

SleeperOne ⑤

INSTRUCTIONS FOR USE

 **WARNING:** Read before first use



Version_EN_NUSMILE_V04
Date of publication: 2024-03-11

Dentahitec

Deliver the best anesthetics





WARNING [ESSENTIAL TO READ BEFORE USING]

ELECTRIC SHOCK PROTECTION

- The installation must have a circuit breaker security system.
- Before any use, check the condition of the cable and the power supply cable.
- Do not pull the cable to remove the plug from the electrical outlet.
- The connection must be made on a single phase alternating current supply.
- The supply connection serves as a disconnection point and must remain accessible.

MAINTENANCE AND USE

- If there is an incident in connection with SleeperOne5™ which would endanger the health of the user, a patient or any other person, Dentalhitec must be notified without delay (either directly or through one of its dealers) as well as the relevant local health authority in the country where the incident occurred.

RULES OF USE

- For safety reasons, do not screw/unscrew the needle near the patient and equip them with protective glasses.

CONTAMINATION & DISINFECTION

- Needles and anesthetic cartridges are for single use and must be destroyed in a clinical incinerator provided for this purpose and refer to the instructions of their manufacturers.
- Containers must be disinfected and sterilized before each anesthesia (see procedures pages 15 and 16).
- The holder and the handpiece must be disinfected after each patient (refer to the indications of manufacturers of disinfectant products).
- Do not leave needles without protection.

BREAKAGE AND OBSTRUCTION OF NEEDLE

- Refer to the notices of needle manufacturers to avoid accidental needle breakage.
- In any case, never bend a needle.
- In the event of a blocked needle, SleeperOne5™ will not be adversely affected. Replace the needle with a new one.



CAUTION

GENERAL RECOMMENDATIONS

- Do not expose SleeperOne5™ to:
 - The sun, near a radiator or air conditioner.
 - Water and chemicals.
 - Flammable mixtures of air, oxygen or nitrogen.
- The voltage of the external power supply must be the same as that indicated on the signage plate of the power supply.
- Always wear single-use surgical gloves when handling and using SleeperOne5™ clinically.

MAINTENANCE AND USE

- It is prohibited to modify SleeperOne5™ without the authorization of Dentalhitec. If it were to be modified, the modification must be made by a repairer approved by Dentalhitec, or by the Technical Service of Dentalhitec. An appropriate control and test must be carried out to ensure that the device is always safe to use. SleeperOne5™ should not be connected to other devices. Such use remains the responsibility of the user.
- It is advisable not to use Portable RF communication devices (including peripherals such as antenna cables and external antennas) closer than 30cm (12inch) to any part of SleeperOne5™, including cables that we specify, otherwise the performance of the device could be altered.

- The use of accessories, transformers and cables other than those specified or supplied with SleeperOne5™ can cause an increase in electromagnetic emissions or a decrease in its resistance to interference and cause incorrect operation.
- In some cases where it is necessary for SleeperOne5™ to be used next to or stacked with other devices, and it is not possible to do otherwise, SleeperOne5™ should be monitored to verify this normal operation (in the envisaged configuration).

ANESTHESIA AND CONSUMABLES USED

It is the users responsibility to systematically ensure that their clinical approach is well founded and takes into account the undesirable side effects or contraindications defined in the notices of pharmaceutical products and the needles used. The user must use SleeperOne5™ in this context, as well as in accordance with the regulations applicable to them and current scientific knowledge.

In addition to their clinical experience, the practitioners must refer to the notices of pharmaceutical products (especially for injection speed) and needles to adapt the injection to the characteristics and pathologies of the patient.

MATERIAL IN CONTACT

Containers contain polysulfone.

INTRODUCTION

PLANNED USE

Electronically controlled administration of a local anesthetic for dental care.

CLINICAL BENEFITS

Achievement of local anesthesia with less pain felt by the patient.

The reduction of stress leads to better patient cooperation.

CLINICAL PERFORMANCE

Delivery of any type of local dental anesthesia.

Painless injection of local anesthetic for dental care.

Promotes patient cooperation (because less anxiety related to the injection process).

TECHNICAL PERFORMANCE

Electronically controlled local anesthetic delivery system.

Injection controlled by the foot.

Ergonomic pen grip with support.

Aspiration system.

Information on the electronic interface (selected injection speed, resistance to the injection).



WARNING

USER

SleeperOne5™ should be used only by qualified dentists who are suitably trained and authorized to carry out loco-regional dental anesthesia in the oral cavity. SleeperOne5™ must always be used under the control of its user.

TARGET PATIENT POPULATION

SleeperOne5™ should only be used in adults and children from 4 years old. Refer to the Instructions For Use for injected anesthetic products concerning the dosage, warnings and precautions according to the age and state of health of the patient.

INDICATION

Dental pathology requiring local anesthesia for treatment.

CONTRAINDICATIONS

Refer to dental anesthetic injectable solutions manual and needle manual.

The use of SleeperOne5™ for intraosseous anesthesia is contraindicated when the patient's bone characteristics in relation to their growth are likely to prevent easy penetration of the needle. The user must ensure, regarding state of the art technology, that the practice of the local anesthesia is not contraindicated with the patient characteristics.

ADVERSE SIDE EFFECTS

No adverse side effects specific to the use of SleeperOne5™ have been identified. However, the undesirable effects presented in the instructions for the products injected and the needles used should be taken into account.

USE OF THE PRODUCT

It is not possible for Dentalhitec to warn the user about every possible danger related to use of the product. The user must use his or her own common sense and good judgement when using the product.

- The practitioner can view an online version of the Manual on the Dentalhitec website in the event that he ever loses his/her copy or in the event that Dentalhitec updates the Manual. Dentalhitec retains the right to modify the Manual as it deems appropriate.

- The practitioner is charged with the knowledge of the modifications set forth in the Manual.

See new version if available : www.dentalhitec.com/mydht Section "Support"

Notice you have to log in and use your password to get access.

N.B. : Your device is identified by a SN serial number **SN**

They are present under the control box, on the back of the foot pedal, and on the packaging box. The format to be entered on www.dentalhitec.com/mydht/ is: S5xxxxxxx

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GENERAL PRESENTATION



WARNING: Clean and sterilize before use [see p.15].

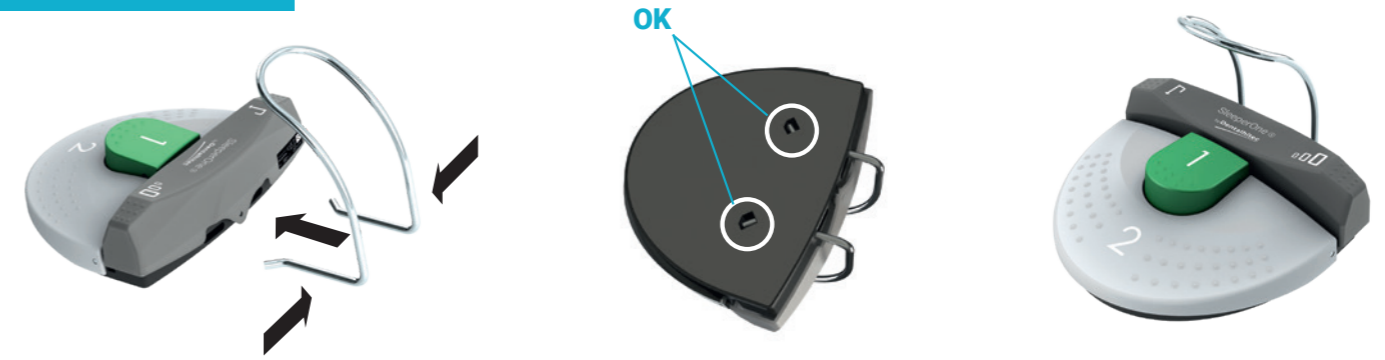
CONTENTS

- 1 Handpiece and control box
- 1 Wireless pedal
- 1 Pedal hoop
- 1 Handpiece holder
- 1 Pack of sterilisable accessories

- 1 Options key
- 1 Power supply
- 1 Power cord
- 1 Pack of consumables, available according to the country
- 1 Documentation pack

ASSEMBLY

WIRELESS PEDAL



HANDPIECE HOLDER

The handpiece holder is designed to be mounted either to the right or to the left on a flat surface.

WARNING: The holder must never be fixed on a surface directly above the patient to avoid any injury in the event of the handpiece falling. Use only Dentalhitec handpiece holder under penalty of damage not covered by the warranty (list of handpiece holder available P.17).



ASSEMBLY

CONTROL BOX

The box can be placed under your dentist/nurse element, in your unit or on the side of a piece of furniture for example.
It is possible to fix the box using the removable adhesive strips [provided] or to suspend it with the integrated 'eye'.
It is advisable to wait at least 2 hours before detaching the control box using fingers or a flat instrument, otherwise the adhesive strips will come off.

NOTICE: For good communication between the box and the wireless pedal, avoid obstacles, especially metallic ones (PC, box, etc.) between the box and the pedal. Do not attach/place the box on an electronic device (computer, etc.).



Ideally, wait 12 hours for optimal adhesion.



Mounting with adhesive strips

Alternative: suspend with a lanyard

Connect the power supply to the SleeperOne5™ at the back of the control box.
Connect the power supply to the mains socket.

The SleeperOne5™ turns on by default in medium speed (pink light).



6

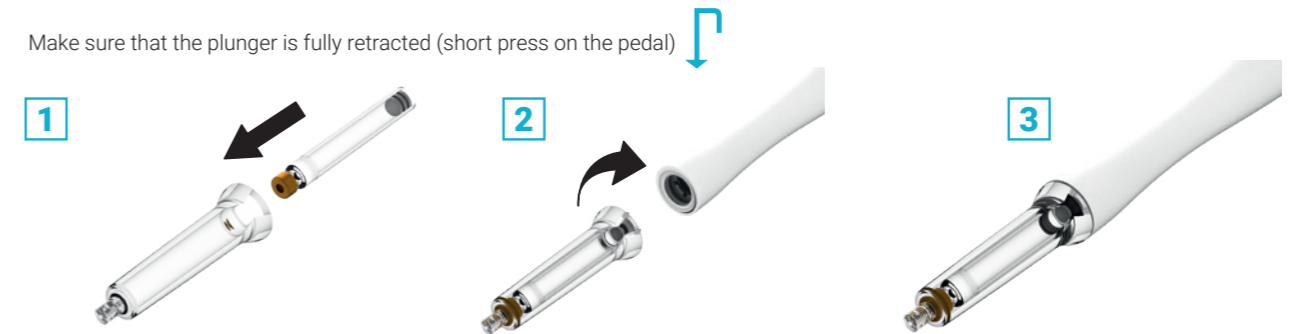
USE

Assembly of the handpiece - cartridge - container - needle

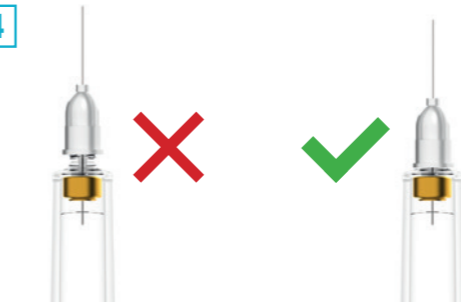
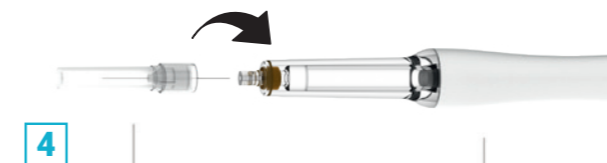
CAUTION:

- Use cartridges with plastic film which reduce the chances of breakage.
- Use only new 1.7ml or 1.8ml ISO 11499 compliant cartridges.
- Use only sterile dental needles conforming to ISO 7885.
- Check that the container is in good condition before each use (absence of cracks or other signs of degradation).
- If any damage is noticed, please replace the container.

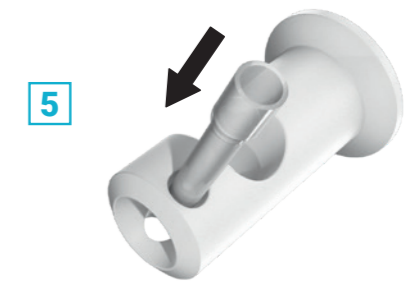
WARNING: The containers must be cleaned and sterilized in accordance with the procedure on p.15 BEFORE EACH USE.



Take a sterile container.
Place a new cartridge in the container.
Screw the container onto the body of the handpiece.



Screw the needle completely onto the container and ensure that it is firmly in place.



When you are ready to work, remove the needle cap and insert it in the cap holder of the handpiece holder.

7

USE

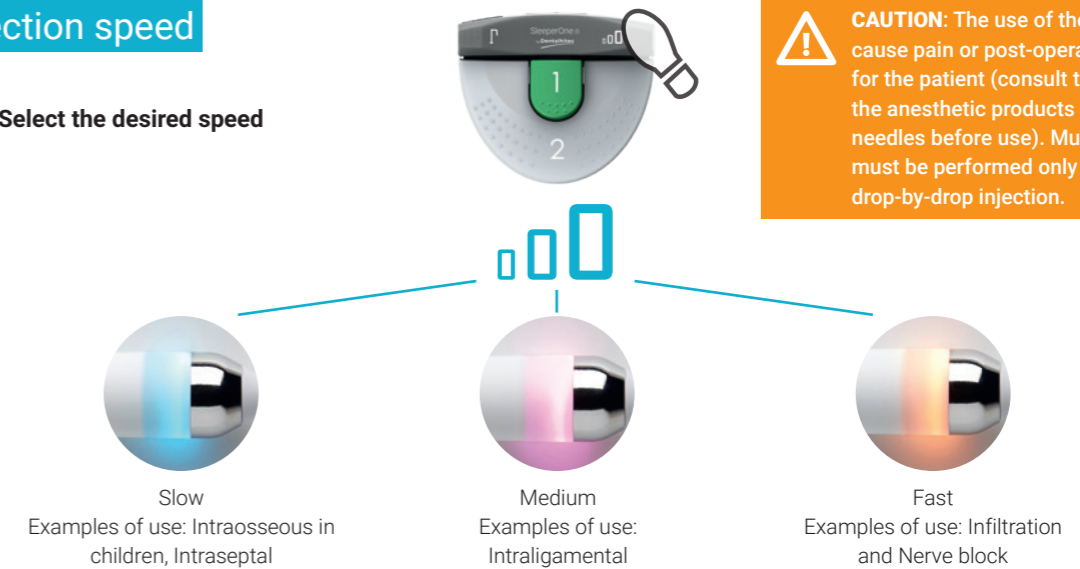
Wireless pedal - detailed illustration



USE

Injection speed

1 Select the desired speed

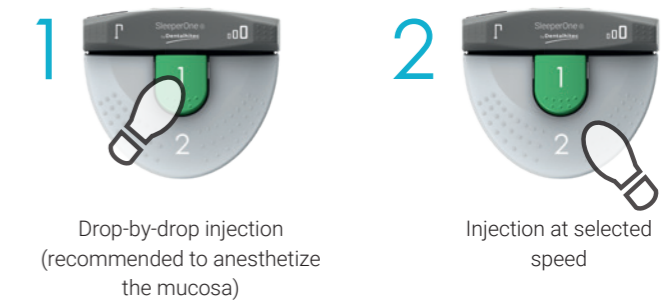


CAUTION: The use of the Fast speed can cause pain or post-operative consequences for the patient (consult the instructions for the anesthetic products injected and the needles before use). Mucosal anesthesia must be performed only by continuous drop-by-drop injection.

2 Inject

Activate the injection by continuously pressing the pedal. This operation can be modified in the OPTIONS section (see p.12).

CAUTION: CHECK BEFORE EACH USE.
- Make sure that the injection speed selection has been chosen correctly.



Quantity injected

The quantity actually injected is visible through the transparent container. Beeps are emitted, as an indication, in order to provide information on the quantity injected. At the end of a full cartridge injection, the plunger automatically returns to the initial position.

Number of beeps	Cartridge
1	1/4
2	1/2
3	3/4

USE

Resistance to the injection

During injection, the rate of the indicator light flashing increases if the resistance to injection increases.
In the event of too much resistance, the device goes into safety mode: emission of a long beep and stopping of the injection.

CAUTION:

- In Slow and Medium speed settings, the speed does not increase if it encounters significant resistance to injection (modifiable speed see OPTIONS).
- If the pressure is too high, the injection stops automatically to avoid the risk of cartridge breakage and an audible signal is emitted.



Aspiration

If the users, based on their training and clinical experience, believe that aspiration should be performed, they must ensure the following:

- Select Fast speed.
- Inject a minimum and sufficient quantity to be able to enable an aspiration (1/8 of a cartridge is an example).
- Press continuously on the upper left pedal.
- Stop pressing when the user has observed the result of the aspiration.



CAUTION: Before each anesthesia requiring aspiration, check that the plunger seal is present and in good condition.

Plunger return



When the required volume has been injected, briefly press the return button to return the plunger to its original position.
At the end of a full cartridge injection, the plunger automatically returns to the initial position.

USE

WARNING: To avoid any risk of needlestick injury, systematically recap the needle using the handpiece holder or directly into a sharps container in accordance with the regulations of the country.

Disassembly

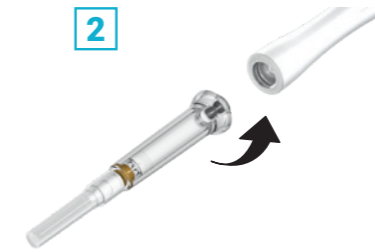
If the plunger has not returned to its initial position, briefly press the return pedal.

1



Resheath the needle using the cap holder in the handpiece holder.

2



Unscrew the container.

3



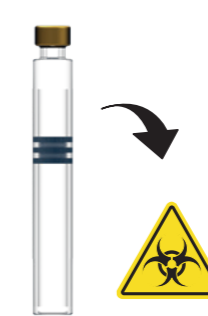
Unscrew and incinerate the used needle using a medical sharps container.

4



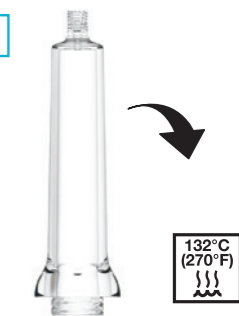
Remove the cartridge.

5



Put the used cartridge into a medical waste container.

6



Clean and sterilise the container as indicated in the maintenance instructions.

Sleep mode

If the device remains inactive for more than 30 seconds, the indicator light dims.
When the plunger is in the initial position and after 10 minutes of inactivity, the indicator light on the handpiece switches off and SleeperOne5™ goes into sleep mode (totally off).
Press and release a button on the pedal to wake SleeperOne5™.

USE

Options

Alternative curves can be selected for each mode.
Use the options key stored in the control box.



Select the injection mode to be modified (see page 8).

By default, curves **a** — are activated.

Press the **a→b** button to change curve.

Emission of two beeps, changed to curve **b** - - - - .

Emission of a single beep, returned to curve **a** — .

The  button is reserved for Dentalhitec or an authorized repairer.

USE

Modification of injection speed



CAUTION: The choice of injection speeds is the responsibility of the user.

In addition to his clinical experience, the practitioner must refer to the instructions for pharmaceutical products (in particular for the speed of injection) and needles to adapt the injection to the characteristics and pathologies of the patient.

Using too fast a speed can cause pain or create postoperative consequences for the patient.

Mucosal anesthesia should be performed using drop-by-drop injection only.



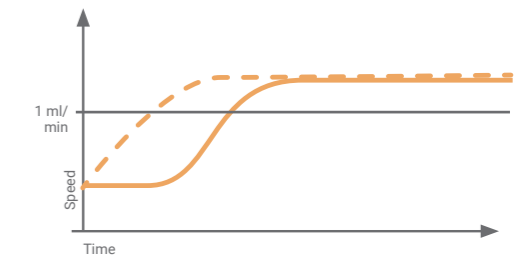
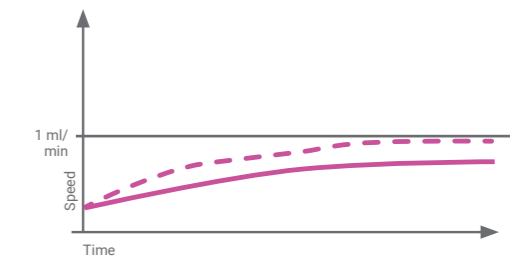
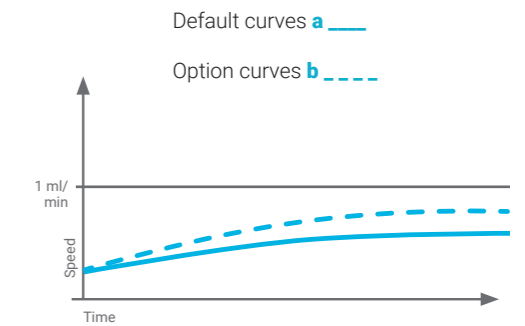
Slow speed
Examples of use: Intraosseous in children, Intraseptal



Medium speed
Examples of use: Intraligamental



Fast speed
Examples of use: Infiltration and Nerve block



EFFITEC NEEDLES*

Dentalhitec recommends the use of Effitec needles with SleeperOne5™. EFFITEC needles have a patented bevel and a specific base mark position for optimized penetration.

CAUTION: Follow the needle model according to the anesthetic technique performed to obtain maximum performance and avoid needle fractures or post-operative consequences. Consult the instructions for use present in the boxes before use and read the safety rules present in this user manual.

Effitec



Model of needle: Color:	30G - 16 mm White	30G - 9 mm Green	27G - 35 mm Grey
Infiltration	★		
Infiltration in attached mucosa	★	★	
Intraseptal adult		★	
Intraosseous child		★	
Intraligamentary		★	
Palatal	★	★	
Block injection			★

(*) EFFITEC needles are not available in all countries.

To be given to the person responsible for sterilization

WARNING: Clean and sterilize before each use. Do not put through a washer-disinfector

CONTAINERS
SleeperOne 5



WARNING: Systematically replace the containers after 50 cleaning/sterilization cycles or risk fracture during injection.

Container cleaning instructions

Initial handling	Isolate the used containers in a temporary storage area for instruments before sterilization (dirty area)	
Cleaning / Disinfection	Clean by immersion, place the container in a disinfectant bath for hand and rotary dental instruments with the use of ultrasound for 4 minutes. Follow the concentrations and temperatures indicated by the disinfectant manufacturer.	
Rinsing	<ul style="list-style-type: none"> Run the container under demineralised water for 1 minute, brushing with a soft bristle brush Soak for 10 minutes in demineralized water Make sure there is no dirt on the container Spray the container with demineralized water (using a wash bottle) Dry the container using a lint-free cloth (or compressed air of class [2,4,2] according to ISO 8573-1) 	
Bagging	Seal the container in a sterilization envelope conforming to standard ATM F88	
Sterilization	<ul style="list-style-type: none"> Sterilize with a class B steam sterilizer Sterilization time of a minimum of 4 minutes at 132°C / 270°F 	

WARNING:

- Make sure that the container is dry and that the indicator on the sterile envelope turns to the color indicated for the positive control of sterility
- Store sterile products in a dry and dust-free place
- For the different steps, follow the standard directives and guidelines specific to your country
- Place unservicable containers in a device for medical waste



MAINTENANCE

Control box and Wireless pedal

- 1 Disconnect the power plug before cleaning.
- 2 Clean these components with a clean cloth and an alcohol solution.
- 3 Never use strong solvents or harsh chemicals.

WARNING:
Never sterilize the control box or the pedal.
Never immerse the control box or the pedal in any liquid.

Handpiece and handpiece holder

- 1 Disinfect these two parts after every patient.
- 2 Clean these parts with a clean cloth and an alcohol solution.
- 3 Use suitable disinfectants for this purpose.

WARNING:
Never sterilize the handpiece.
Never immerse the handpiece in liquid.

CAUTION: carry out a preliminary test to ensure that the product used does not damage the surface of the part to be cleaned.

Repairing the device

In the event of a problem, contact your authorized distributor or the registered office of Dentahitec.

After-sales service: Tel.: +33 (0)2 41 56 42 04
@ sav_ext@dentahitec.com

Conditions of Warranty

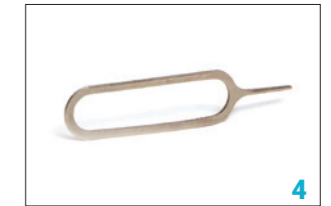
SleeperOne5™ is covered by the manufacturer's warranty.
For the terms and conditions of the guarantee, refer to the general conditions of sale or to the information present in the packaging.

REPLACEMENT PARTS

You can order the following accessories by contacting your distributor or Dentahitec (see www.dentahitec.com).

(Telephone : +33 (0)2 4156 16 16 or mail@dentahitec.com)

1. Container..... Ref. SA7600
2. Power supply..... Ref. M0146 or M0148
3. Power cord..... Ref. M012X
4. Options key Ref. SA6785
5. Control box lanyard..... Ref. SA7070
6. Removable adhesive strips Ref. SA7060
7. Handpiece holder Ref. SA7500
8. A-dec adaptor..... Ref. SA7760
(Other adapter models available at www.dentahitec.com)



TROUBLESHOOTING

Fault code	Problem	Causes	Solutions
01	Appearance of white marks or cracks on the containers.	Protocol not respected or too many sterilization cycles.	Replace the container and review the cleaning / sterilization methods (see maintenance procedure).
02	The handpiece does not work	Fall	Do not use. Contact Dentahitec or your authorized Dentahitec dealer.
03	The handpiece does not respond to a push of the pedal	Local electromagnetic disturbances.	Contact your dealer or the Dentahitec after-sales service. Keep devices likely to interfere with the radio signal (mobile phone, etc.) away.
04	No injection and emission of an audible signal.	Injection into very resistant tissues.	• Change injection site. • Inject more slowly.

APPENDICES

Miscellaneous information

- The class of protection against electric shock is type BF.
- The class of protection of the pedal is IPX1.
- SleeperOne5™ should not be used in an oxygen rich environment.
- The pedal is of the SleeperOne5™ type.



This appliance must not be disposed of with household waste.

It contains hazardous substances, which can have significant consequences for the environment and human health. It must be recycled in a specific treatment facility.

If you are concerned by the European WEEE directive, please contact your distributor or Dentahitec, who will take all of the necessary steps to enable you to have your device collected and recycled.

CE: Declaration of conformity

We declare on our own responsibility that this product complies with community regulatory provisions.

As part of product improvement, Dentahitec reserves the right to make changes to its products without notice.



Dentahitec
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FRANCE

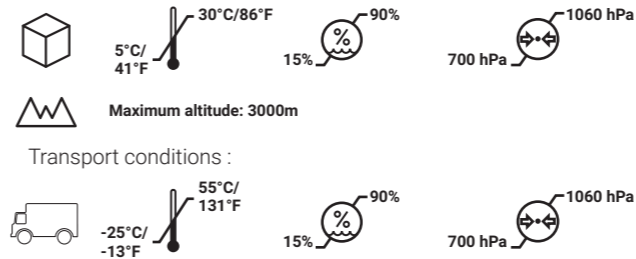


Tel.: +33 (0)2 41 56 41 91
mail@dentahitec.com

APPENDICES

Technical data sheet

Name: SleeperOne™ Model: 5
Device classification: IIA
Rated voltage: AC 100-240V 50/60Hz
Conditions of use and storage:



Power supply included in the device:
M0146: 24VDC 36W Mean Well GSM36B24
or,
M0148: 24VDC 42W MASCOT 3321-24

Characteristics of the radio transmitter:

Frequency / Transmission power:
902 MHz (Type C) / max. 10mW EIRP
Data rate / Bandwidth / Modulation type:
120 kbps / 280 kHz / ASK

Dimensions

Handpiece: Diameter: 21.5 mm Length: 175 mm Weight: 65 g
Control box: Length: 66mm Width: 65.8mm Height: 21.7mm
Weight: 73g
Pedal: Length: 200mm Width: 205mm Height: 150mm Weight: 700g

Applied part (needle + container):



Essential performance

The essential performances identified for SleeperOne5™:

- Injection must stop when the user releases the injection buttons of the wireless pedal.
- Prevention of untimely triggering of an injection.

In exceptional cases, electromagnetic interference may result in failure to comply with these performance criteria.

If the injection does not stop, we recommend that you remove the handpiece from the injection site and briefly press the injection button. If the injection does not stop, unplug the power cord.

To stop any untimely injection, briefly press one of the injection buttons.

If these problems appear, make sure that the distances between SleeperOne5™ and equipment likely to cause electromagnetic disturbances are respected (see tables and recommendations p.20, 21 and 22). Contact your dealer if problems persist.

APPENDICES

Electromagnetic compatibility

NOTICE:

- Use of accessories, transducers, and cables other than those specified or supplied by the manufacturer of this device may result in increased electromagnetic emissions or decreased immunity of this device and may result in improper operation.
- Portable RF communications devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the SleeperOne5™, including specified cables by the manufacturer. Otherwise, the performance of these devices may be affected.

SleeperOne5™ is intended for use in an electromagnetic environment where the electromagnetic disturbances are controlled and defined in Tables 1 and 2.

The customer or the user of the device should ensure that it is used in an environment as described and prevent interference by maintaining the minimum distance between RF (portable) communications devices (transmitters) and SleeperOne5™ as recommended in Table 3, depending on the transmit power of the communication device.

Table 1. MANUFACTURER'S GUIDELINES AND DECLARATIONS - ELECTROMAGNETIC EMISSIONS

SleeperOne5™ is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - Directives
RF emissions CISPR 11	Group 1	The SleeperOne5™ uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SleeperOne5™ is suitable for use in all premises, including domestic premises and those directly connected to the public low-voltage power supply network supplying buildings used for domestic purposes.
Harmonics transmission IEC 61000-3-2	Class A	
Voltage variations / Flicker Emissions IEC 61000-3-3	Compliant	

APPENDICES

Table 2. Guidance and Manufacturer's Declaration - ELECTROMAGNETIC IMMUNITY

SleeperOne5™ is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – Directives
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	
Transient overvoltage IEC 61000-4-5	± 1 kV for input/output lines ± 2 kV common mode	± 1 kV for input/output lines ± 2 kV common mode	
Voltage drops, short interruptions and voltage variations on input power-supply lines. IEC 61000-4-11	< 5% UT (> 95% dip in UT) for 0.5 cycles < 5% UT (> 95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25 cycles (50 Hz) 70 % UT (30 % dip in UT) for 30 cycles (60 Hz) < 5 % UT (> 95 % dip in UT) for 250 cycles (50 Hz) < 5 % UT (> 95 % dip in UT) for 300 cycles (60 Hz)	< 5% UT (> 95% dip in UT) for 0.5 cycles < 5% UT (> 95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25 cycles (50 Hz) 70 % UT (30 % dip in UT) for 30 cycles (60 Hz) < 5 % UT (> 95 % dip in UT) for 250 cycles (50 Hz) < 5 % UT (> 95 % dip in UT) for 300 cycles (60 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the SleeperOne5™ requires continued operation during mains power outages, it is recommended that the SleeperOne5™ be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the main supply voltage before applying the test level

APPENDICES




































Manufacturer's Declaration And Directives – ELECTROMAGNETIC IMMUNITY			
The SleeperOne5™ is intended for use in the electromagnetic environment specified below. The user of the SleeperOne5™ should ensure that it is used in such an environment.			
Immunity test	IEC 60601-1-2 - Test level	Compliance level	Electromagnetic environment – Directives
Conducted RF disturbances IEC 61000-4-6	3 V rms 150 kHz to 80 MHz outside of ISM bands 6 Vrms within ISM and amateur radio bands	3 V rms	Portable and mobile RF communications equipment should be used no closer to any part of the SleeperOne5™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,17\sqrt{P}$ $d = 1,17\sqrt{P}$ 80 MHz to 800 MHz $d = 2,33\sqrt{P}$ 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur near equipment marked with the following symbol: 
Radiated RF disturbances IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, will not cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SleeperOne5™ is used exceeds the applicable RF compliance level above, the SleeperOne5™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or repositioning the SleeperOne5™. b) Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.			

Table 3 - Recommended separation distances between portable and mobile RF communications equipment and the SleeperOne5™			
The SleeperOne5™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of SleeperOne5™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and SleeperOne5™, as recommended below, according to the operating power, maximum emission from the communication devices.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz · d = 1.17√P	80 MHz to 800 MHz · d = 1.17√P	800 MHz to 2.7 GHz · d = 2.33√P
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33
For transmitters rated maximum transmit power not given above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum transmit power rating of the transmitter in watts (W), according to the manufacturer of the transmitter. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.			

APPENDICES

Symbols used

	Applied part of type BF		Manufacturer		Date of manufacture		Instructions for use		Follow the instructions for use
	WARNING		Catalogue reference		Batch code		Serial number		Radio transmitter
	Keep away from sunlight		Temperature limit		Humidity limit		Atmospheric pressure limit		Do not use if the packaging is damaged
	Class II device		Pedal		Sterilization at 132°C (270°F)		UDI Unique device identification		Biohazard: Incinerate in accordance with protocol for infectious waste
	Altitude		Transport conditions		Charger and power supply		Ultrasonic bath		Medical device
	50 Sterilization cycles		Storage conditions		Telephone		Email		Disinfectant for dental instruments hand and rotary
	Alternative curves option		Maintenance reserved for Dentahitec or authorized repairer		Keep dry		CE marking 0459		



Risk of death, serious bodily injury, or serious property damage



Risk of minor or moderate injury to the user or patient or damage to the equipment or other property



Information considered important but not hazard related

SleeperOne [®]5

For further information, contact our advisors:

Customer service: +33 (0)2 41 56 41 91

or export@dentalhitec.com

After-sales service: +33 (0)2 41 56 42 04


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Dentalhitec


Deliver the best anesthetics



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