SleeperOne ⑤

INSTRUCTIONS FOR USE

⚠ WARNING: Read before first use

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Dentalhitec
The future of dental anesthesia

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 Denthalitec 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.

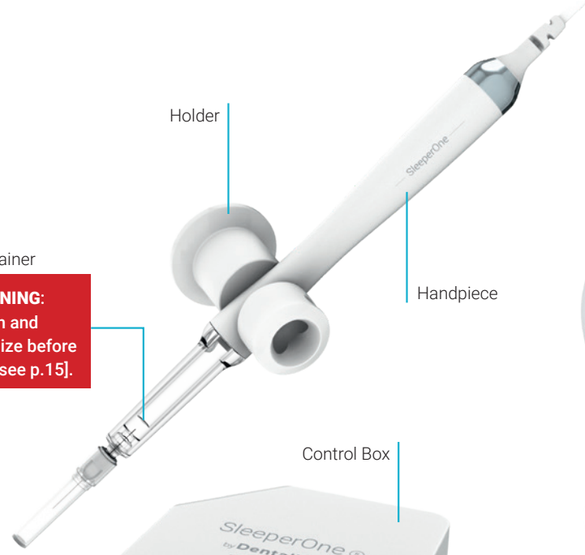
- The practitioner can view an online version of the Manual on the Dentalhitec website in the event that he ever loses his/her copy or in the event that Dentalhitec updates the Manual. Dentalhitec retains the right to modify the Manual as it deems appropriate.
- The practitioner is charged with the knowledge 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: S5xxxxxxxx

CONTENTS

GENERAL PRESENTATION



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

Mean Well GSM36B24 Power Supply (M0146)

OR

Mascot Power Supply 3321-24 (M0148)

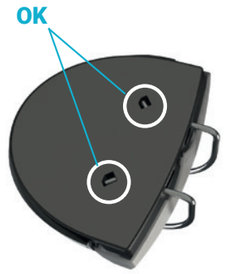
WARNING: Use only with the power supply and cable provided.

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.

1

Clean the bonding surface with the wipe provided.

2

3

Press against the flat surface

1 minute

4

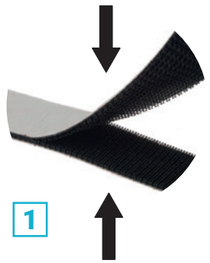
Make sure that the support is well fixed before installing your handpiece on it.

ASSEMBLY

CONTROL BOX

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.).

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.


1


2


3

4

Ideally, wait 12 hours for optimal adhesion.

5

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

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

Make sure that the plunger is fully retracted (short press on the pedal)

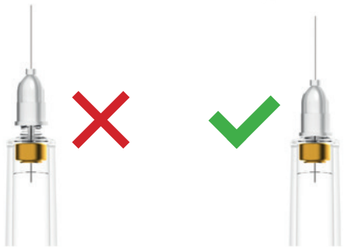
1

2

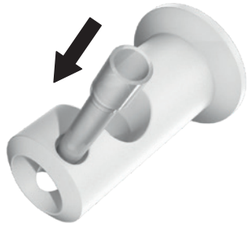
3

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


4



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


5

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

USE

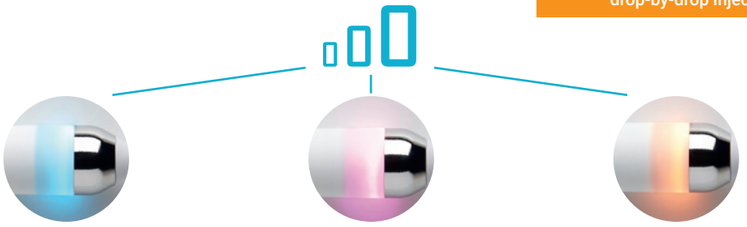
Wireless pedal - detailed illustration

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.



Slow
Examples of use: Intraosseous in children, Intraseptal

Medium
Examples of use: Intraligamental

Fast
Examples of use: Infiltration and Nerve block

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.

1

Drop-by-drop injection (recommended to anesthetize the mucosa)

2

Injection at selected speed

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

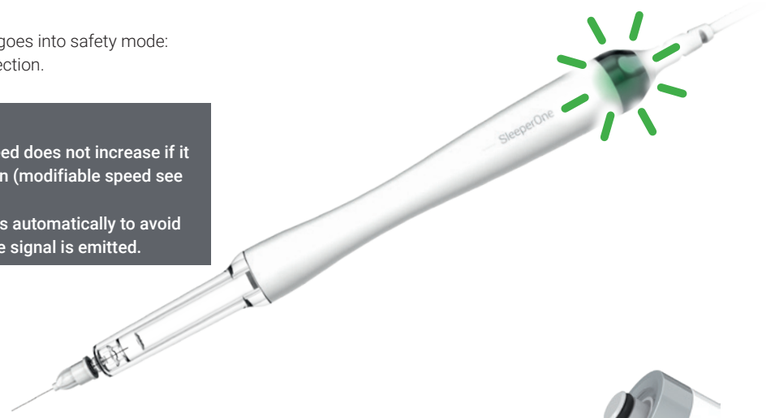
USE

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.

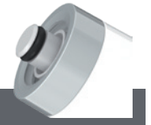
NOTICE:
- **In Slow and Medium speed settings, the speed does not increase if it encounters significant resistance to injection (modifiable speed see OPTIONS).**
- **If the pressure is too high, the injection stops automatically to avoid the risk of cartridge breakage and an audible signal is emitted.**



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.



NOTICE: 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.

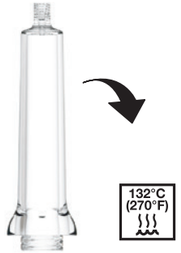
4

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™.

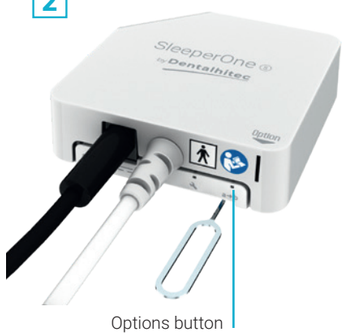
USE

Options

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

1

2



3

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** ___ .

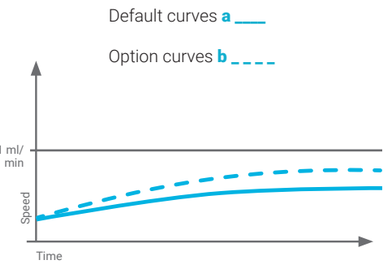
The 🔧 button is reserved for Dentalhitec or an authorized repairer.

USE

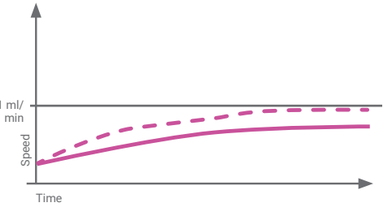
Modification of injection speed

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.

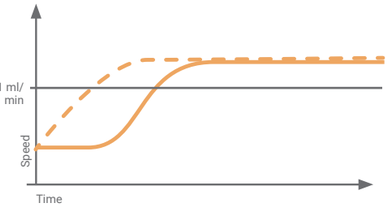
Slow speed
Examples of use: Intraosseous in children, Intraseptal



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.

WARNING: 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 sterilisation

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

PLASTIC CONTAINERS

SleeperOne 5

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

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	• 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 EN 868-5	
Sterilization	• Sterilize with a class B steam sterilizer • Sterilization time of a minimum of 4 minutes at 132°C / 270°F	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**

Contact manufacturer : Dentalhitec - ZI de l'Appentière - Rue de Champ Blanc - 49280 Mazières-en-Mauges - France

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.

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

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.

Repairing the device

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

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

WARNING:
- It is forbidden to modify your SleeperOne5™ without the authorization of Dentalhitec. If your SleeperOne5™ needs to be modified, the modification must be carried out by a repairer approved by Dentalhitec or by the technical department of Dentalhitec.
- Appropriate inspection and testing should be carried out to ensure that your device is still safe to use. The use of SleeperOne5™ with other equipment is the responsibility of the practitioner.
- SleeperOne5™ does not require regular maintenance.

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

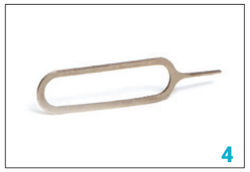
You can order the following accessories by contacting your distributor or Dentalhitec (see www.dentalhitec.com).
(Telephone : +33 (0)2 4156 16 16 or mail@dentalhitec.com)

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.dentalhitec.com**)


1


2


3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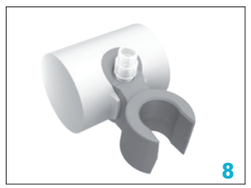
8

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 Dentalhitec or your authorized Dentalhitec dealer.
03	The handpiece does not respond to a push of the pedal	Local electromagnetic disturbances.	Contact your dealer or the Dentalhitec 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

Miscillaneous 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 Dentalhitec, who will take all of the necessary steps to enable you to have your device collected and recycled.

Dentalhitec
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Rue de Champ Blanc
49280 MAZIÈRES-EN-MAUGES - FRANCE

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

APPENDICES

Technical data sheet

Name: SleeperOne5™

Device classification: IIA

Rated voltage: AC 100-240V 50/60Hz

Conditions of use and storage:

Maximum altitude: 3000m

Transport conditions :

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: 868.3 MHz (Type B) or 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 Radiated RF disturbances IEC 61000-4-3	3 V rms 150 kHz to 80 MHz outside of ISM bands 6 Vms within ISM and amateur radio bands 10 V/m 80 MHz to 2.7 GHz	3 V rms 10 V/m	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√P d = 1.17 √P 80 MHz to 800 MHz d = 2.33 √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:
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	REF Catalogue reference	LOT Batch code	SN 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	132°C (270°F) Sterilisation 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	MD Medical device
50 Sterilization cycles	Storage conditions	Telephone	@ Email	Disinfectant for dental instruments hand and rotary
a→b Alternative curves option	Maintenance (reserved for Dentalhitec or authorized repairer)	Keep dry	CE 0459 CE marking	

WARNING	Risk of death, serious bodily injury, or serious property damage
CAUTION	Risk of minor or moderate injury to the user or patient or damage to the equipment or other property
NOTICE	Information considered important but not hazard related

SleeperOne ⑤

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