

Implant Center 2

User's manual • Manuel d'utilisation • Manual de uso
Benutzerhandbuch • Manuale d'uso • Handleiding voor de gebruiker
Manual de utilização • Användningshandbok • Εγχειρίδιο χρήσης

SATELEC
ACTEON Equipment

English 4

ENGLISH

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The list of accessories referred to in this manual is non exhaustive. Consult your local dealer for further details.

I - INTRODUCTION

Congratulations! You have just taken possession of your IMPLANT CENTER 2.

Designed by SATELEC®, the IMPLANT CENTER 2 is a multifunction device intended for:

- dental implantology, with its I-SURGE micro-motor.
- surgical procedures (osteotomy, osteoplasty, periodontal and implant surgery) with its PIEZOTOME or PIEZOTOME LED handpiece.
- mechanical ultrasonic treatment (prophylaxis, periodontics, endodontics) with its NEWTRON or NEWTRON LED ultrasonic handpiece.

The I-SURGE micro-motor coupling developed by SATELEC means that the IMPLANT CENTER can be used with most contra-angles (without internal spray or light) found on the market.

In order to get the most out of this high-technology device and ensure it has a long working life, please read this manual carefully before installing, using or maintaining it.

Points preceded by the symbol ⚠ should be given particular attention.

II - WARNINGS

⚠ **CAUTION:**

United States Federal Law restricts the use of this device solely to qualified, trained and competent dental health practitioners or under their supervision.

The tips designed for PIEZOTOME 2 and IMPLANT CENTER 2 are not compatible with PIEZOTOME and IMPLANT CENTER, and vice versa.

To reduce the risk of accidents, the precautions stipulated below must be taken:

Device users:

- Use of the IMPLANT CENTER 2 is restricted solely to qualified, trained and competent dental health practitioners in the normal context of their work.
- If you have received this device by error, please contact the supplier so that it can be removed.

Interactions:

- The IMPLANT CENTER 2 must not be used if the patient and/or the operator has a cardiac stimulator (pacemaker) or any other active implant (e.g. a cochlear implant).
- The device complies with applicable electromagnetic compatibility standards. The user should nevertheless ensure that any potential electromagnetic interference does not cause an additional risk (presence of radiofrequency emitters, electronic devices, etc.).
- The device is not designed to withstand shocks delivered by an electric defibrillator.
- Do not attempt to connect to the IMPLANT CENTER 2 any other accessories than those supplied by SATELEC.

Electrical connection:

- Your Implant Center 2 must be connected to the electric power supply by a certified dental installation technician.
- Warning: To avoid any risk of electric shock, this device must be connected to an electrical power supply with a protective ground.
- The electric supply to which the device is connected must comply with the standards in force in your country.
- If loss of electrical power during use is likely to generate an unacceptable risk, the device must be connected to a suitable power source (e.g. UPS).

Using the device:

- Do not use the device if it appears to be damaged or faulty.
- Turn the device off before unplugging the power cord.
- To unplug the power cord, grip the cord plug and hold the wall socket.
- Never use any other irrigation solution containers than those intended for suspension from the supplied brackets.
- The device must only be used with bottles or bags of physiological saline or sterile water.
- The capacity of the irrigation solution containers used must not exceed one litre.
- When the device is not to be used for a long period of time, unplug the device from the electric supply.
- Do not exert excessive force on the screen.
- Do not move Implant Center 2 during use.

Environment:

- Do not cover the device or obstruct the ventilation vents.
- Do not immerse the device in liquid, and do not use it outdoors.
- Do not tilt the device at an angle greater than 5°.
- Do not place the device near a heat source.
- Make sure that the cords are not in a traffic path.
- The device must be stored in its original packaging in an appropriate and safe place.
- The device is not designed for use in the presence of anesthetic gases or any other flammable gas.
- Do not expose the device to water vapor, or splashes.
- Any condensation inside an electrical device is potentially dangerous.
- If the device is to be moved from a cold environment to a hot one, it must not be used until it has reached room temperature.
- The device is not designed to work near ionizing radiation.
- Do not insert metal objects into the device (risk of electric shock, short-circuit or projection of hazardous substances).

Maintenance:

- Before and after each use, your Implant Center 2 must be disinfected with SATELEC-approved agents.
- Before each procedure, it is essential to make sure that the accessories to be used have been cleaned, disinfected and sterilized.

Accessories:

- The device has been designed and developed for use only with SATELEC accessories to ensure maximum safety and performance.

- Use of accessories from other manufacturers is a potential hazard for you or your patients.

Repair:
- Warning: Do not repair or modify the device without prior authorization from SATELEC.
- Warning: If the device is modified or repaired, specific checks and tests must be performed to ensure that the device can still be used safely.
- In the case of a fault, contact the supplier of your device. Do not use unauthorized repairers, who might make your device dangerous for you and your patients.

If in any doubt, contact an approved dealer or our customer support department:
- www.acteongroup.com
- E-mail: satelec@acteongroup.com.

III - DESCRIPTION

3. 1 PHYSICAL DESCRIPTION

The IMPLANT CENTER 2 has the following components:
- a control unit (Fig. 1),
- a multifunction footswitch (Fig. 11),
- a micro-motor cord with connectors (Fig. 1-2),
- two brackets for irrigation solution (Fig. 1-3),
- an I-SURGE micro-motor (Fig. 1-4) without contra-angle,
- a grounded power cord (Fig. 1-5),
- an LCD (Liquid Crystal Display) touch screen (Fig. 1-6),
- a motor cord connector (Fig. 1-7),
- two peristaltic pump housings (Fig. 1-8),
- a cord connector for the two ultrasonic functions (Fig. 1-9),
- a NEWTRON scaler cord or PIEZOTOME 2 LED handpiece with cord (Fig. 1-10) (according to option),
- a NEWTRON LED handpiece or a PIEZOTOME 2 LED handpiece with its cord (Fig. 1-11) (according to option).

Located at the back of the unit are:
- 1 power cord socket with ground pin (Fig. 2-1),
- 1 footswitch connector (Fig. 2-2),
- 1 fan (Fig. 2-3),
- 2 bracket holders (Fig. 2-4),
- 1 power switch (Fig. 2-5).

3. 2 TECHNICAL DESCRIPTION

a) LCD touch screen

The LCD touch screen (Fig. 3) is used to define the settings of your IMPLANT CENTER 2.
The IMPLANT CENTER 2 is adjusted by applying moderate pressure to the screen keys.

Identification of key areas common to all modes (Fig. 3):
- 4: Reduce irrigation flow rate.
- 5: Increase irrigation flow rate.
- 6: Reduce value.
- 7: Increase value.

Identification of information display areas common to all modes (Fig. 3)
- 2: Irrigation flow rate value.
- 9: Operating fault indicator.

Identification of key areas common to all modes that also display information (Fig. 3)
- 1: Flush/prime.
- 3: Irrigation ON/OFF.
- 8: Save, store data.
- 10: Select footswitch mode.

- 11: ON/OFF of light function on handpiece
- 12: Select mode (according to connected handpiece type).

Key areas and displays specific to the selected mode

PIEZOTOME mode:
Identification of information display areas (Fig. 4)
- 13: Selected program power level.

Identification of key areas that also display information (Fig. 4)
- 14: Select program: D1, D2, D3, D4.

NEWTRON mode:
Identification of information display areas (Fig. 5)
- 15: Selected program power level.

Identification of key areas that also display information (Fig. 5)
- 16: Select program: Soft, Medium, High, Boost.

I-SURGE mode:
Identification of information display areas (Fig. 6)
- 17: Contra-angle ratio.
- 18: Motor speed value.
- 19: Motor delivered torque value.

Identification of key areas (Fig. 6)
- 20: Adjust contra-angle ratio.
- 21: Adjust motor speed.
- 22: Adjust motor delivered torque.

Identification of key areas that also display information (Fig. 6)
- 23: Select micro-motor rotation (clockwise or counterclockwise).
- 24: Select program: P1, P2, P3, P4.

Contra-angle, speed and torque setting adjustment page
Identification of common information display areas (Fig. 7)
- 25: Contra-angle ratio.
- 26: Maximum delivered speed.
- 27: Maximum delivered torque.

Identification of common key areas (Fig. 7)
- 28: Exit from the page without changes.
- 29: Delete last character entered.
- 30: Return to main page and save settings to screen memory.
- 31: Numeric keypad.

Preprogrammed contra-angle adjustment page
Identification of information display areas (Fig. 8)
- 38: Contra-angle ratio.
- 39: Motor speed value.
- 40: Motor delivered torque value.

Identification of key areas (Fig. 8)
- 32: Exit from the page without changes.
- 33: Select custom contra-angle.
- 34: Return to main page and save settings to screen memory.

Identification of key areas that also display information (Fig. 8)
- 35: Select a multiplier contra-angle.
- 36: Select direct contra-angle.
- 37: Select a divider contra-angle.

Startup page

Identification of key areas (Fig. 9)

- 41: Enter *TOOLBOX* mode.

Toolbox

Identification of information display areas (Fig. 10)

- 43: Audio volume symbol.
- 44: Screen brightness symbol.
- 45: Light off time-out symbol.
- 48: Relative audio volume value.
- 49: Relative brightness level value.
- 50: Selected time-out value.
- 51: Software version.

Identification of key areas (Fig. 10)

- 42: Reset factory configuration.
- 46: Reduce value.
- 47: Increase value.
- 52: Validate the configuration.

b) Control unit back panel

The power receptacle (Fig. 2-1) with its grounding pin is used to connect the IMPLANT CENTER 2 to the power supply using a plug-in power cord.

The footswitch connector (Fig. 2-2) is used to connect the IMPLANT CENTER 2 to the multifunction control footswitch.

The fan (Fig. 2-3) protected by a metal grille, keeps the IMPLANT CENTER 2 at its optimal performance level.

The bracket holders (Fig. 2-4) are used to install the brackets.

The power switch (Fig. 2-5) is used to switch the device ON or OFF.

c) Control unit sides

The pump housings (Fig. 1-8) are designed to accommodate SATELEC irrigation line cassettes.

The irrigation cassettes are installed by lifting the pump covers and inserting the cassettes horizontally into the cassette housings.

d) Front panel

- The left connector is designed to accept the connector of the I-SURGE micro-motor cord. Only a SATELEC micro-motor cord must be used.
- The right-hand connector is designed to accept the connector of the NEWTRON / NEWTRON LED cord or the connector of the PIEZOTOME 2 / PIEZOTOME 2 LED handpiece cord.

e) Control footswitch

Having access to a large number of functions on the control footswitch allows the practitioner to work in a perfectly sterile environment, avoiding the risk of cross-contamination.
Once the various settings have been adjusted, the user has no further need to touch the keypad. Depending on the mode, the control footswitch buttons have different functions.

I-SURGE mode:

Footswitch button definitions (Fig. 11):

- 1: I-SURGE motor control (ON/OFF or progressive).
- 2: Rotation direction.
- 3: Change program (P1 to P4).
- 4: Irrigation ON/OFF.
- 5: Select active handpiece.

PIEZOTOME mode:
Footswitch button definition (Fig. 11):
- 1: Ultrasonics control (ON/OFF or progressive).
- 2: Flush/prime.
- 3: Change program (D1 to D4).
- 4: Irrigation ON/OFF.
- 5: Select active handpiece.

NEWTRON mode:
Footswitch button definition (Fig. 11):
- 1: Ultrasonics control (ON/OFF or progressive).
- 2: Flush/prime.
- 3: Change program (Soft to Boost).
- 4: Irrigation ON/OFF.
- 5: Select active handpiece.

f) Technical characteristics
Manufacturer: SATELEC
Device name: IMPLANT CENTER 2
Electrical power supply:
- Voltage: 100 VAC to 230 VAC.
- Frequency: 50 Hz/60 Hz.
- Rated power: 250 VA at 230 VAC.

I-SURGE function
Operation:
Intermittent service: 20 sec. ON / 30 sec. OFF at 2 N.cm
Output characteristics:
I-SURGE micro-motor speed: 100 rpm to 40 000 rpm
I-SURGE micro-motor torque: max. 6 N.cm
Irrigation flow rate: 10 to 120 ml/min. (nominal value).
Adjustment in 10 ml/min. steps
Flush/prime flow rate: 120 ml/min.

PIEZOTOME function
Operation:
Intermittent service: 10 min. ON / 5 min OFF
Output characteristics:
No-load voltage: 250 volts (nominal value without handpiece)
Min. ultrasonic frequency: 28 kHz
Irrigation flow rate: 10 to 120 ml/min. (nominal value)
Adjustment in 10 ml/min. steps (nominal value)
Flush flow rate: 120 ml/min. (nominal value)

NEWTRON function
Operation:
Intermittent service: 10 min. ON / 5 min. OFF
Output characteristics:
No-load voltage: 150 volts (nominal value without handpiece)
Min. ultrasonic frequency: 28 kHz
Irrigation flow rate: 10 to 40 ml/min. (nominal value)
Adjustment in 1 ml/min. steps (nominal value)
Flush flow rate: 120 ml/min. (nominal value)

Protection
Electrical equipment class: Class 1
Electrical safety class:
Type BF in I-SURGE mode
Type BF in PIEZOTOME mode
Type BF in NEWTRON mode

Safety devices
Thermal safety shut off to avoid overheating of the I-SURGE micro-motor
Safety shut off if internal malfunction
2 fuses (power cord receptacle): 5 mm x 20 mm - 2 AT for 100 VAC to 230 VAC
1 internal fuse not accessible to the user reference F1: 5 mm x 20 mm – 10 AT / 250 VAC

Overall dimensions
Control unit:
Width: 472.9 mm
Height: 149.5 mm
Height with bracket: 471.1 mm
Depth: 339.9 mm
Weight: 5 kg without accessories

Footswitch:
Width: 311 mm
Depth: 209 mm
Height: 181 mm
Weight: approximately 3.5 kg

LCD screen:
Height: 86 mm
Width: 115 mm

Micro-motor cord: 2 000 mm (2 900 mm optional)
Scaler handpiece cord: 2 000 mm (2 900 mm optional)
Piezotome handpiece cord: 2 000 mm (2 900 mm optional)

I-Surge micro-motor:
Length: 99 mm
Diameter: 21 mm
Weight: 120 g
Coupling type: according to standard ISO 3964

Temperatures
Operation: +10°C to +40°C
Storage: -20°C to +70°C

Humidity
Operation: 30% to 75%
Storage: 10% to 100% including condensation

Atmospheric pressure
Between 500 hPa and 1060 hPa

Measuring units displayed and meaning
Ncm = torque (N.cm)
Rpm = speed (r/min.)

IV - INSTALLATION / FIRST USE

4. 1 UNPACKING THE DEVICE

Upon receipt of the device, check for any damage caused in transit.
Contact your supplier if necessary.

4. 2 RECOMMENDATIONS

Have your Implant Center 2 connected to the power electricity supply by a certified dental installation technician.
The electrical connection of the Implant Center 2 must comply with the applicable standards in your country.

Warning:
To avoid any risk of electric shock, this device must be connected to an electrical power supply with a protective ground.

4. 3 INSTALLATION

⚠ **Important:**
Do not place the Implant Center 2 close to or on top of another device.
Do not place the power cord and the footswitch cord in a wire cover or in a cable gland.

- Place the control unit in position on a fixed surface, horizontal or with a slope of no more than 5°.

- Check that the power switch (Fig. 2-5) is in position O (OFF).
- Connect the power cord to the receptacl of the device.
- Connect the power cord to a power socket with a ground pin.
- Connect the control footswitch to the footswitch connector (Fig. 2-2).
- Position the footswitch so that it is easily accessible for your feet.
- Insert the brackets into the bracket holders (Fig. 2-4).
- Connect the micro-motor cord to the connector (Fig. 1-7).
- Align the I-SURGE micro-motor and cord connector electrical contacts, then screw the motor onto the connector.
- Connect the NEWTRON scaler cord or the PIEZOTOME 2 handpiece cord to the connector (Fig. 1-9) (according to option).
- Connect the NEWTRON handpiece to the scaler cord (delivered according to option).
- Check that the device is close enough to the work area to be used without pulling on the cords. If it is not, move the device closer.
- Place the I-SURGE micro-motor on its rest.
- Place the NEWTRON or PIEZOTOME 2 handpiece on the handpiece support.
- Suspend the bottles or bags of physiological saline or sterile water from the brackets.
- Adjust the position of your device to suit your angle of view.

4. 4 FIRST USE

Before using the IMPLANT CENTER 2 for the first time, all the equipment must be given routine maintenance and/or sterilized according to the procedures defined in chapter 11.

V - IRRIGATION SOLUTION

IMPLANT CENTER 2 is not designed to administer drugs. It must be used only with bottles or bags of physiological saline or sterile water with an individual capacity not exceeding one litre.

VI - IRRIGATION LINES

IMPLANT CENTER 2 must be used exclusively with SATELEC irrigation lines.

VII - ADJUSTMENTS / SETTINGS / MODES / INTERFACE

7. 1 STARTUP

⚠ **Important:**
After stopping the device, wait four seconds before restarting it.

Each time the device is switched on, the screen displays program P1 of the I-SURGE function after displaying the welcome page.

7. 2 SETTINGS

The settings are saved when each program is configured and are retrieved whenever that program is selected.

7. 3 IRRIGATION FUNCTION

a) Flush / prime

The flush / prime function is available on the LCD screen and on the footswitch.

Press button (Fig. 3-1) or the footswitch button (Fig. 11-2) (PIEZOTOME and NEWTRON modes) to switch on the flush / prime function.
The flush / prime function stays on as long as the button is pressed.
The flush can be switched on while the device is being used.

b) Flow rate adjustment

The irrigation flow rate is adjusted using buttons (-) and (+) (Fig. 3-4 and 5).
Each time the corresponding button is pressed, the flow rate is adjusted.
The adjusted value is displayed on the LCD screen (Fig. 3-2) and stored in the current program.
The flow rate can be adjusted while the device is being used.

c) Irrigation ON/OFF

The irrigation is switched ON or OFF by pressing button (Fig. 3-3) or the footswitch button (Fig. 11-4).

When irrigation is selected, the symbol is highlighted.
When irrigation is not selected, the symbol is darkened.

7. 4 LIGHT FUNCTION

The light function is displayed on the LCD screen.

Pressing button (Fig. 3-11) switches the light function available for the NEWTRON and PIEZOTOME functions ON or OFF.
The light function has a default light-off time-out of nine seconds.
Switching off the light function becomes effective when the time-out has elapsed.
If necessary, you can lengthen the time-out (refer to 7.7).

7. 5 I-SURGE FUNCTION

a) Selecting the rotation direction

The rotation direction of the I-SURGE micro-motor is controlled by the control footswitch button (Fig. 11-2).
When clockwise rotation is selected, the symbol is displayed on the LCD screen (Fig. 6-23).
When counterclockwise rotation is selected, an audible signal is emitted and the symbol is displayed on the LCD screen (Fig. 6-23).

b) Program setting adjustment

⚠ Important:
When programming the maximum instrument end speed, the entered value cannot exceed the pre-programmed value.
Do not go below the minimum motor speed value (100 rpm, 1:1 contra-angle).
Do not exceed the maximum pre-programmed value of the instrument end torque, and do not go below 10% of this value.

When setting the torque, please refer to the contra-angle and implant system manufacturers' recommendations.

Select the I-SURGE function by pressing button I-SURGE (Fig. 3-12).
On the LCD screen, the I-SURGE tab must be highlighted.
Select the program for which settings are to be adjusted using buttons P1, P2, P3 or P4 (Fig. 6-24) or using the footswitch button (Fig.11-3); the various programmed parameter settings are displayed.

The contra-angle CA (Fig. 6-20) value is displayed (Fig. 6-17).

The speed Rpm (Fig. 6-21) value is displayed (Fig. 6-18).

The torque Ncm (Fig. 6-22) value is displayed (Fig. 6-19).

c) Selecting a contra-angle
Selecting a pre-programmed contra-angle:

Press button CA (Fig. 6-20): the preprogrammed contra-angle options are displayed (Fig. 8).
Select a multiplier contra-angle using the red buttons (Fig. 8-35) or a direct contra-angle using the blue button (Fig. 8-36) or a divider contra-angle using the green buttons (Fig. 8-37).
The value of the selected contra-angle is displayed (Fig.8-38).
The maximum permitted speed (Fig.8-39) and torque (Fig.8-40) are displayed for each contra-angle.

Button ⇦ (Fig. 8-32) is used to return to the main screen without saving the changes.
Confirm the selected contra-angle by pressing button OK (Fig. 8-34); the main screen is displayed.

Programming a user-defined contra-angle:
IMPLANT CENTER 2 enables specific contra-angles to be used. A contra-angle value can be programmed.

On the main screen press button CA (Fig. 6-20); the preprogrammed contra-angle options are displayed (Fig. 8).

Press button (Fig. 8-33); the button is highlighted.

Press button OK (Fig. 8-34); the contra-angle adjustment screen is displayed (Fig. 7).

Program the contra-angle using the numeric keypad (Fig. 7-31).
The programmed contra-angle value is displayed (Fig. 7-25).

Press button DELETE (Fig. 7-29) to delete the last digit.

Press button ⇦ (Fig. 7-28) to return to the main screen without saving the changes.
Confirm your customization of the contra-angle by pressing button OK (Fig. 7-30); the main screen is displayed.
The maximum permitted speed (Fig. 6-18) and torque (Fig. 6-19) are displayed for the programmed contra-angle.

d) Speed adjustment

On the main screen, press button Rpm (Fig. 6-21); the speed adjustment screen is displayed (Fig. 7).
Program the speed using the numeric keypad (Fig. 7-31).
The programmed speed is displayed (Fig. 7-26).

Press button DELETE (Fig. 7-29) to delete the last digit.

Press button ⇦ (Fig. 7-28) to return to the main screen without saving the changes.
Confirm the speed adjustment by pressing button OK (Fig.7-30); the main screen is displayed.

Note: The instrument speed can be adjusted directly using buttons − or + (Fig. 3-6 and 3-7) for programs P1, P2 or P3 even when the multifunction footswitch is switched on.
To obtain a stable speed adjustment result, it is recommended to press the footswitch fully (Fig. 11-1).

Pressing buttons − or + (Fig. 3-6 and 3-7) increases or reduces the speed value.

Pressing and holding buttons − or + (Fig. 3-6 and 3-7) for longer than 3 seconds causes faster increase or reduction of the speed value.
If a torque or speed value outside the permitted range is entered, !min! or !max! is displayed. The maximum or minimum permitted value is then displayed, depending on the case.

e) Torque adjustment

On the main screen, press button Ncm (Fig. 6-22); the torque adjustment screen is displayed (Fig. 7).
Program the torque using the numeric keypad (Fig. 7-31).
The programmed torque is displayed (Fig. 7-27).

Press button DELETE (Fig. 7-29) to delete the last digit.

Press button ⇦ (Fig. 7-28) to return to the main screen without saving the changes.

Confirm the torque adjustment by pressing button OK (Fig. 7-30); the main screen is displayed.

Note: The instrument torque can be adjusted directly using buttons − or + (Fig. 3-6 and 3-7) for program P4, even when the multifunction footswitch is switched on.

f) Selecting footswitch type
Change the footswitch type if necessary by pressing button (Fig. 3-10) to toggle between ON/OFF and progressive .

g) Completion of setting adjustment

Confirm the new settings by pressing button  (Fig. 3-8).
The storing of the various settings is confirmed by an audible signal.
Repeat this sequence if necessary in order to adjust all the programs.

7. 6 PIEZOTOME FUNCTION

⚠ **Important:**
The PIEZOTOME function settings can be customized by the user.
The PIEZOTOME function settings can be adjusted when no PIEZOTOME 2 handpiece is connected to the device.

The program giving the highest power is D1.

	Program	Main functions
Very powerful	D1	Osteotomy, osteoplasty
Powerful	D2	
Medium	D3	
Low	D4	Soft tissue detachment

Select the Piezotome function by pressing button PIEZOTOME (Fig. 3-12) or by pressing the footswitch button (Fig. 11-5).

On the LCD screen, the PIEZOTOME tab must be highlighted.
Select the program to be used by pressing button D1, D2, D3 or D4 (Fig. 4-14) or using the footswitch button (Fig. 11-3); the selected program is highlighted on the LCD screen.

Adjust the programs and the power level according to the tip data sheet recommendations.
If necessary, modify the irrigation function (flow rate value, etc.) (refer to 7.3).
If necessary, modify the program power level (1 to 5) using buttons − (Fig. 3-6) and + (Fig. 3-7).
The power level of the program concerned is shown as a number and a bar-graph  (Fig. 4-13).
Modify the footswitch type if necessary by pressing button  (Fig. 3-10) to toggle between ON/OFF  and progressive .

⚠ **Important:**
In progressive mode, for programs D1 to D3, the delivered power ranges between power level 1 of program D3 and the configuration defined by the user (program and power level).
In progressive mode, the power delivered by program D4 ranges only between levels 1 and 5, according to the value defined by the user.

If necessary, select handpiece light function ON/OFF by pressing button  (Fig. 3-11).
Confirm the new settings by pressing button  (Fig. 3-8).
The saving of the various settings is confirmed by an audible signal and a visual signal (button flashing).

Repeat this sequence if necessary in order to adjust all the programs.

Caution: The tips designed for PIEZOTOME 2 and IMPLANT CENTER 2 are not compatible with PIEZOTOME and IMPLANT CENTER, and vice versa.

7. 7 NEWTRON FUNCTION

Important:
A scaler cord and its NEWTRON handpiece must be connected to the device in order to be able to configure the various settings.
The NEWTRON function settings can be customized by the user.

Select the NEWTRON function by pressing button NEWTRON (Fig. 3-12) or by pressing the footswitch button (Fig. 11-5).
On the LCD screen, the NEWTRON tab must be highlighted.
Select the program for which settings are to be adjusted by pressing buttons SOFT, MEDIUM, HIGH or BOOST (Fig. 5-16) or by pressing the footswitch button (Fig. 11-3).
Adjust the power level according to the TipBook recommendations.
If necessary, modify the program power level (1 to 10) using buttons − (Fig. 3-6) and + (Fig. 3-7).
The power level of the program concerned is shown as a number and a bar-graph 09 (Fig. 5-15).

Modify the footswitch type if necessary by pressing button (Fig. 3-10) to toggle between ON/OFF and progressive.

If necessary, select handpiece light function ON/OFF by pressing button (Fig. 3-11).

Confirm the new settings by pressing button (Fig. 3-8). The saving of the various settings is confirmed by an audible signal and a visual signal (flashing button).

Repeat this sequence if necessary in order to adjust all the programs.

7. 8 TOOLBOX

Important:
IMPLANT CENTER 2 has a *TOOLBOX* function used to make various adjustments, including brightness, light off time-out, audio volume and factory configuration reset.

To access the *TOOLBOX* function, switch OFF the device, wait four seconds, switch the device ON again, then press button (Fig. 9-41) on the welcome screen (Fig. 9).

a) Audio volume adjustment

Adjust the audio volume value (Fig. 10-43) using buttons − and + (Fig. 10-46 and 47). The audio volume is adjustable from 0% to 100%.

The relative value of the audio volume is displayed (Fig. 10-48).

b) Screen brightness adjustment

Adjust the brightness value ☼ (Fig. 10-44) using buttons [-] and [+] (Fig. 10-46 and 47). The brightness is adjustable from 30% to 100%.

The brightness level setting is displayed (Fig. 10-49).

c) Light off time-out adjustment

Adjust the time-out length value ☼ (Fig. 10-45) by pressing buttons [-] and [+] (Fig. 10-46 and 47).

The length of the adjustable time-out (from nine seconds to 18 seconds) is displayed (Fig. 10-50).

d) Storing the settings

To store the modified settings, press button [OK] (Fig. 10-52). The screen shown in Fig. 9 reappears.

e) Factory configuration reset

Press button [ ] (Fig. 10-42) to restore the factory configuration settings.

The factory configurations for the PIEZOTOME and NEWTRON functions are effective when button [OK] (Fig. 10-52) is pressed. The screen shown in Fig. 9 reappears.

f) Software version

The version of the software is displayed at the bottom of the screen (Fig. 10-51).

IMPLANT CENTER 2 is configured in the factory with the following settings:

I-SURGE mode:

Program	Contra-angle ratio	Speed at instrument end	Torque at instrument end	Irrigation	Functions
P1	20:1	1200 rpm	80 N.cm	80 ml/min.	Implant site marking
P2	20:1	800 rpm	80 N.cm	100 ml/min.	Pilot drilling
P3	20:1	15 rpm	20 N.cm	100 ml/min.	Boring / tapping
P4	20:1	30 rpm	20 N.cm	0	Screwing

PIEZOTOME mode:

	Program	Power	Irrigation	Main functions
Very powerful	D1	3	60 ml/min.	Osteotomy, osteoplasty
Powerful	D2	3	60 ml/min.	
Medium	D3	3	60 ml/min.	
Low	D4	3	60 ml/min.	Soft tissue detachment

NEWTRON mode:

Program		Power	Irrigation	Main functions
Green	Soft	P=5	15 ml/min.	Periodontics
Yellow	Medium	P=5	15 ml/min.	Endodontics
Blue	High	P=5	15 ml/min.	Scaling
Orange	Boost	P=5	15 ml/min.	Loosening

VIII - SAFETY

The IMPLANT CENTER 2 is equipped with a self-diagnosis system to detect malfunctions.

When an excessively high temperature of the I-SURGE micro-motor is detected, symbol 1 (chap. XVII - Symbol) is displayed in the error zone (Fig. 3-9) and the device beeps four times.
The device switches to degraded mode so that it can complete the dental procedure.
The available torque value is set at 25% in order to protect the I-SURGE micro-motor.
It is recommended that the I-SURGE micro-motor be allowed to cool down until symbol 1 (chap. XVII - Symbol) disappears.

In the case of a motor malfunction, symbol 2 (chap. XVII - Symbol) is displayed in the error zone and the device beeps four times.
It is recommended that you check the connections of your motor and your motor cord. If the fault persists, switch the device off at the power switch (Fig. 2-5) and switch it back on again.

In the case of an internal operation malfunction, symbol 3 (chap. XVII - Symbol) is displayed in the error zone and the device beeps four times.
It is recommended that the device be switched off (Fig. 2-5) and switched back on again.

IX - USING THE DEVICE

⚠ **Important:**

- **Do not disconnect the micro-motor cord or the scaler cord when the device is switched on and the footswitch is pressed.**
- **Do not disconnect the micro-motor or the ultrasonic handpieces when the device is switched on and the footswitch is pressed.**
- **Do not connect the instrument to, or disengage it from, the contra-angle when the micro-motor is running.**
- **Do not screw or unscrew tips when the handpieces are on.**
- **All accessories must be cleaned, disinfected and sterilized before use.**

- **For your safety and that of your patient, IMPLANT CENTER 2 must not be used with accessories other than those supplied or recommended by SATELEC.**
- **Check the integrity of the device and its accessories before and after each use in order to detect any problem.**
- **If necessary, do not use the device and replace any faulty component.**

The IMPLANT CENTER 2 is prepared for use as follows:
- Make sure that the device is connected correctly and properly insulated.
- Switch the power switch (Fig. 2-5) to position I (ON).
- Suspend the bottles or bags of physiological saline or sterile water from the brackets.
- Raise the irrigation pump covers.
- Insert the irrigation line cassettes horizontally into their housings.
- Close the covers.
- Insert the irrigation line perforating pins into the bottles or pouches of physiological saline and open the cap on the pins.
- Make any necessary setting adjustments (irrigation flow rate, speed, torque, power, power mode, program, etc.) (refer to chapter 7).

Note: This sequence must be completed under conditions of controlled asepsis for the safety of your patients. An operating assistant may be needed.

Note: The data is saved automatically, in order to maintain the display parameters as previously used upon switchover from the various modes.

I-SURGE function
- Check that there are no traces of moisture on the I-SURGE micro-motor or micro-motor cord connections. If there are, remove by wiping and drying with the multifunction syringe fed with medical-quality filtered air.
- Connect the micro-motor cord to the lefthand connector of the device (Fig. 1-7).
- Align the micro-motor and cord connector electrical contacts, then screw the motor onto the connector.
- Connect a contra-angle to the I-SURGE micro-motor.
- Fit an instrument (drill, bur, etc.) to the contra-angle.
- Fasten the irrigation line to the cord using line clips.
- Connect the end of the irrigation line to the contra-angle.
- Run the motor fitted with its contra-angle and its instrument without irrigation at moderate speed for 10 to 15 seconds in order to diffuse the lubricant and eliminate excess.
- Prime the irrigation circuit by pressing the control keypad flush/prime button (Fig. 3-1).
- When the irrigation solution reaches the end of the contra-angle, release the footswitch.
- Use IMPLANT CENTER 2 in accordance with good dental practice.

PIEZOTOME function
- Connect the PIEZOTOME 2 handpiece cord to the righthand connector of the device (Fig. 1-9).
- Screw the selected tip onto the handpiece using a tip wrench (according to the recommendations of the clinical booklets).
- Fasten the irrigation line to the cord using line clips.
- Connect the end of the irrigation line to the PIEZOTOME 2 handpiece.
- Prime the irrigation circuit by pressing the flush/prime button on the screen (Fig. 3-1) or the multifunction footswitch (Fig. 11-2).
- When the irrigation solution reaches the end of the tip, release the footswitch.
- Use the IMPLANT CENTER 2 in accordance with good dental practice.

NEWTRON function

- Check that there are no traces of moisture on the NEWTRON handpiece or the scaler cord connections. Remove any moisture by wiping and by drying with the multifunction syringe fed with medical-quality filtered air.
- Connect the scaler cord to the righthand connector of the device (Fig. 1-9).
- Align the electrical contacts of the NEWTRON handpiece and the scaler cord, then plug the handpiece into the cord.
- Screw the selected tip onto the handpiece using a tip wrench (according to the *TIPBOOK* recommendations).
- Fasten the irrigation line to the cord using line clips.
- Connect the end of the irrigation line to the scaler cord.
- Prime the irrigation circuit by pressing the flush/prime button on the screen (Fig. 3-1) or the multifunction footswitch (Fig. 11-2).
- When the irrigation solution reaches the end of the tip, release the footswitch.

- Use the IMPLANT CENTER 2 in accordance with good dental practice.

X - SHUTTING DOWN THE DEVICE

Upon completion of the dental procedure:

- Remove the bottles or bags of physiological saline or sterile water from the brackets.
- Remove the irrigation line perforating pins from the bottles or bags.
- Immerse the irrigation line perforating pins in a vessel containing distilled water.
- Rinse each irrigation line alternately, along with the contra-angle and the handpiece, by running the flush/prime function until the vessel and the irrigation lines are completely empty.
- Remove the irrigation line clips.
- Disconnect the single-use irrigation lines from the contra-angle and from the handpieces and dispose of them in a safety container for soiled medical items.
- Remove the rotary instruments fastened to the contra-angle and the tip screwed onto the handpiece.
- Disconnect the contra-angle from the I-SURGE micro-motor.
- Disconnect the micro-motor cord from the I-SURGE.
- Disconnect the PIEZOTOME 2 handpiece or the NEWTRON handpiece and the scaler cord.
- Switch the device OFF (O).

XI - ROUTINE MAINTENANCE / STERILIZATION

⚠ **Important:**

The device must be switched OFF during cleaning and disinfection procedures.

The only irrigation lines that can be sterilized are those identified as sterilizable.

During sterilization, items made of different metals must not come into contact. Any contact would establish galvanic couples and cause localized damage.

To avoid this happening, place the items in individual sterilizable bags or in a sterilization box.

To maintain the sterility or asepsis of the accessories (contra-angle, micromotor, micromotor cord, cords, handpieces, etc.),

store them in sealed bags or containers suitable for medical practice.

The maintenance and/or sterilization instructions below must be applied before each use of the device.

Avoid using cleaning and disinfection agents containing flammable substances.

If this is not possible, make sure that all the agent has evaporated and that there is no combustible matter on the device or its accessories before it is switched on.

Sterilized items must be allowed to dry and cool to room temperature before they are reused.
Before sterilization, check that your autoclave is clean and that the water used is of adequate quality.

After each sterilization cycle, remove the items from the autoclave immediately in order to minimize the risk of metal corrosion.

11. 1 IRRIGATION LINE MAINTENANCE

Sterile irrigation line
The irrigation lines supplied by SATELEC are disposable and must always be discarded after use. Re-use of an irrigation line may result in contamination of your patients and expose you to de facto liability. Do not attempt to resterilize the single-use irrigation lines. Do not attempt to modify the irrigation lines.

Sterilizable irrigation line
Refer to the user's manual delivered with the equipment.

11. 2 CONTRA-ANGLE MAINTENANCE

Refer to the manufacturer's instructions for your contra-angle.

11. 3 ROTARY INSTRUMENT MAINTENANCE

Please refer to the manufacturer's instructions for your instruments (burs, drills, etc.).

11. 4 DEVICE MAINTENANCE

⚠ **Important:**
Never use an abrasive cleaning agent on the device.
Do not use sprays or liquids to clean and disinfect the IMPLANT CENTER 2 control unit.
The device, the brackets and the multifunction footswitch are not sterilizable.

The IMPLANT CENTER 2 control unit, the control footswitch and the bracket must always be cleaned and disinfected after each procedure, using alcohol, disinfectant agents or disinfectant wipes for dental practices, such as SEPTOL™ wipes.
Regular monitoring of the IMPLANT CENTER 2 unit is necessary in order to detect any problem.
It is important to keep the control unit ventilation vents clean in order to avoid abnormal heating.

11. 5 MICROMOTOR CORD AND SCALER CORD MAINTENANCE

⚠ **Important:**
Never use an abrasive cleaning agent on the cords.
The cords must not be immersed or disinfected using agents containing acetone, chlorine or bleach.
The cords must not be cleaned in an ultrasonic bath.

a) Cleaning and disinfection
The cords must always be cleaned, disinfected and sterilized after each procedure, using alcohol, disinfectant agents or disinfectant wipes for dental practices, such as SEPTOL™ wipes.

b) Sterilization
The cords can be sterilized in an autoclave under the following conditions:
- Autoclave: Class B
- Sterilization temperature: 134°C at 2 Bar.
- Time at sterilization temperature: 18 minutes.

CAUTION: Not all autoclaves can reach 134°C. Not all autoclaves draw a pre-vacuum. Please refer to your autoclave manufacturer for specific sterilization instructions.

11. 6 I-SURGE MICRO-MOTOR MAINTENANCE

⚠ **Important:**
Never use an abrasive cleaning agent on the I-SURGE micro-motor.
The I-SURGE micro-motor must not be immersed or disinfected using agents containing acetone, chlorine or bleach.
The I-SURGE micro-motor must not be cleaned in an ultrasonic bath or disassembled.

The I-SURGE micro-motor is a high-technology device. To maintain optimal performance, the following recommendations must be complied with.

a) Cleaning and disinfection
Use cleaning and disinfection agents compatible with the I-SURGE micro-motor (such as SPRAYNET®).
When using a spray, spray the outside and inside of the I-SURGE micro-motor moderately to expel residues.
Clean and disinfect the surfaces using a clean, lint-free cloth impregnated with the agent.

b) Lubrication
Lubricate before each sterilization or at least twice a day.
Use lubricants compatible with the I-SURGE micro-motor (such as LUBRIFLUID®).
Place a clean cloth over the I-SURGE micro-motor ventilation vents to absorb the surplus lubricant.
Inject the lubricant through the nose of the micro-motor using an oilcan of lubricant (or a spray) for one-half to one second.

c) Sterilization
The I-SURGE micro-motor can be sterilized in an autoclave under the following conditions:
- Autoclave: Class B.
- Sterilization temperature: 134°C.
- Time at sterilization temperature: 18 minutes.

11. 7 ULTRASONIC HANDPIECE MAINTENANCE

After each use, the handpiece irrigation circuit must be rinsed with distilled or demineralized water for 20 to 30 seconds.
Disconnect the NEWTRON handpiece from its cord before cleaning, disinfection and sterilization.

Cleaning and disinfection:
The handpieces must always be cleaned, disinfected and sterilized after each procedure, using alcohol, disinfectant agents or disinfectant wipes for dental practices, such as SEPTOL™ wipes. For handpiece sterilization, refer to the manual for each product.

11. 8 TIP MAINTENANCE

a) Lifetime
Tip shape and weight are the determining characteristics for obtaining maximal efficiency of the ultrasonic generator.

Careful monitoring of these two characteristics by the user will ensure that optimal performance of the device is maintained.

Consequently, you are strongly advised not to alter the structure of the tips by filing or twisting them or modifying them in any other way.

Similarly, through normal wear, tip aging leads to alteration of its characteristics. Always replace a tip that has been damaged by wear or by accidental impact (dropped, bent, etc.).

Use the *TIPCARD* to check scaler tip wear. Replace routinely-used tips at least once a year.

b) Pre-disinfection / chemical cleaning
To be carried out immediately after treatment, wearing thick gloves. Immerse in an ultrasonic bath (enzymatic, quaternary ammonium base detergent / disinfectant solution), carefully respecting the concentration and contact time recommended by the manufacturer of the solution.

Use a solution that bears the EC marking or that is in compliance with any standard required by the national regulations.
Rinse under running water for at least 30 seconds.

c) Mechanical / chemical cleaning
To be carried out immediately after pre-disinfection/chemical cleaning, wearing thick gloves. Scrub the products in a new bath of enzymatic, quaternary ammonium base detergent / disinfectant solution, for at least 30 seconds, and in any case until all remaining traces of contamination have been removed.
Rinse again under running water for at least 30 seconds.

d) Drying
Dry with a clean, non-woven single-use cloth, so as to remove any traces of liquid.

Pack in single-use sterilization pouches or bags in compliance with the specifications defined in standard EN ISO 11607-1 or in any equivalent standard required by the national regulations.

e) Sterilization

The tips must be sterilized individually in an autoclave, according to the following parameters:

- autoclave: type B, compliant with standard EN 13060;
- sterilization temperature: 134°C;
- sterilization stabilization time: 18 minutes;
- pressure: 2 Bars min.

f) Storage

Store the sterilized products in a dry place protected from dust. Before re-use, if the integrity of the packaging is not certain, repackage then re-sterilize in accordance with the defined protocol.

If contamination is visible inside the bag, destroy the product.

g) Disposal of the product

Dispose of the product in receptacles for waste materials of healthcare activities involving infectious risks.

CAUTION: Not all autoclaves can reach 134°C. Not all autoclaves draw a pre-vacuum. Please refer to your autoclave manufacturer for specific sterilization instructions.

XII - MONITORING / MAINTENANCE

⚠ **Important:**

In the case of a fault, you are advised to contact the supplier of your device. Do not use unauthorized repairers, who might make your device dangerous for you and your patients.

12. 1 MONITORING

Regular monitoring of the device and its accessories is necessary in order to detect any insulation fault or damage. Replace them if necessary.

It is important to keep the control unit ventilation vents clean in order to avoid abnormal heating.

12. 2 MAINTENANCE

I-SURGE micro-motor inspection/overhaul: SATELEC recommends inspection or overhaul of the I-SURGE micro-motor at least once a year.

12. 3 FUSE REPLACEMENT

IMPLANT CENTER 2 is protected by two fuses located in the power receptacle (Fig. 2-1).

The replacement procedure is as follows:

- Switch the device OFF (position O).
- Unplug the power cord from the electricity supply.
- Unplug the power cord from the receptacle (Fig. 2-1). Insert the tip of a flat screwdriver into the notch above the fuse drawer to release it.
- Remove the old fuses.
- Replace the old fuses with fuses of the same type and rating.
- Push the fuse drawer back into its housing until it clicks to indicate the correct position.
- Plug the power cord into the receptacle (Fig. 2-1). Plug the power cord into the electrical supply.

Note:
The device also has an internal fuse not accessible to the user.
Contact SATELEC after-sales service (see Chapter 2 - Repairs).
All the information necessary for the repair of faulty components is made available by SATELEC to the technical personnel of the SATELEC-approved dealer network who carry out the work.

12. 4 OPERATION FAULTS

Refer to the tables on the next page:

Fault	Possible cause	Remedy
Aucun fonctionnement (Ecran LCD éteint) Device does not operate (LCD screen off)	Power cord not plugged in properly.	Check the electric socket. Return to SATELEC after-sales.
	Power switch in position O (OFF).	Place the power switch in position I (ON).
	No power voltage.	Call an electrician.
	Power receptacle fuse(s) blown.	Replace the power receptacle fuses.
	Internal fuse blown	Return to SATELEC after-sales.
Device does not operate (LCD screen on)	Transmission fault.	Switch the device OFF then ON again. Return to SATELEC after-sales.
Motor does not operate	Motor or motor connections problem.	Check the motor cord connector. Check that the cord connector is properly plugged into the motor connector of the device. Return to SATELEC after-sales.
Torque fault	Thermal cut-out.	Allow the micro-motor to cool down.
	Incorrect torque adjustment.	Adjust the torque in accordance with good dental practice.
	Wrong contra-angle.	Change the contra-angle. Return to SATELEC after-sales.
Speed fault	Incorrect speed adjustment.	Adjust the speed in accordance with good dental practice.
	Wrong contra-angle.	Change the contra-angle. Return to SATELEC after-sales.
No spray	Irrigation solution bag or bottle empty.	Replace the bag or bottle of irrigation solution.
	Irrigation off.	Press the irrigation ON/OFF button.
	Irrigation line clogged.	Change irrigation line.
	Line end piece on contra-angle clogged.	Clear the contra-angle line end piece.

Fault	Possible cause	Remedy
Inadequate spray	Incorrect irrigation flow rate adjustment.	Adjust the irrigation flow rate.
Micro-motor does not operate	Faulty micro-motor cord connector electrical contacts.	Clean the electrical contacts of the micro-motor cord connectors.
	Faulty micro-motor electrical contacts.	Clean the electrical contacts of the micro-motor.
	Micro-motor cord wires cut.	Return to SATELEC after-sales to replace the cord.
	Motor damaged.	Return to SATELEC after-sales to replace the motor.
Power fault weak tip vibration	Tip worn or distorted.	Replace the tip.
	Incorrect power adjustment.	Refer to the *TIPBOOK* and the clinical booklet for the necessary information.
	Incorrect use: incorrect angle of attack or inadequate pressure on the tooth.	Refer to the *TIPBOOK* and the clinical booklet for the necessary information.
	Liquid or moisture present between handpiece and cord.	Dry the electrical contacts thoroughly.
No ultrasonic function	Incorrect tip tightening.	Retighten the tip with the wrench.
	Faulty connector contact.	Clean the connector contacts.
	Handpiece cord wire cut.	Return to SATELEC after-sales to replace the cord.
No light	Handpiece light ring absent.	Install the light ring.
	Faulty light ring.	Replace the light ring.
	Faulty light ring connector contacts.	Clean the light ring connector contacts.
	Light ring the wrong way around.	Position the light ring according to the foolproofing stud.
	Faulty handpiece and/or cord connector contacts.	Clean the handpiece and/or cord connector contacts.
	Other.	Contact your installer-fitter.
Leak between the NEWTRON handpiece and the handpiece cord	Worn handpiece 1.15x1 seal	Replace the seal (kit F12304).
Liquid leak in the irrigation pump	Broken tube in the irrigation line cassette.	Replace the irrigation line.

XIII - ELECTROMAGNETIC COMPATIBILITY

⚠ **Important:**
The power cord, the ultrasonic handpiece cords and the multifunction footswitch cord must be kept away from each other.

IMPLANT CENTER 2 requires special precautions to be taken with regard to electromagnetic compatibility.
It must be installed and prepared for use as described in chapter 4.
Certain types of mobile telecommunication devices such as mobile telephones are likely to interfere with the IMPLANT CENTER 2.
The recommended separation distances in this paragraph must therefore be complied with.
IMPLANT CENTER 2 must not be used near or on top of another device.
If this cannot be avoided, its operation under the conditions of use must be checked beforehand.
The use of accessories other than those specified or sold by SATELEC as replacement parts may have the consequence of increasing the emissions or decreasing the immunity of the IMPLANT CENTER 2.

13. 1 ELECTROMAGNETIC EMISSIONS

IMPLANT CENTER 2 is intended for use in the electromagnetic environment specified in the table below.
The user and/or installer must ensure that the IMPLANT CENTER 2 is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emission - CISPR 11.	Group 1	IMPLANT CENTER 2 uses RF energy for internal operation. Therefore, its radiofrequency emissions are very low and are not likely to cause any interference in nearby equipment.
RF emission - CISPR 11.	Class A	IMPLANT CENTER 2 is suitable for use in all establishments, except domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic current emission IEC 61000-3-2.	Class A	
Voltage fluctuation and flicker IEC 61000-3-3.	Complies	

13. 2 ELECTROMAGNETIC IMMUNITY

IMPLANT CENTER 2 is intended for use in the electromagnetic environment specified in the table below. The user and/or installer must ensure that the device is used in such an electromagnetic environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2.	± 6KV contact ± 8KV air	± 6KV contact ± 8KV air	Floors must be wood, concrete, cement or tiled. If floors are covered with synthetic material (carpet, etc.), the relative humidity must be at least 30%.
Electrical fast transients IEC 61000-4-4.	± 2KV for power supply lines	± 2KV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment (hospital, clinic).
Surges IEC 61000-4-5.	± 1KV differential mode ± 2KV common mode	± 1KV differential mode ± 2KV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations IEC 61000-4-11.	<5% UT (>95% dip in UT) for 0.5 cycles. 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 250 cycles	<5% UT (>95% dip in UT) for 0.5 cycles. 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the use of the IMPLANT CENTER 2 requires continued operation during power mains interruption, it is recommended that the product be powered from a separate power supply (UPS, etc.).

13. 3 ELECTROMAGNETIC IMMUNITY / RADIOFREQUENCY MOBILE EQUIPMENT

The IMPLANT CENTER 2 is intended for use in the electromagnetic environment specified in the table below. The user and/or installer must ensure that the device is used in such an electromagnetic environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Portable and mobile radiofrequency communications devices must not be used near the IMPLANT CENTER 2 (including its cables) at a distance less than that recommended and calculated according to the frequency and power of the emitter.			
Conducted disturbance, radiofrequency fields. IEC61000-4-6	3 V/m 150 KHz to 80 MHz	3 V/m	Recommended separation distance: $d = 1.2 \sqrt{P}$
Radiated radiofrequency electromagnetic field. IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80MHz to 800MHz. $d = 2.3 \sqrt{P}$ 800MHz to 2.5GHz. Where P is the maximum power rating of the emitter in watts (W) according to the manufacturer's specifications and d is the recommended minimum separation distance in meters (m).
The electromagnetic field strengths of fixed radiofrequency emitters, as determined by an electromagnetic environment measurement (a), must be less than the compliance level in each frequency range (b). Interference may occur near equipment marked with the symbol below: 			

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These specifications may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and persons.

(a): The electromagnetic field strengths of fixed radiofrequency emitters, such as base stations for mobile telephones (cellular/cordless), mobile radios, amateur radio, AM/FM radio broadcasts and TV broadcasts cannot be determined exactly by theory. To assess the electromagnetic environment due to fixed radiofrequency emitters, an electromagnetic environment measurement must be made. If the measured radiofrequency field strength in the immediate environment where the product is used exceeds the compliance level specified above, the performance of the product must be tested to verify whether it conforms to the specification. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the product.

(b): In the 150 kHz to 80 MHz frequency range, the electromagnetic field strengths must be less than 3 V/m.

13. 4 RECOMMENDED SEPARATION DISTANCES

IMPLANT CENTER 2 is intended for use in an electromagnetic environment in which radiated radiofrequency disturbances are controlled.

The IMPLANT CENTER 2 user and/or installer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radiofrequency communications equipment emitters and the IMPLANT CENTER 2, according to the maximum output power of the equipment, as recommended in the table below.

Rated max. power of the emitter (W)	Separation distance in metres (m) according to emitter frequency		
	150 KHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0,01	0.12 m	0.12 m	0.23 m
0,1	0.38 m	0.38 m	0.73 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m
For emitters rated at max. power not listed above, the recommended separation distance d in meteres (m) can be estimated using the equation applicable to the frequency of the emitter, where P is the max. power rating of the emitter in watts (W) according the manufacturer.			

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These specifications may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and persons.

13. 5 CABLE LENGTHS

Cables and accessories	Maximum length	Complies with:
Handpiece cords Footswitch cord Power supply cord	Less than 3m	RF emission, CISPR 1 - Class A/Group 1 Harmonic current emission: IEC61000-3-2 Voltage fluctuation: IEC61000-3-3 Immunity to electrostatic discharge: IEC61000-4-2 Immunity to electrical fast transients/bursts: IEC61000-4-4 Immunity to surges: IEC61000-4-5 Immunity to voltage dips, short interruptions and voltage variations: IEC61000-4-11 Immunity to conducted disturbances induced by radiofrequency fields: IEC61000-4-6 Immunity to radiated radiofrequency electromagnetic fields: IEC61000-4-3

XIV - DISPOSAL AND RECYCLING

As electrical and electronic equipment, the device must be disposed of according to a specialized procedure for collection, pick-up and recycling or destruction (in particular on the European market, with reference to Directive 2002/96/EC of 27/01/2003).

When your device reaches the end of its life, we consequently recommend that you contact your dental equipment dealer (or, failing this, the ACTEON Group website, the address of which is given in chapter 18), for information on how to proceed.

XV - MANUFACTURER'S LIABILITY

The manufacturer is not liable if:
- the manufacturer's installation recommendations have not been followed (supply voltage, electromagnetic environment, etc.)
- repairs or other work have been done on the device by persons not authorized by the manufacturer
- the device has been used connected to an electrical system that does not comply with current regulations
- the device has been used in ways other than those specified in this manual
- accessories (tips, handpiece, irrigation lines, etc.) other than those supplied by SATELEC have been used
- the instructions in this document have not been followed.

Note: The manufacturer reserves the right to modify the device and/or the user's manual without notice.

XVI - REGULATIONS

This medical device is classified as class IIa according to European Directive relevant to Medical Devices currently in force.
This equipment is manufactured in compliance with the current IEC 60601-1 standard.
This equipment has been designed and manufactured according to an ISO 13485-certified quality assurance system.

	Audio level / Niveau sonore / Nivel sonoro / Lautstärke / Livello acustico / Geluidsterkte / Nível sonoro / Ljudnivå / Ένταση ήχου
	Brightness / Luminosité / Luminosidad / Kontrast / Luminosità / Helderheid / Luminosidade / Ljusstyrka / Φωτεινότητα
	Time-out length / Durée de temporisation / Duración del temporizador / Abschaltzeit / Durata di temporizzazione / Wachttijd / Duração de temporização / Fördröjningstid / Διάρκεια χρονομέτρου
	Factory configuration / Configuration usine / Configuración de fábrica / Werksseitige Konfiguration / Configurazione di default / Fabrieksinstellingen / Configuração de fábrica / Fabriksinställning / Εργοστασιακές ρυθμίσεις
	Refer to the accompanying documentation / Se référer à la documentation d'accompagnement / Consultar documentación que acompaña / Siehe Begleitunterlagen / Fare riferimento alla documentazione allegata / Meegeleverde documenten raadplegen / Consultar a documentação de acompanhamento / Se medföljande dokumentation / Ανατρέξτε στα συνοδευτικά έγγραφα
	Class BF / Classe BF / Clase BF / Niederfrequenz / Classe BF / Klasse BF / Classe BF / Κλάση BF
I	Class 1 / Classe 1 / Clase 1 / Klasse 1 / Classe 1 / Klasse 1 / Classe 1 / Klass BF / Klass 1 / Κλάση 1
	Sterilization at 134°C in an autoclave / Stérilisation à 134°C dans un autoclave / Esterilización a 134°C en autoclave / Sterilisation im Autoklav bei 134°C / Sterilizzazione a 134°C in autoclave / Sterilisatie op 134°C in een autoclaaf / Esterilização a 134°C numa autoclave / Sterilisering vid 134°C i autoklav / Αποστείρωση στους 134°C σε αυτόκλειστο
	EC marking / Marquage CE / Marca CE / CE-Kennzeichnung / Marcatura CE / CE-markering / Marcação CE / CE-märkning / Σήμανση CE
	Do not dispose of in household waste / Ne pas jeter dans les poubelles domestiques / No tirar en los contenedores domésticos / Nicht mit Hausmüll entsorgen / Non gettare nei cassonetti dei rifiuti domestici / Niet bij het huishoudelijke afval zetten / Não deitar no lixo doméstico / Ej hushållsavfall / Μην απορρίπτετε σε κάδους για οικιακά απορρίμματα
XXXX 	Year of manufacture / Année de fabrication / Año de fabricación / Baujahr / Anno di fabbricazione / Bouwjaar / Ano de fabrico / Tillverkningsår / Έτος κατασκευής
	Alternating current / Courant alternatif / Corriente alterna / Wechselstrom / Corrente alternata / Wisselstroom / Corrente alternativa / Växelström / Εναλλασσόμενο ρεύμα
	Control footswitch / Pédale de commande / Pedal de mando / Fußpedalkabel / Pedale di comando / Bedieningspedaal / Pedal de comando / Kontrollpedal / Εξωτερικό κομβίο ελέγχου
O	Device power OFF / Appareil hors tension / Equipo sin tensión / Gerät AUS / Apparecchio fuori tensione / Apparaat Uit / Aparelho fora de tensão / Apparat ur spänning / Απενεργοποιημένη συσκευή
I	Device power ON / Appareil sous tension / Equipo con tensión / Gerät EIN / Apparecchio sotto tensione / Apparaat Aan / Aparelho sob tensão / Apparat under spänning / Ενεργοποιημένη συσκευή
	Motor ON / Partie active moteur / Pieza activa motor / Aktives Motorteil / Parte attiva motore / Actieve motordeel / Parte activa do motor / Aktiv del motor / Ενεργό μέρος μοτέρ
	Ultrasound part ON / Partie active ultrasons / Pieza activa ultrasonido / Aktives Ultraschallteil / Parte attiva ultrasuoni / Actieve ultrasone deel / Parte activa ultra-sons / Aktiv del ultraljud / Ενεργό μέρος υπέρηχοι

XVIII - CUSTOMER RELATIONS / RELATIONS CLIENTELE / RELACIÓN CON EL CLIENTE / ANSCHRIFTEN / RELAZIONI CON I CLIENTI / KLANTENBETREKKINGEN / RELAÇÕES COM OS CLIENTES KUNDRELATIONER / ΕΠΙΚΟΙΝΩΝΙΑ ΠΕΛΑΤΩΝ

18. 1 MANUFACTURER IDENTIFICATION / IDENTIFICATION DU FABRICANT / IDENTIFICACIÓN DEL FABRICANTE / IDENTIFIKATION DES HERSTELLERS / IDENTIFICAZIONE DEL PRODUTTORE / IDENTIFICATIE VAN DE FABRIKANT / IDENTIFICAÇÃO DO FABRICANTE / IDENTIFIERING AV TILLVERKAREN /ΣΤΟΙΧΕΙΑ ΤΟΥ ΚΑΤΑΣΚΕΥΑΣΤΗ

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18. 2 SUBSIDIARIES / ADRESSE FILIALES / DIRECCIÓN FILIALES / ADRESSEN DER TOCHTERGESELLSCHAFTEN / INDIRIZZI DELLE FILIALI / ADRESSEN VAN FILIALEN / MORADA DAS FILIAIS / DOTTERBOLAGSADRESSER / ΔΙΕΥΘΥΝΣΕΙΣ ΘΥΓΑΤΡΙΚΩΝ

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Fig. / Afbeelding 1



Fig. / Afbeelding 2

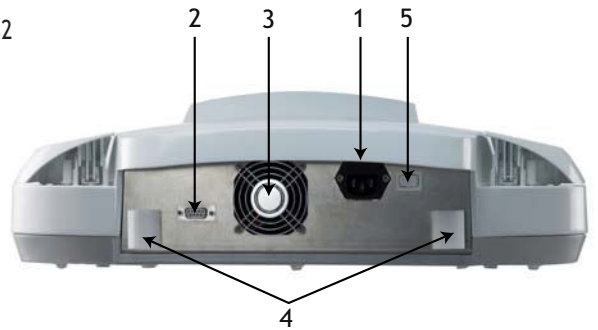


Fig. / Afbeelding 3

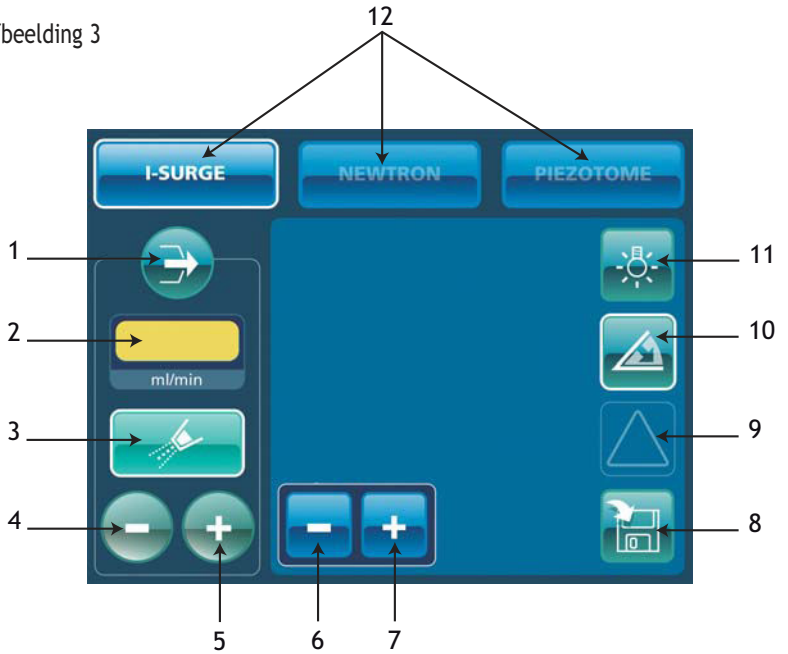


Fig. / Afbeelding 4



Fig. / Afbeelding 5



Fig. / Afbeelding 6

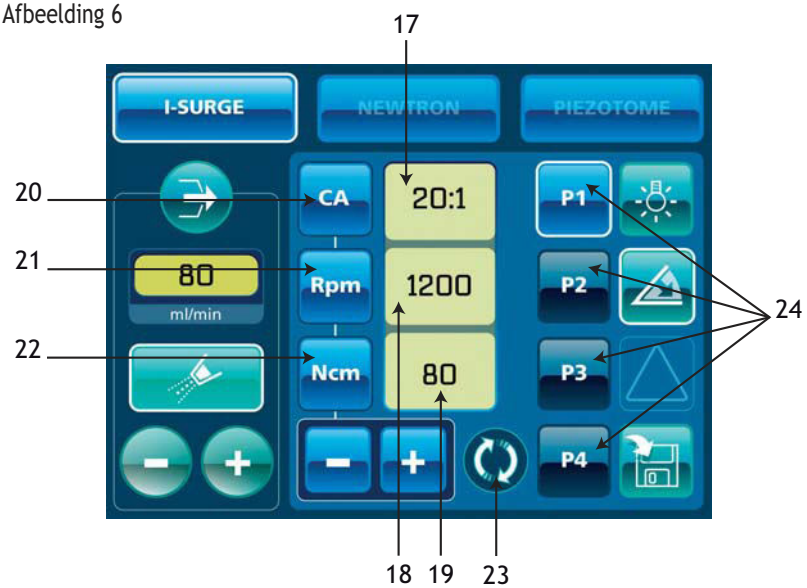


Fig. / Afbeelding 7

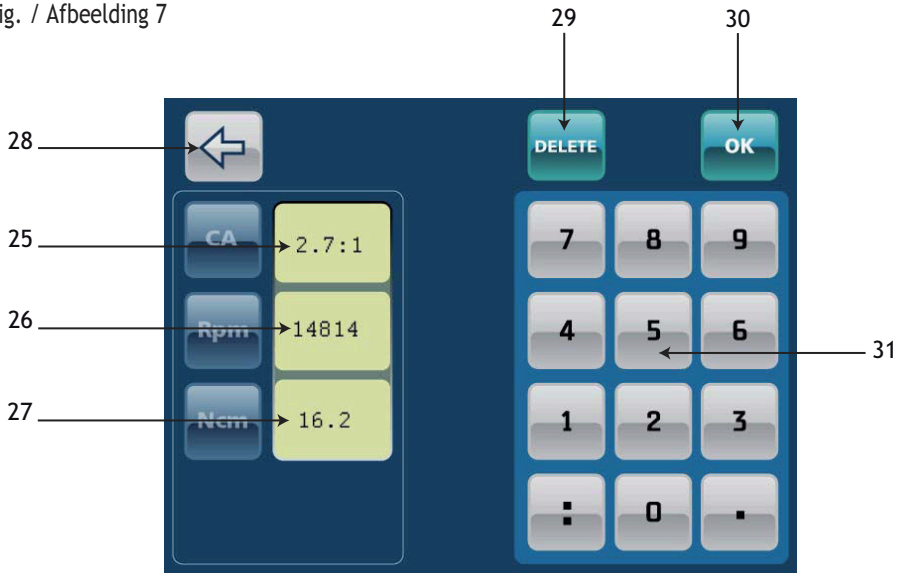


Fig. / Afbeelding 8

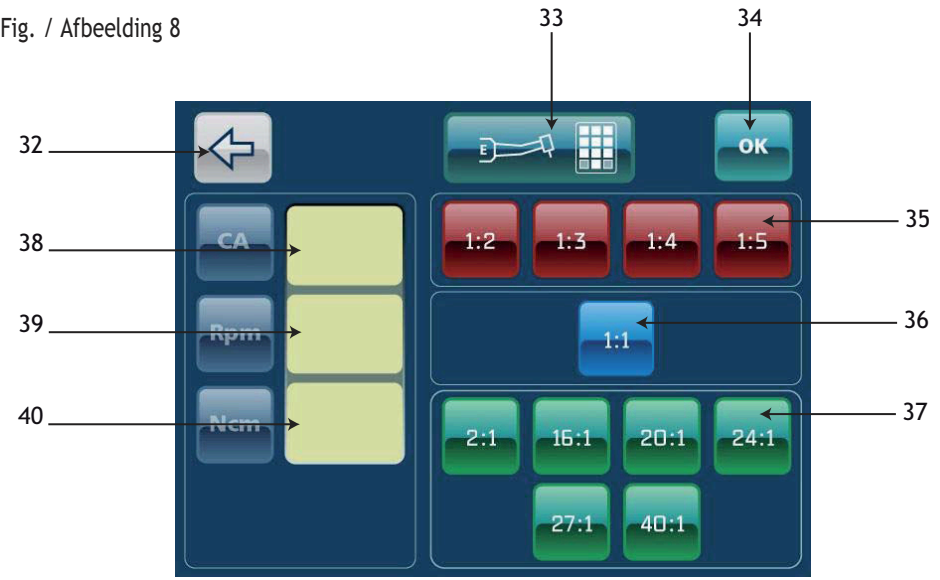


Fig. / Afbeelding 9



Fig. / Afbeelding 10

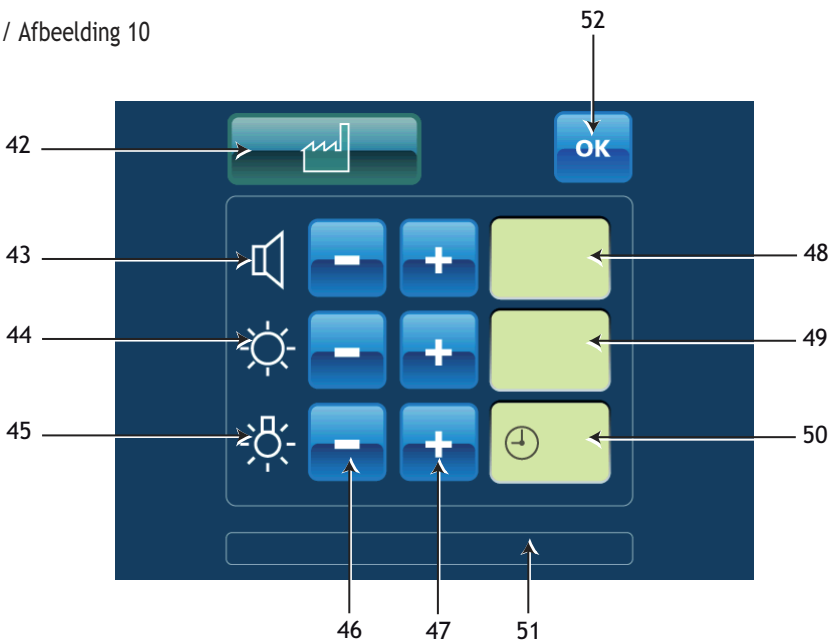
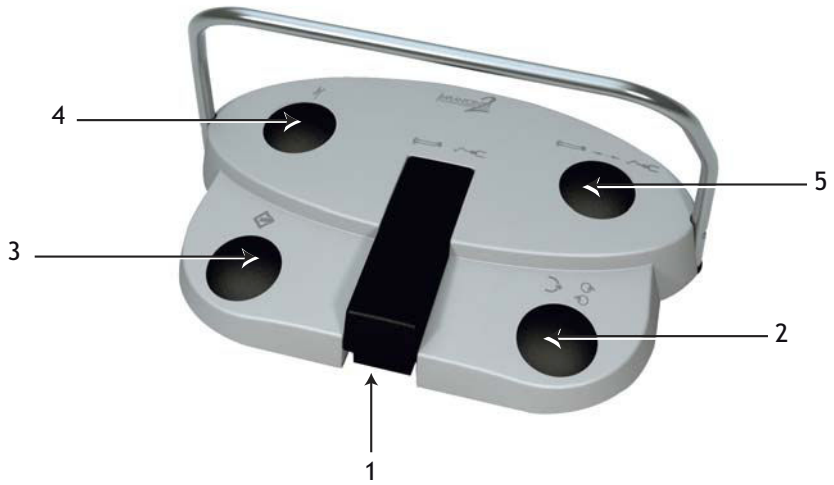


Fig. / Afbeelding 11



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