very gradually, particularly if the emission mode includes rest times or frequency variation.** During these times the patient can no longer respond as the emission has been interrupted. It is therefore important when setting the intensity that you confirm the actual status of the emission as shown by the orange LED for each channel.

LED off	**LED flashing**	**LED continuously lit up**
Channel not active	The pulses are actually being emitted at a frequency proportional to the flashing rate.	The channel is active although the emission has been temporarily suppressed (rest time).

Figure 6: SETTING INTENSITY ON EACH CHANNEL

Stopping treatment

Automatic stopping with the TIMER

The right part of the display shows you the programmed time on the top line and the actual treatment time delivered on the bottom. When the treatment time has reached the programmed value, stimulation stops automatically.

An audible signal is produced and the messages "TREATMENT TIME IS OVER" alternating with "RESET THE CHANNELS TO ZERO" appear on the display.

Reminder: The programmed treatment time can always be increased or reduced regardless of the status of the device. The treatment time can therefore be increased even if treatment has already started, or alternatively, stimulation can be stopped manually by reducing the treatment time to a value at or below the treatment time which has actually passed.

Maunually stopping

Stimulation can be stopped at any time,

- either by channel by resetting the corresponding intensity knob to zero,
- or completely, by resetting the TIMER knob to zero.

Safety cut out

As a safety measure, the **AGISTIM DUO** detects any change in one of the 5 frequency or emission mode setting knobs and stops stimulation immediately if it is active. The LEDs for the active channels light up continuously and the message "RESET THE CHANNELS TO ZERO" appears on the display.

The average power emitted by each channel of course depends on the current setting but also on the frequency and emission mode. Any change in these settings may cause a sudden increase in average power which can be painful for the patient.

Output current test

The output current test box supplied with your **AGISTIM DUO** can be used to check that the instrument and all of the cables used are operating correctly.

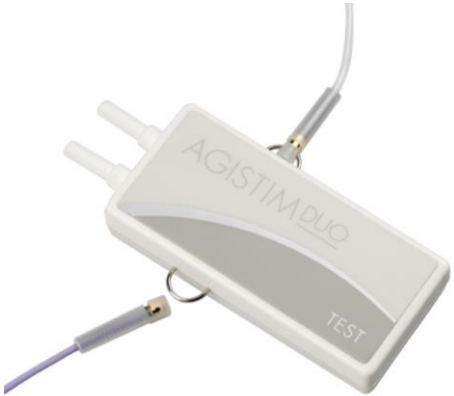
Connect the test box as shown in figure 7 depending on whether an device direct output current test or cable electrical continuity test is to be performed.

Then switch the instrument on and choose the settings as described in the previous paragraphs (figures 3, 4 and 5).
Turn the current intensity adjustment knob (figure 6). The test box then emits an audible signal with each output current pulse. The sound will be emitted at the same frequency as the output current and will be more or less intense depending on the intensity settings. All of the features of the current emitted by the **AGISTIM DUO** can be tested this way.
When the test box is connected through a cable it is recommended that the whole length of the cable be checked by handling during the test to ensure that it has no conduction defects.

Electrode cable testing.

Needle cable and
"4 needle modules" testing

Note: it is normal for the sound to be less loud in the "4 needle modules" test as the energy is divided between the two pairs of needles. The other parameters are unchanged.



Mainbox output current testing

Figure 7: CONNECTING THE TEST BOX

Maintenance

Your **AGISTIM DUO** does not require any specific maintenance and can be cleaned with a cloth soaked in alcohol.

If it has not been used for a long time or if there is an impending storm **(in which case the instrument must not be used**), we always recommend that you disconnect the supply from the mains.

The needle or electrode connection cables represent a compromise between thinness and robustness. Particular care is recommended with these in order to avoid tangling or knotting them, which could cause poor contacts.

List of accessories and part numbers

Material	**SEDATELEC part number**
Main power supply	AGIDUO-063
Needle connector (grey)	AGIDUO-011
Needle connector (pink)	AGIDUO-012
Needle connector (purple)	AGIDUO-013
Needle connector (green)	AGIDUO-014
Electrode connector cables	AGIDUO-02
Test box	AGIDUO-05

Accessories

Four reusable stimulation electrodes Ø 30 mm	AGIDUO-041
Lipolysis kit	AGIDUO-03
"4 Needle Module" grey	AGIDUO-031
"4 Needle Module" pink	AGIDUO-032
"4 Needle Module" purple	AGIDUO-033
"4 Needle Module" green	AGIDUO-034
Styl Module	AGIDUO-09

Your AGISTIM DUO must only be used with needles or electrodes carrying the CE mark.

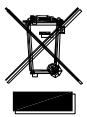
Note: A density of current higher than 2 mA RMS. /cm2 on the electrodes could cause redness. To avoid this problem, we recommend not to use electrodes of surface lower than 2 cm ²

Instrument recycling procedure

The following safety and environmental protection measures should be taken at the end of the devices life:

- The case of the **AGISTIM DUO** is made of polypropylene and contains polyurethane foam. This should be disposed of following the local procedure for plastics.

- The **AGISTIM DUO** main box is made of "A.B.S." plastic. It contains electrical components which should be recycled following the local procedure for disposing of electronic products.



Periodic technical safety tests

Like all class IIa diagnostic and therapeutic medical devices, your device must have technical safety tests at least every 24 months. These tests must be performed by people who can carry these out in the state of the art through their training, knowledge and experience without the need for specific recommendations before performing the tests.

- Visual examination:
  - of this user guide and the device booklet,
  - the entire device
  - all of the labels and writing: manufacturer's address, device number, setting and control instructions.
- Operating test according to the user guide
  - switching on
  - selecting frequencies and treatment modes,
- Energy emission test
  - duration and amplitude on a load of 1000 ohms,
- Technical safety tests
  - requirement to reset the channels to zero to change emission frequency or mode,

The user is responsible for checking that the instrument operates correctly by carrying out the periodic tests recommended by the manufacturer. SEDATELEC can do this testing for you at your request.

Appendix A: technical features

MANUFACTURER	SEDATELEC
NAME	**AGISTIM DUO**
CLASSIFICATION	Nerve and muscle electric stimulator - class IIa according to directive 93/42 EEC MD - class II according to the Canadian regulation of medical devices (DORS/98-282)
NUMBER OF CHANNELS	4 channels into two groups
STIMULATION CURRENT	No offset alternating pulsed current
Type of current	Asymmetrical rectangular
Pulse shape	0.4 ms.
Pulse duration	adjustable: from 1 to 9.9 Hz in steps of 0.1 Hz from 10 to 99 Hz in steps of 1 Hz or by selecting programmed NOGIER frequencies: 1.14 – 2.28 – 4.56 – 9.12 – 18.25 – 36.50 – 73 Hz.
Pulse frequency	

Pulse amplitude	Adjustable from 0 to 12 mA peak
Maximum intensity per channel	3.4 mA RMS on 1000 Ohm
Maximum voltage	95 V
SETTINGS	
Intensity	by channel: potentiometer
Emission frequency and mode	by a group of 2 channels: by switch and potentiometer
POWER SUPPLY	
Via specific safety supply	Input 100-240 ~Volts/ 50-60 Hz/ 250mA Output 24V⎓ /250 mA
MECHANICS	
External dimensions	60 x 230 x 300 mm
Total weight	1270 g
Classification of applied parts	BF Type 
Use and storage conditions	Between 0°C and 40°C, humidity < 70%

Conditions of Use

Temperature	between 0 °c and 40 °c
Humidity	> 30% and < 70%
Atmospheric pressure	70.0 kpa to 106.0 kpa

Storage conditions

Temperature	between-20 °c and 50 °c
Humidity	< 90%
Atmospheric pressure	70.0 kpa to 106.0 kpa

Appendix B: stimulation current

Current pulses

The electrical stimulation generated by the **AGISTIM DUO** is a **"constant current"**, i.e. the current intensity (I) remains constant with varying load impedance. Intensity is set independently on each channel at **between 0 and a maximum of 12 mA**.

Note: This is generally true although in some situations of electrode use the maximum current may become limited.

The current pulse is positive and negative, with a rectangular asymmetrical shape, and a width 0.4 ms. This is shown in FIGURE 8.

The positive and negative parts are defined by connections marked as (+) and (-) for each channel. This indicates that the current coming from the (+) needle or electrode to the (-) needle or electrode will take the shape of the positive part of the pulse shown in FIGURE 8. The current running the opposite direction in the circuit will be the shape of the negative part.

Pulses do not contain any offset. The positive energy of the pulse represented by the surface area under curve A1 is equal to the negative energy A2. This abolishes any charge accumulation in the electrodes or needles and therefore avoids the burns which could occur as a result.

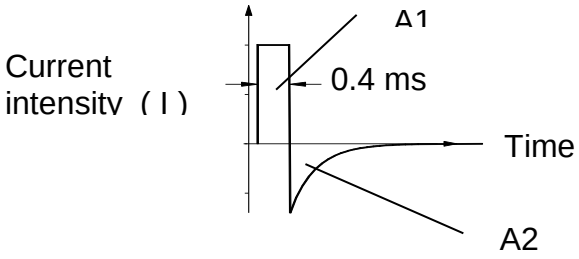


Figure 8: CURRENT PULSE

	Needle or electrode impedance (Ω)			
	200	500	1000	2000
Current pulse intensity at mid-setting (mA)	6	6	6	6
Current pulse intensity at maximum setting (mA)	12	12	12	12

Table 2: CURRENT ACCORDING TO LOAD AND SETTING

Pulse frequency

The current pulses are repeated between 1 and 99 times per second depending on the selected frequency. **This frequency can be set independently on each of the 2 groups** of channels using a range switch (knob 1e) and a adjustment potentiometer (knob 1f). The different possibilities for these are shown in FIGURE 9 and TABLE 3.

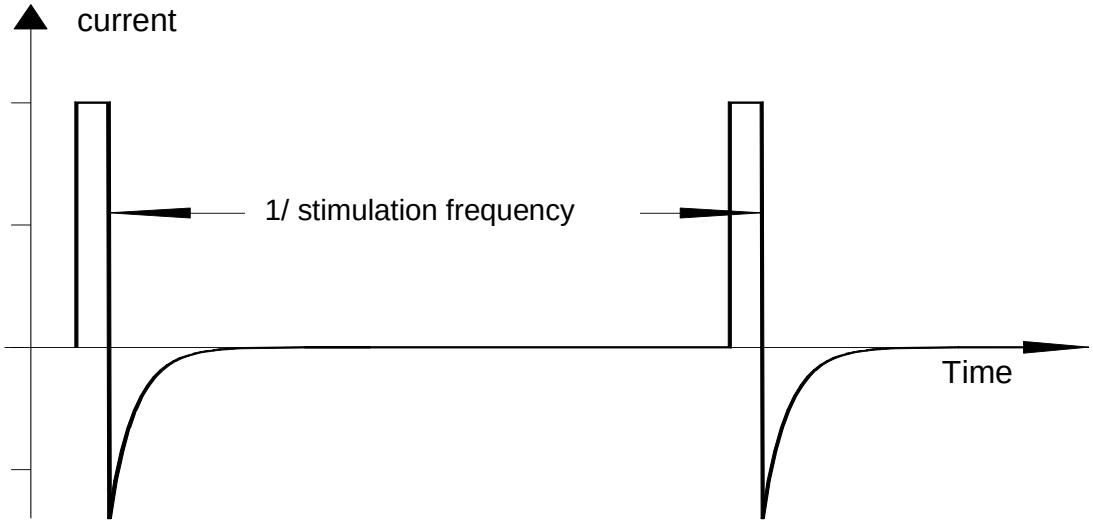


Figure 9: REPETITION FREQUENCIES

switch (1e)	Adjustment potentiometer (1f)
1 – 9.9 Hz	Free choice by steps of 0.1 Hz
10 – 99 Hz	Free choice by steps of 1 Hz
A – G A B C D E F G	Memorised Nogier frequencies 2.28 Hz 4.56 Hz 9.12 Hz 18.25 Hz 36.50 Hz 73 Hz 1.14 Hz

Table 3: FREQUENCY SETTING OPTIONS

Emitted energy

The electrical energy emitted through a channel depends firstly on the pulse intensity setting and also on the repetition frequency, emission mode and load impedance.
FIGURE 10 shows the maximum RMS intensity by frequency for a continuous emission mode at 3 impedance values. One thousand Ohms (1 000 Ω) is the typical impedance of the needle. Electrodes generally have an impedance of between 10,000 and 30,000 Ω. For emission modes with rest periods these values are reduced in proportion to the rest time: 12.5% for short rest times and 50% for long rest times. In scanning mode, intensity varies over time following these curves up to the frequency selected.

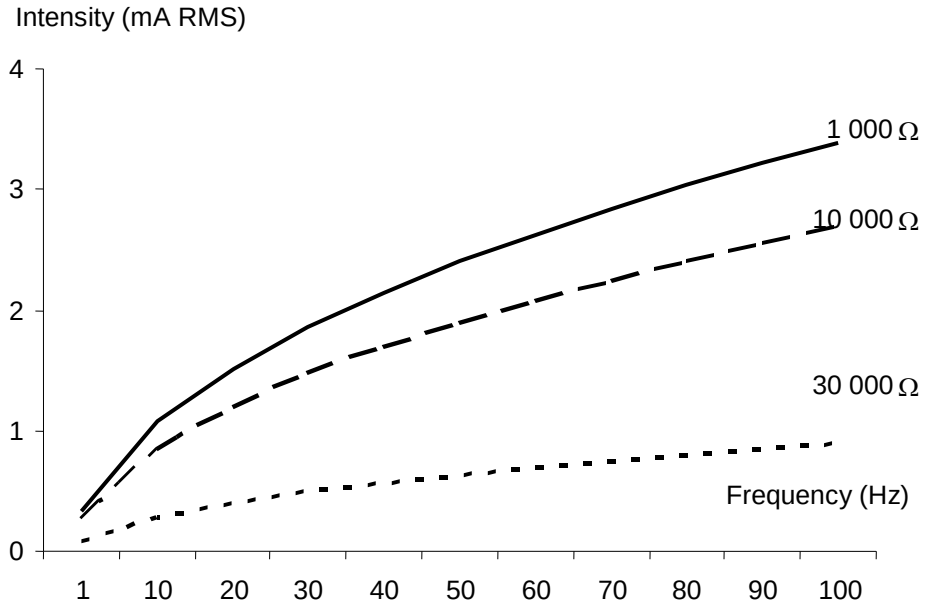


Figure 10: MAXIMUM RMS CURRENT ACCORDING TO FREQUENCY

Appendix C: troubleshooting

The green LED does not come on.	- Check that the safety supply is correctly connected to the main box and to the mains plug. - Switch on the start button (1b).
The green LED lights on but the display window does not light up or displays nonsense messages.	- Switch the instrument off and switch it on again after a few seconds.
After switching on, the message "RESET THE CHANNELS TO ZERO" appears in the display window.	- The device will only start if the stimulation current settings intensity knobs for all the channels are reset to zero.
Stimulation stops (the orange LEDs are continuously on) and the messages "TREATMENT TIME IS OVER" and "RESET THE CHANNELS TO ZERO" appear in the display window.	- Stimulation has finished correctly, reset all the channels to zero to move into setting mode or to repeat stimulation with the same settings.

Stimulation stops (the orange LEDs are continuously on) but the treatment time has not finished and the message "RESET THE CHANNELS TO ZERO" appears on the display window.	- Stimulation has been interrupted by turning the mode knob or one of the frequency adjustment potentiometers. Reset the intensities for all channels to zero, check the settings and gradually increase the intensity of the active channels again.
Stimulation stops (the orange LEDs are continuously on) but the treatment time has not finished and no setting knob has been turned.	- The instrument is in internal safe mode. Stop it completely and try again. If the problem persists the instrument will need to be repaired.

If you need to return your device for repair because of a persistent fault, please kindly return all of the parts (main box, supply, cables, etc.) together with a detailed description of the problem you have experienced.

Appendix D: bibliography

Bazzoni G., 1995, *Cafalea e Auricoloterapia,* G. italiano di riflessoterapia ed agopuntura, libreria Cortina, Torino, n°3, 107:116.

Chen A., Oct. 1992, An introduction to sequential electric acupuncture (SEA) in the treatment of stress related physical and mental disorders, Acupunct. Electroth. Res., 17(4), 273:283.

Cheng R. and al., 1980, *Electroacupuncture elevates blood cortisol levels in naive horses ; sham treatment has no effect*, International J. Neuroscience, vol. 10.

Comunetti A., Laage S., Schiessl N., Kistler A., 1995, *Characterisation of human skin conductance at acupuncture points,* Experientia, **51(4):**328-331**.**

Niboyet J.E.H., 1970, *La moindre résistance à l'électricité de surfaces ponctiformes et de trajets cutanés concordants avec les points et méridiens, base de l'acupuncture", Thèse de doctorat 1963 et Traité d'acupuncture*, tome 1, Maisonneuve France*.*

Vibes J. et al., 1997, *Effets de la stimulation électrique de neiguan (MC6) sur les taux plasmatiques de thromboxane A2 (TXA2) et de prostacycline (PGI2) et sur les activités thromboxane et PGI2-synthétases du cœur chez le lapin: relations avec le rôle dévolu à ce point d'acupuncture dans le traitement de l'angor pectoris*, Congrès FAFORMEC, Bordeaux, 12:19.

Wang B and Al., Aug. 1997, *Effect of the intensity of transcutaneous acupoint electrical stimulation on the postoperative analgesic requirement*, Anesth. Analg., 85 (2), 406:413.

Appendix E: Frequencies used by Dr Y. Meas
(According to Prof. Roques – Pain Management)

Site	Frequency	Intensity	Duration
Loco dolenti	80 Hz	Low (cotton bud sensation)	Effective during stimulation (e.g. suture)
Segmental control on metamere: nerve path, e.g. thumb C 6. If lesion is distal to stimulation	Scanning (modifies the lemniscal axes) 10 Hz – 80 Hz or 20Hz – 80 Hz	Clear sensation	Immediate Prolonged effect for 15 minutes
Supra-segmental, e.g. L4 - L5 crural disc hernia. Two levels above the cause of the pain (inter-neurones) For sciatica: level L 2 (V 23 Right and L.)	Scanning 10 Hz – 100 Hz	Clear sensation	Immediate. Prolonged effect for 15 minutes
Endorphine (analgesic) Heterotopic with respect to stimulation	1-2 Hz to 10 Hz	Offset scanning usually random, e.g. 1, 2, 3, 4, 5, 1, 4, 8 etc. and if possible obtain motor action (if puncture is peripheral)	Just below the pain sensation (e.g. ear point painful on palpation) Unpleasant sensation

Appendix F: electromagnetic compatibility and manufacturer's declaration

The **AGISTIM DUO** conforms to the standard 60601-1-2, 2014

– recommendation

The **AGISTIM DUO** is suitable for the use in all establishments, including domestic premises and those connected directly to the low voltage mains electricity supply supplying domestic buildings

– electromagnetic emissions

The **AGISTIM DUO** uses only RF energy for internal functioning. As a result its RF emissions are extremely low and are not liable to cause interference in a nearby electronic instrument.

– electromagnetic immunity

The **AGISTIM DUO** is sensitive to electrostatic, between 6Kv and 15Kv, air and contact. The display can be disrupted. In this case turn off then back off the **AGISTIM DUO**.

The **AGISTIM DUO** is designed to be used in the electromagnetic environments described below. The client or user of the **AGISTIM DUO** should ensure that it is used in such an environment.

Flooring should be wood or tiled. If floors are covered by synthetic material, relative humidity should be at least 30%.

The **AGISTIM DUO** is designed to be used in an electromagnetic environment in which RF interference is controlled. The client or user of the **AGISTIM DUO** can prevent electromagnetic interferences by keeping a minimum distance between portable RF communication equipment and the **AGISTIM DUO** as recommended below depending on the maximum power emitted from the equipment in question.

Portable telecommunications or mobile RF equipment should not be used close to the **AGISTIM DUO** either the main box or the cables or within the recommended separation distance calculated from the emitter frequency equation.

In the case of drop of tensions, short breaks and changes in supply voltage power quality must be identical to the commercial or hospital environment. If the user of the product needs a continuous during power failure operation, it is recommended that the unit be powered by backup power (inverter type)

Device booklet

Type of device: **AGISTIM DUO**		Inventory number:	
Device number:		Date of manufacture:	
Manufacturer:	**SEDATELEC** Chemin des Mûriers F-69540 IRIGNY		
Supplier/Distributor:			
Year acquired:		Place:	
Manufacturer's authorisation number:	**CE 0123 - TÜV product service**		

COMMISSIONING

Date	Manufacturer/Distributor	Approved senior person

STAFF TRAINING

The users below declare that they have read the user guide and have the necessary information to use this device.

Date	Trained user	Signature

VISUAL EXAMINATION

Date	Performed by	Comments

OPERATIONAL TEST ACCORDING TO USER GUIDE

Date	Performed by	Comments

ENERGY EMISSION TEST

Date	Performed by	Result	Comments

TECHNICAL SAFETY TEST

Date	Performed by	Comments

PERSISTENT BREAKDOWN OR OPERATING ERRORS

Date	description of problem and consequences

Your **AGISTIM DUO** is a particularly high performance electrical stimulator allowing you to stimulate up to 8 or even 16 points simultaneously through 4 channels, divided into 2 independent groups. You can adjust the intensity and frequency of the pulses on each channel, use a continuous or alternating emission mode and stimulate through needles or electrodes.

All electro-acupuncture applications from classical point stimulation to mobilising endorphins to reduce pain are at your fingertips with a few simple adjustments combined with complete safety to protect your patient.

Your **AGISTIM DUO** will provide you with many years of effective everyday practice.

Your Local Agent

Sedatelec®
YOUR WAY OF CARE, OUR QUALITY DEVICES

Chemin des Mûriers • F-69540 IRIGNY – LYON • France
Tel +33 (0)472 663 322 • Fax +33 (0)478 508 903 • sedatelec@sedatelec.com