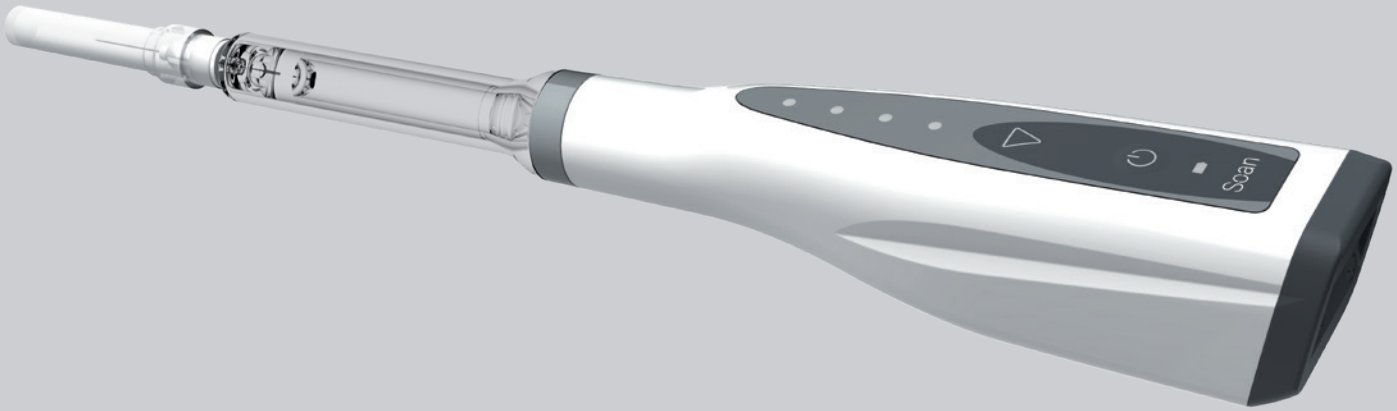
Soan

INSTRUCTIONS FOR USE

⚠ WARNING: Read before first use



IT IS RECOMMENDED TO FULLY CHARGE THE DEVICE BEFORE ITS 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 Soan™ 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.
- Do not touch the charger [battery charging] contacts as long as it is connected.

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 17 and 18).
- The holder and the handpiece must be disinfected after each patient (refer to the indications of manufacturers of disinfectant products).
- Do not leave the 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, Soan™ will not be adversely affected. Replace the needle with a new one.

CAUTION

GENERAL RECOMMENDATIONS

- Do not expose Soan™ to:
  - The sun, near a radiator or air conditioner.
  - Water and chemicals.
  - Flammable mixtures of air, oxygen or nitrogen.
- If the battery light goes red, place the Soan™ on the battery charger.
- 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 Soan™ clinically.

MAINTENANCE AND USE

- It is prohibited to modify Soan™ 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. Soan™ 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 Soan™, 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 Soan™ 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 that the device is used next to other devices or stacked with them, and that it is not possible to do otherwise, it should be checked for 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 Soan™ 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

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

TARGET PATIENT POPULATION

Soan™ 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 pathologies requiring local anesthesia for their treament.

CONTRAINDICATIONS

Refer to dental anesthetic injectable solutions manual and needle manual.
The use of Soan™ 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.

UNDESIRABLE SIDE EFFECTS

No undesirable side effects specific to the use of Soan™ have been identified. However, it is necessary to take into account the undesirable effects presented in the notices of the injected products and the needles used.

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.

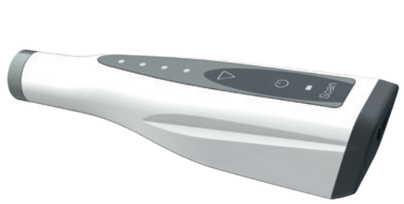
- The practitioner can view an online version of the Manual on the Dentalhitec website in the event that he ever loses his/her copy or in the event that Dentalhitec updates the Manual. Dentalhitec retains the right to modify the Manual as it deems appropriate.
- The practitioner is charged with the knowledge 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.
It is on the back of the pedal, on the handpiece and on the packaging card.
The format to be filled in on your customer area www.dentalhitec.com/mydht is: SAXXXXX

SUMMARY

GENERAL PRESENTATION



Container

Handiece holder

OR

Power supply

Support documentation

WARNING: To be cleaned and sterilized before use

WARNING: Use only with the power supply and the cables provided

CONTENT

1 handpiece (ref. SE8410)

1 wireless pedal + pedal hoop (ref. SE8800)

1 battery charger (ref. SE8600)

1 handpiece holder (ref. SA8700)

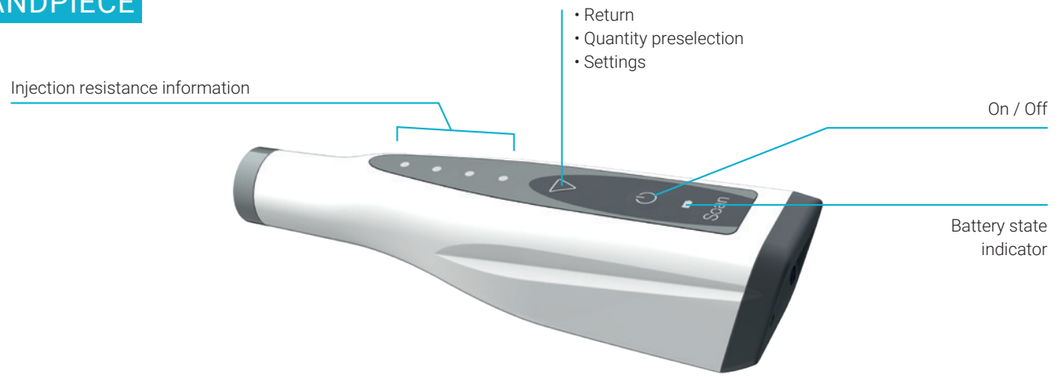
1 set of sterilizable containers and consumables available depending on the country

1 power supply (ref. M0150 or M0155)

1 set of documentation

GENERAL PRESENTATION

HANDPIECE



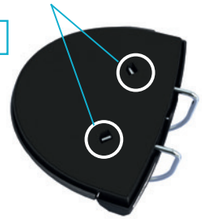
WIRELESS PEDAL

INSTALLATION

WIRELESS PEDAL

1

2



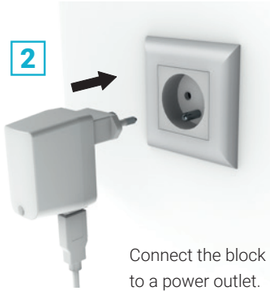
3

CHARGER

1

Connect the USB plug of the charger to the power supply.

2



Connect the block to a power outlet.

HANDPIECE HOLDER

- The handpiece holder is designed to be stuck either to the right or left of a wall.

Other handpiece holder versions, suitable for your unit, are available on www.dentalhitec.com

WARNING: The holder must never be fixed on a wall located above the patient to avoid any injury in the event of the handpiece falling.

1

Clean the flat surface with the wipe provided.

2

3

1 min

Press against the surface.

4

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

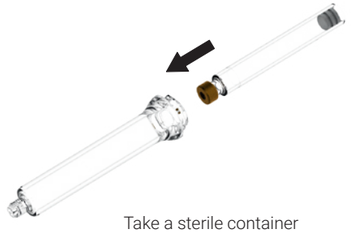
USE

Handpiece assembly - Cartridge - Needle

WARNING:
- Use cartridges with a plastic film that limits the risk of breakage.
- Use only new 1.7 ml or 1.8 ml cartridges that comply with the ISO 11499 standard.
- Only use sterile dental needles that comply with ISO 7885.
- Check that the container is in good condition before each use [absence of cracks or other damage].
- If any damage is noticed, please replace the container.
- The containers must be cleaned and sterilized in accordance with the procedure in p.18 before each use.

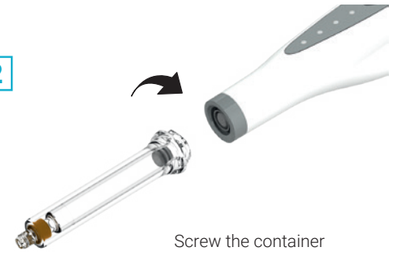
Ensure that the plunger has returned completely (short press on the return pedal or on the handpiece button).

1



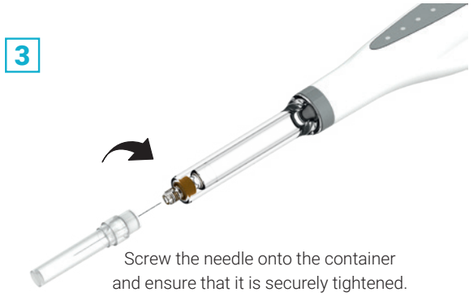
Take a sterile container and insert a new cartridge.

2



Screw the container onto the handpiece lightly.

3



Screw the needle onto the container and ensure that it is securely tightened.

4

To start working: Remove the needle cap and insert it into the slot on the handpiece holder.

USE

Unscrew the needle

Make sure that the plunger has returned completely (short press on the return pedal or on the handpiece button).

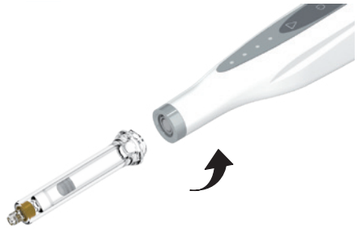
1

WARNING: To avoid any risk of needle stick injury, systematically re-sheath the needle using handpiece holder or place directly into a needle incinerator in accordance with the country's regulations.

2

Remove and incinerate the used needle using a medical waste device.

3



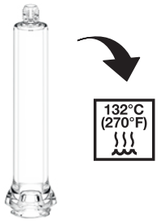
Unscrew the container.

4

Remove the cartridge.

5

6



Clean and sterilize the container as indicated on the maintenance sheet.

USE

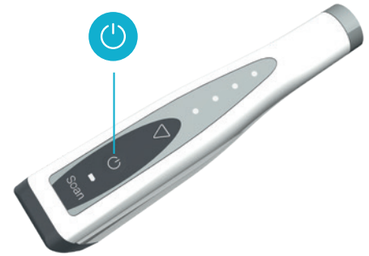
NOTICE: INFORMATION BEFORE USE
- For optimal use, it is recommended to charge the device fully before its first use.
- For optimal performance, remember to recharge Soan™ before each use.
- Clean the handpiece and its holder before each use.

Turn on

• To turn on the device, briefly press the button.

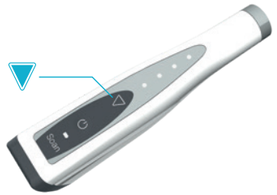
The device turns off after 10 min without activity, (modifiable time - See Configuration). It is necessary to briefly press on the button to turn on Soan™, the device will retain the same settings as before turning off.

To force the device to turn off, perform a long press of the button.

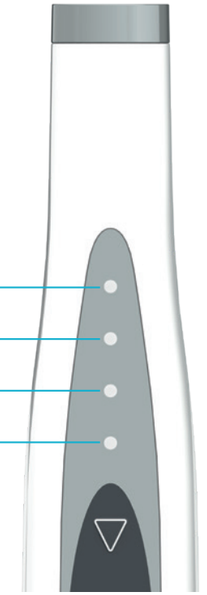


Quantity Preselection (option)

By default, Soan™ stops when the user commands it using the pedal.
It is also possible to program an automatic stop at a pre-defined quantity.



• Press the button until a beep is heard and the white preselected quantity light* illuminates.
• Release the button
• Each new short press allows you to modify the preselection.
• Long press (until a beep is heard) on the button or no action for 15 seconds cancels this mode.



* Quantity indicated

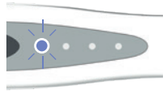
USE

Selection of injection speed

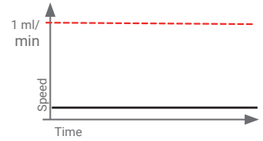
3 injection speeds are available to the user. The user must use their initial training and their clinical experience to choose the appropriate injection speed. This choice depends in particular on the type of anesthesia, the injection site, the patient (in particular pathology, state of health, age, etc.), the anesthetic product and the needle used.
The injection speeds can be modified in the SETTINGS section (see p. 13 and 14).

NOTICE: Electromagnetic disturbances can, in exceptional cases, alter the performance of the device.
If the injection does not stop, it is recommended to remove the handpiece from the injection site and briefly press the injection button, the injection will stop.
If the injection is triggered unexpectedly, a brief press on one of the injection buttons will stop it.
If these problems occur, ensure that Soan™ is sufficiently far from equipment likely to cause electromagnetic disturbances. Contact your dealer if the problems persist.

Drop by drop
Very slow speed: continuous drip
Example of use: mucosal anesthesia

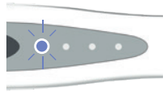


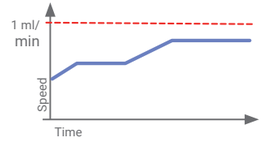
Slow flashing in the colors of Hi or Lo mode



Lo

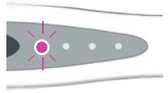
Slow speed: drop by drop start then gradual acceleration.
Examples of use: intraligamentary, intraosseous anesthesia in children...

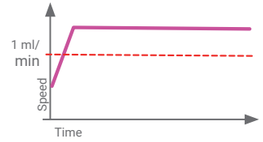




Hi

Fast Speed: Rapid acceleration to maximum speed.
Examples of use: infiltration and nerve block.





CAUTION: The use of the Hi 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 should only be performed by continuous drip injection.

Activation of the injection

Activate the injection by shortly pressing the pedal.
This operation can be modified in the SETTINGS section (See p. 13)

NOTICE: CHECK BEFORE EACH USE.
- Ensure that the device is switched on and the battery level is sufficient (see "charging the battery" on page 12).
- Make sure that the injection speed selection has been chosen correctly.

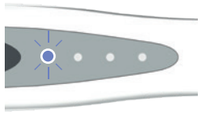
Drop by drop injection (recommended to anesthetize the mucosa).

Lo or Hi injection

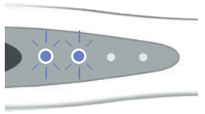
USE

Information on the current injection

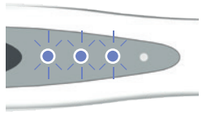
- Soan™ continuously monitors the resistance it encounters when injecting.
- Flashing light: injection in progress.



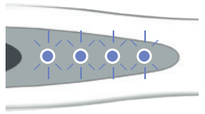
No resistance



Low resistance



Average resistance



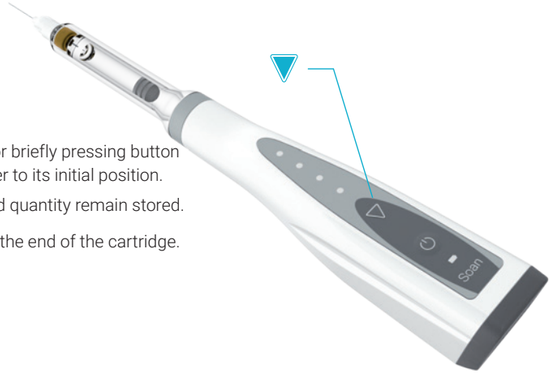
Significant resistance

NOTICE:
- The injection speed is intelligent: in Lo or Hi mode the speed does not increase if it encounters significant resistance to injection (modifiable speed see SETTINGS).
- If the pressure is too high, the injection stops automatically to avoid the risk of cartridge breakage and an audible signal is emitted.

- The amount injected is visible through the clear container when looking at the anesthetic cartridge. As an indication, beeps provide information on the estimated quantity injected: 1 beep = ¼, 2 beeps = ½, 3 beeps = ¾

Return of the plunger

- Pressing button ▽ on the handpiece or briefly pressing button ▽ on the foot pedal returns the plunger to its initial position.
- The mode selected and the pre-selected quantity remain stored.
- The return is triggered automatically at the end of the cartridge.



USE

Aspiration (Hi speed only)

If the users, based on their training and clinical experience, believes that aspiration should be performed, they should ensure the following:
- Select Hi mode
- Inject a minimum and sufficient quantity to be able to create space for return (1/8 of a cartridge is an example)
- Press continuously on the upper left pedal.
  Beeps are emitted and the LEDs alternately flash pink.
- Stop pressing when the user has observed the result of the aspiration.

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

Battery charging / recharging

To charge Soan™, place it on its charger.

DEVICE ON THE CHARGER

LED green
Battery fully charged

LED orange
Battery charging

LED red
Battery low

→ Put the device on the charger

Approximately 4h charge to 100%

Approximately 2h charge to 80%

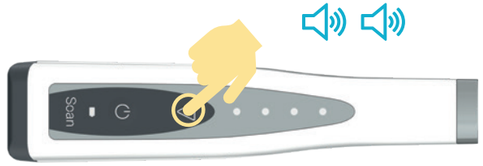
The average use on a full charge is 30 injections with the default setting. This value is given as an indication and varies according to the type of anesthesia performed and chosen standby time set (see page 15).

SETTINGS

Selection of settings to modify

It is possible to configure Soan™ to adapt it to its user. 4 parameters can be modified:
- Sound management
- Adjustment of injection speeds
- Time before shutdown
- Mode of operation of the injection pedal

1



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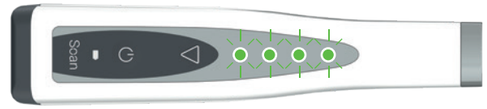
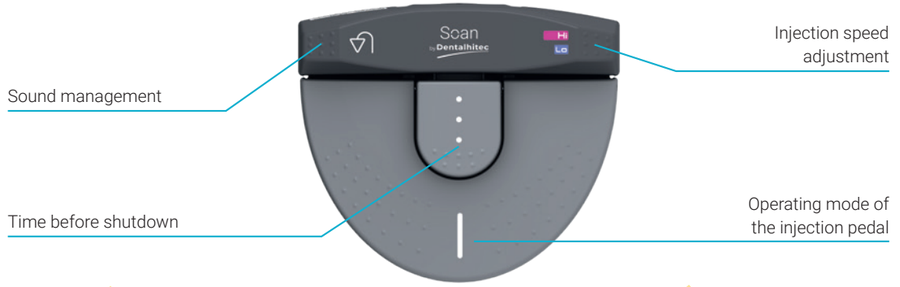


Press the ▼ button and release it when the SECOND beep sounds and all 4 indicator lights are green.
DO NOT RELEASE AFTER THE FIRST BEEP.

3 Press the pedal corresponding to the desired setting.



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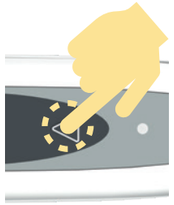


Briefly press the ▼ button to select the desired option (see pages 14 and 15).

5

Press the ▼ button until the beep is heard to exit the setting.

If no action is performed for 15 s, the device exits the setting.

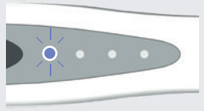
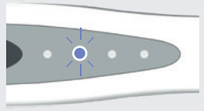
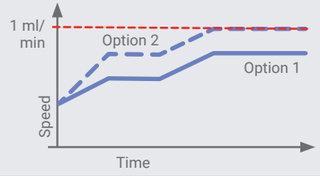
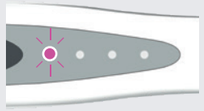
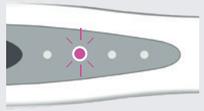
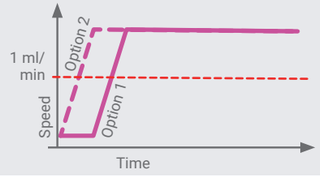
SETTINGS

Sound adjustment

Option 1 [default]	Option 2
All beeps	No sound, only warnings

Injection speed adjustment

- Different speeds can be selected for each injection mode, the mode can be changed by pressing the upper right mode selection pedal again.
- Each press is followed by an audible signal.

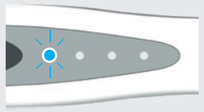
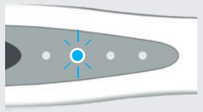
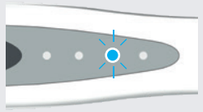
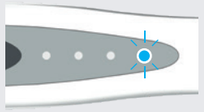
Mode	Option 1 [default]	Option 2	Details of injection curves
Lo			
Hi			

CAUTION: The choice of injection speeds is the sole responsibility of the user. In addition to their clinical experience, the practitioners 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.

SETTINGS

Adjustment of the time before shutdown

- Soan™ allows you to set the automatic switch-off time.

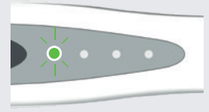
1	2 [default mode]	3	4
Switch-off after 2 minutes	Switch-off after 10 minutes	Switch-off after 20 minutes	Switch-off after 40 minutes
			
Average capacity: 50 injections*	Average capacity: 30 injections*	Average capacity: 20 injections*	Average capacity: 10 injections*

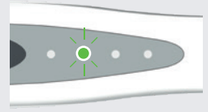
*These values are given as an indication and vary according to the type of anesthesia performed.

Adjustment of the injection pedal operation

- Soan™ has 2 modes to activate the injection.

Option 1 [default]	Option 2
Cruise mode Short press to start the injection and another short press to stop it 2 short beeps	Drive mode Hold the pedal for the desired injection time 1 long beep





CONTAINERS, CONSUMABLES AND ACCESSORIES

EFFITEC NEEDLES*

Dentalhitec recommends the use of Effitec needles with Soan™.

EFFITEC needles have a patented bevel and a specific base mark position for optimized penetration.

Recommendation for use of Effitec needles

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.

WARNING: Follow the needle choice according to the type of anesthesia performed to obtain maximum performance and avoid needle fractures or post-operative consequences. Consult the instructions for use found in the boxes before use and read the safety rules found in this Instructions For Use.

ACCESSORIES

The following components can be ordered by contacting an authorized Dentalhitec distributor or the company Dentalhitec.

Container
Ref.: SA8500

Mean Well GEM12I05-USB
Ref.: M0155

OR

Friwo FW8002MUSB/05
or Friwo FW8002.1MUSB/05
Ref.: M0150

Power supply

Handpiece holder
Ref.: SA8700

Options and specific models

Handpiece holder for A-DEC™ chairs
Ref.: SA8750

Handpiece holder for PLANMECA™ chairs
Ref.: SA8720

SERVICING

To be given to personnel responsible for sterilization, instructions on the back.

CONTAINERS

WARNING: Delivered non-sterile.
Clean and sterilize before each use.

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

To be given to personnel responsible for sterilization

CONTAINERS

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

Instructions for cleaning and sterilizing containers		
Initial point-of-use treatment	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 manufacturer of the disinfectant used.	
Rinsing	• Run the container under demineralised water for 1 minute, brushing with a soft bristle brush • Rinse by soaking 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 sterilized container is dry and that the indicator of the sterile envelope turns to the color indicating 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**
- **Deposit damaged/defective containers in a device for medical waste**

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

CARE, MAINTENANCE, AFTER-SALES SERVICE

Cleaning handpiece, handpiece holder, charger and wireless footpedal

1. Disconnect the power plug before cleaning.
2. Clean these components with a clean cloth and an alcohol solution or a disinfection product provided for this purpose after each patient.
3. Never soak in a liquid.

N.B.: Container maintenance is described on the detachable sheet on pages 17 and 18.

WARNING: Never sterilize handpiece, handpiece holder, charger and pedal.

CAUTION: Never leave liquid residues on the contacts of the charger as it will result in degradation (corrosion, malfunction, etc.).
Test a small area to ensure that a cleaning product does not damage the surface of the part to be cleaned.
Failure to comply with these rules may lead to irreparable damage not covered by the warranty.

Device repair

In the event of a problem, contact your authorized distributor directly or the head office of the company Dentalhitec.

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

Conditions of Guarantee

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

TROUBLESHOOTING

Breakdown	Issue	Causes	Solutions
01	Appearance of white marks or cracks on containers	Not following the protocol or too many sterilization cycles	Replace container and review cleaning and sterilization methods (see Maintenance process).
02	The handpiece does not work	Battery not charged	Place the handpiece on the battery charger, the battery indicator should turn orange [charging].
		Damage due to dropped handpiece	Do not use. Contact Dentalhitec or your authorized dealer.
03	The handpiece does not respond to footpedal operation	Environmental disturbance	Contact your authorized dealer or Dentalhitec.
			Keep away from devices likely to interfere with the radio signal (mobile phone, etc.).
		Uncharged battery	Place the handpiece on the battery charger, the battery indicator should turn orange [charging].
04	No injection and audible signal	Injection into very dense tissues	• Change injection site. • Reduce the injection speed.
05	Bad communication between handpiece and wireless footpedal	Obstacles (particularly metallic (PC, box, etc.)) between the handpiece and the pedal	Do not fix/place the charger on an electronic device (computer, etc.).

APPENDICES

Technical Sheet

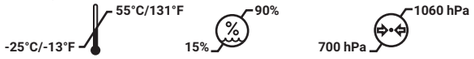
Name: Soan™ Model: 1

Device classification: II

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

Battery specifications: Li/po 3.7V – 480mA

Transport conditions :



Conditions of storage and use:

Maximum altitude: 3000m

Separate power supply supplied class II 5V DC output:

- 7W: Friwo FW8002MUSB/05

Or

- Friwo FW8002.1MUSB/05

Or

- 12W: Mean Well GEM12I05-USB

Characteristics of the radio transmitter:

Transmission frequency / power: 2.4 GHz / max. 5mW

Communication protocol: Zigbee IEEE 802.15.4

Dimensions

Handpiece: Width: 28 mm Length: 132 mm

Height: 32mm Weight: 86g

Charger: Width: 70mm Length: 90mm Height: 51mm Weight: 122g

Handpiece holder: Length: 74 mm - Diameter: 37.3 mm

Pedal: Length: 205 mm Width: 180 mm Height: 150 mm

Weight: 700 g

Applied parts: Needles and containers

Use only with supplied power supply and cables

Essential performance

- Soan™ will remain functional according to the environment in which it is intended to be used (lighting, temperature, electrostatic discharges, electromagnetic disturbances, etc.) in accordance with the normative and regulatory requirements applicable to it.
- Soan™ will not start without the intervention of its user.

Miscellaneous information

- The degree of protection against electric shock is type BF.
- The protection class of the pedal is IPX1.

This device 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, contact your distributor or Dentalhitec who will take all the necessary measures for the collection and recycling of the device.

APPENDICES

Technical Sheet EMC test specifications

Measurement of conducted emissions

Limit: CISPR 11 – Group 1 and 2, Class B

Frequency range MHz	Rated input power ≤ 20 kVA	
	Quasi-peak dB (µV)	Average value dB (µV)
0,15 – 0,50	66 to 56	56 to 46
0,50 – 5	56	46
5 – 30	60	50

Electrostatic Discharge Immunity

Severity:

- Discharges on direct contact ± 8 kV
- Indirect contact discharges ± 8 kV
- Discharges in the air ± 15 kV

Measurement of voltage fluctuations

Limit: 4%

Mains Frequency Magnetic Field Immunity

Level: 30 A/m

Frequency: 50Hz and 60Hz

Exposure time: 1 minute per axis

Immunity to currents induced by radiofrequency fields

Applicable standard	Professional/home health care facility environment
IEC 61000-4-6	3 V [m] 0,15 MHz – 80 MHz 6 V [m] in ISM bands and bands between 0.15 MHz and 80 MHz [n] 80 % MA at 1 kHz [e]

Immunity to electrical fast transients:

Severity:

Environment of a professional health care facility

Level: ±2 kV

Repetition rate: 100 kHz

Measurement of radiated emissions

Limit: CISPR 11 – Group 1, Class B

Frequency range MHz	Measuring distance 3m Rated input power ≤ 20 kVA
	Quasi-peak dB (µV)
30 – 230	40
230 – 1000	47

Immunity to radiated electromagnetic fields

Level before modulation: 10 V/m

Frequency band: [80 – 2700] MHz

Modulation: AM 80% at 1kHz

Exposure time: 1 second

Voltage shock immunity

Severity:

Environment of a professional health care facility

- ± 0.5 kV in differential mode
- ± 0.5 kV, ± 1 kV and ± 2 kV in common mode

Immunity to voltage dips and interruptions

Severity:

Environment of a professional health care facility

Applied levels		
Voltage drops (% U_T)	Cycles	Sync angle (degrees)
> 95	0,5	0, 45, 90, 135, 180, 225, 270, 315
> 95	1	0
30	25 (50 Hz), 30 (60 Hz)	0
Voltage drops (% U_T)	Cycles	Sync angle (degrees)
> 95	250 (50 Hz), 300 (60 Hz)	0

APPENDICES

Technical Sheet

Test specifications for immunity from access through the enclosure to RF wireless communication equipment:

Exposure time: 3s

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity test level (V/M)
385	380 - 390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 - 470	GMRS 460, FRS 460	MF [c] deviation ± 5 kHz Sinus. 1 kHz	2	0,3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 - 1 990	GSM 1800; CDMA 1900; GSM 1900;DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 - 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 - 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary, to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the EQUIPMENT or ME SYSTEM can be reduced to 1 m. The test distance of 1 m is allowed by IEC 61000-4-3.

a) For some services, only uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As a variant of FM modulation, 50% pulse modulation at 18 Hz can be used because while it does not represent the actual modulation, it would represent the worst case.

APPENDICES

Meaning of symbols used

BF type applied part	Manufacturer	Date of manufacture	Operator's manual	Refer to instruction manual
WARNING	Catalogue reference	Lot code	Radio transmitter	Keep away from sunlight
Temperature limit	Humidity limit	Serial number	Do not use if packaging is damaged	Class II device
Pedal	Sterilization at 132°C (270°F)	Atmospheric pressure limit	Biohazard: Incinerate in accordance with protocol for infectious waste	Altitude
Transport conditions	Charger and power supply	Unique device identification	Medical device	50 sterilization cycles
Storage conditions	Ultrasonic bath	Disinfectant for dental instruments, hand and rotary	Telephone	Email
Keep dry				

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

Soan

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
or support@dentalhitec.com

Dentalhitec
The future of dental anesthesia

USA contact information:

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