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User Instruction

calaject™

Computer Assisted Local Analgesia

RØNVIG Dental Mfg. A/S

REF 2111, 2116, 2118, 2126

CONGRATULATIONS ON YOUR NEW CALAJECT™

Please read these instructions thoroughly before you start using your CALAJECT™.

INTENDED USE

CALAJECT™ is intended for performing dental local analgesia.

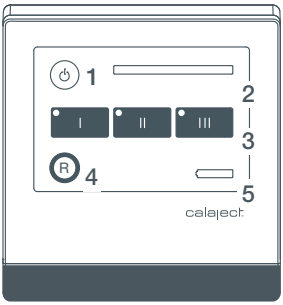
CALAJECT™ MAY ONLY BE USED BY TRAINED PERSONNEL authorized to perform dental injections. For this reason, this manual does not include specific instructions in injection techniques. The manufacturer cannot be held liable for injuries in patients due to unauthorized or incorrect use.

CONTENTS

1 Control unit
1 Handpiece with cord
1 Foot switch
6 Cartridge barrels, material PSU polymer
1 Stand for handpiece
1 Charger (Friwo FW7401M/12)
1 User instructions
1 Maintenance Kit

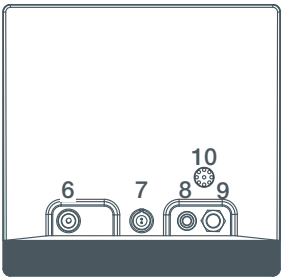
DESCRIPTION OF CONTROL UNIT

FRONT PANEL WITH FINGER TOUCH DISPLAY



1. On/Off switch
2. Bar-scale for display of current injection pressure/resistance
3. Program selection I, II, III
4. Piston rod retraction. Returns the piston rod to start position
5. Charging and battery level indicator

REAR PANEL



6. **Charge** socket
   Battery charger plug is the disconnecting device
7. Socket for handpiece
8. **Pedal** connection to foot switch
9. **Volume** control for sound signal
10. Sound aperture

REPROCESSING INSTRUCTIONS

	Unit, Handpiece, Cord and Footswitch	Cartridge Barrel
WARNINGS 	Do not immerse into liquid. Do not autoclave. The CALAJECT™ unit and the handpiece contain sensitive electronic components that do not withstand sterilization or immersion in liquid.	Avoid cleaning the cartridge barrel in a dental washer disinfector as this can lead to clouding of the transparent barrel.
Limitations on reprocessing	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.
Instructions		
Containment and transportation	No particular requirements	No particular requirements
Prepration for cleaning	No particular requirements	No particular requirements
Cleaning: Automated	Do not use	Do not use
Cleaning: Manual	Use disinfectant wipes.  Do not spray liquids directly on the control unit surfaces. Aerosols of disinfectant may enter at the touch panel and impair the function of the touch keys.	Rinse excess soil from barrel. In tap water and a household dishwash soap. Rinse with water.
Disinfection	Disinfect with an EPA-registered disinfectant unless the item is visibly contaminated with blood; in that case a tuberculocidal agent (or a disinfectant with specific label claims for HBV and HIV) or a 1:100 dilution of a hypochlorite solution (500–600 ppm free chlorine) should be used.	No particular requirements
Drying	No particular requirements	Air-dry on a clean paper tissue
Maintenance	No particular requirements	No particular requirements
Inspection and function testing	No particular requirements	No particular requirements
Sterilization	Do not sterilize	Sterilize it in a pre-vacuum (ISO 13060 Class B) steam sterilization autoclave at 121°C / 250°F for 15 minutes, or at 134°C / 275°F for 3 minutes.
Additional Information	No particular requirements	When sterilizing multiple instruments in one autoclave cycle ensure that the sterilizer's maximum load is not exceeded.

The instructions provided above have been validated by the medical device manufacturer as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

TEST AND TRAINING

New users must read these instructions carefully and familiarize themselves with the functions and different programs before using CALAJECT™.

PLACING

CALAJECT™ should be placed on a stable base during use. Ensure good access to all sockets and plugs during use and charging.

CHARGING

CALAJECT™ may only be charged with the charger supplied with the system. Use of other chargers may damage the equipment and compromise the electrical safety.

For battery lifetime reasons it is recommended to remove the mains cable during use and operate on battery only. Avoid draining the battery completely - that might shorten longevity as well.

MAINTENANCE BY USER

Replace the piston O-ring annually or if worn or damaged.

Extend the piston out. Use your fingers or a rubber tipped instrument to remove the old O-ring - do not use a metal tool. Clean the piston with a moistened clean tissue or a disinfectant wipe.

Roll a new O-ring into the piston groove. Coat the O-ring and piston surface with a thin layer of food-grade PTFE grease by using a cotton swab or microbrush. Move the piston back and forth. Wipe off excess grease with a clean tissue. IMPORTANT: Do not use other types of lubricants, especially any containing solvents or silicone.

Repeat the described cleaning and lubricating procedure if anesthesia fluid has leaked into the handpiece.

SERVICE WARRANTY & REPAIR

CALAJECT™ is covered by a 2-year guarantee on materials and construction. Normal wear and tear and damages due to inadequate use or maintenance are not covered by the warranty. In the event of malfunction, please return the device to your CALAJECT™ dealer for repair. Repairs must be performed by authorized technical personnel only. CALAJECT™ may not be serviced or maintained during use.

PREVENTIVE INSPECTION OF EQUIPMENT

The user should check if the cords are intact and also inspect the parts for possible damages and wear. Possible traces of leaked analgesic at the piston rod opening in the CALAJECT™ handpiece can be removed by using a cotton stick moistened with a surface disinfectant - blow it dry with clean air.

GETTING STARTED

Do not place CALAJECT™ in an environment of flammable gases.

CALAJECT™ should not be placed close to devices that are sensitive to – or generate – electromagnetic interference.

- **Connect the handpiece cord plug to the CALAJECT™ rear panel**
  – the red dot on CALAJECT™ and the handpiece plug must be aligned. Unplug by pulling the grooved sliding ring backwards (do not turn).

Do not touch patient and connectors of control unit / battery charger at the same time.

- **Turn on CALAJECT™** by touching the on/off key at the front panel. By this, the piston will automatically return to starting position.
- **Check the battery status on the display.** At one remaining dot at the battery display, max one injection can be completed. Charging time approx. 3 hours. Operating time approx. 5 hours, when fully charged.
- **Attach a needle on the cartridge barrel and insert an anaesthetic cartridge.** To avoid leakage at the membrane of the cartridge it is advised to screw on the needle first and then insert the cartridge. The cartridge barrel fits standard 1.7/1.8 ml dental cartridges and standard dental needles.

Make sure that the needle is completely mounted and that the needle fits the applied cartridge barrel (standard metric thread (M6) or imperial inch thread (7/32")).

- **Mount the loaded cartridge barrel onto the handpiece.** Before the barrel is screwed onto the handpiece, the piston rod should be retracted to starting position. It will automatically return to starting position, when CALAJECT™ is turned on. The piston rod can also be returned to starting position by pressing "R" on the display.
- **Prime the needle**, by applying a quick tap on the foot switch. The plunger will then move forward for 2 sec. after which it will stop automatically. Now the piston is fully engaged in the cartridge and CALAJECT™ is ready for injection. This priming mode is indicated by a rotating light signal at the front panel.

Do not inject in prime-needle mode.

- **Select program.** When the foot switch is activated again, the chosen injection program will be active.
- CALAJECT™ will stop automatically, when the cartridge is empty - a long beep will be heard. Return the piston rod by pressing "R" at the display. Make sure to let the piston retract completely, before you unscrew the barrel from the handpiece.

CALAJECT™ will stop automatically when it reaches the pre-programmed maximum pressure. In such case, a long sound signal will be heard and the pressure bar-scale on the display will turn off. Wait a moment or move the needle to a new position before you continue the injection.

Change the needle if you suspect a clogging of the cannula. Otherwise this may result in a high back pressure and automatic stop. CALAJECT™ will also turn off automatically, if it has been turned on for a continuous period of 6 hours (=battery protection). Can be restarted in the normal way after such incident.

ASPIRATION

CALAJECT™ aspirates automatically whenever the foot switch is deactivated during injection in Program I, II and III.

SAFE NEEDLE HANDLING

The cavity in the CALAJECT™ handpiece holder is designed for parking the needle sheath during injection. It facilitates one-handed recapping after and between injections and allows you to place the handpiece safely in the holder with reduced risk of injuring yourself on a used, contaminated needle.

AUDIBLE SIGNALS

Two-tone signal: By injection in program I, II, and III, the frequency of the sound indicates the current injection speed.

Deeper two-tone signal: In program I the sound will change when the foot switch has been activated for 5 seconds. That indicates that autoflow is active if your foot is lifted from the foot switch. After 10 seconds, CALAJECT™ will resume the normal two-tone signal. The brief time window of a deeper tone level indicates when autoflow is possible without continuous activation of the foot switch.

Long, continuous beep: • cartridge is empty • automatic stop

The beep intensity may be adjusted by the volume button (9) by using a flathead screwdriver or a mini-spatula.

VISUAL SIGNALS

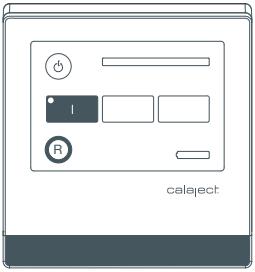
When CALAJECT™ has been prepared and is switched on, Program II will illuminate as default. The piston will retract automatically, which is indicated by three illuminated LEDs rotating around the “R” key. During activation, the LED of the selected program will blink with the two-tone signal and thereby reflect the injection speed. The back pressure on the piston can be read on the bar-scale at top of the display. At increased counter pressure, the bar will iluminate gradually from left to the right with green LEDs. Finally the bar will turn orange and red, after which CALAJECT™ will stop automatically. The battery indicator is green only. 4 LED dots indicate full charge.

CLINICAL RECOMMENDATIONS

It is recommended to apply a topical local anesthetic gel before needle insertion. Generally, the authorized user bear the responsibility to perform dental local anesthesia according to current text-book guidance.

PROGRAM I

Recommended for intraligamental – and also palatal – analgesia



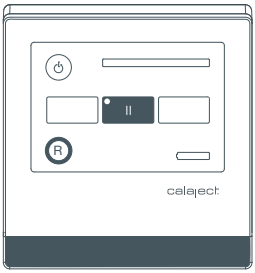
- Activate the foot switch and hold it down. CALAJECT™ starts in slow injection mode, 0.006 ml/sec. Option: The speed can be increased to 0.009 ml/sec by a quick release/re-activation of the foot switch. The speed can be changed back again by a renewed release/re-activation.
- The PDL-technique requires a relatively high injection pressure initially. This is why Program I allows a substantially higher injection pressure / resistance than program II and III before the automatic stop is activated.
- Automatic suck-back / aspiration when foot switch is deactivated. Minimizes after-dripping from the needle.
- Autoflow - five seconds after program start the sound signal is changing. This indicates that you can release the foot control and let the autoflow take over. You stop the injection again by tapping the foot switch. Note, AutoFlow is only an option in program I.

TIP: For intraligamental (PDL) analgesia it is recommended to dose 0.2 – 0.9 ml per root depending on the size of the root and the expected duration of the procedure. For further guidance on the PDL technique, we refer to the published literature on the subject.

TIP: If the pressure has become so high that CALAJECT™ stops, the needle opening may have become blocked and it is recommended to rotate the needle slightly in order to obtain a good flow.

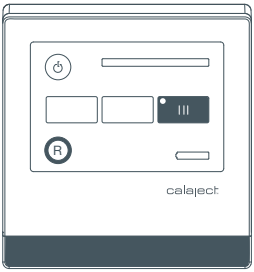
PROGRAM II — Recommended for infiltration analgesia

- Activate the foot switch and hold it down throughout the injection. The sequence begins with 10 seconds slow speed (0.006 ml/sec) followed by a gradual increase to medium injection speed 0.03 ml/sec.
- When the injection has been stopped and is reactivated again, the same sequence will repeat: First 10 seconds slowly with gradual increase to medium speed. No option of speed change in Program II.
- Aspirates automatically whenever the foot switch is released. The small suck-back will also prevent after-dripping from the needle.



PROGRAM III — Recommended for regional nerve block analgesia

- Activate the foot switch and hold it down throughout the injection. CALAJECT™ begins slowly, 0.006 ml/sec. By releasing/re-activating the foot control in one swift movement, the injection speed will increase gradually to high speed (approx. 0.04 ml/sec). Hereafter, high speed at every stop/start.
- Aspirates automatically whenever the foot switch is released. The small suck-back will also prevent after-dripping from the needle.



Technical specifications

CALAJECT Type CJ2	Control unit	Handpiece	Stand
Length	100 mm Foot switch cable: 2.2 m	200 mm (incl. barrel) Handpiece cord: 1.7 m	
Width	117 mm	Ø 13 mm	Ø 60 mm
Height	115 mm		34 mm
Weight	757.5 g	50 g	405 g
Nominal voltage	7.2 V, 1.2Ah		
Battery (Lithium-ion)	5 hours on each charge		
Charging time	Approx. 3 hours		
Dental Cartridge		1.7/1.8 ml standard cartridges	
Dental Needles		Standard M6 and 7/32"	
Charging:	12V-DC/1ADC		

CHARGER: 100-240V - 50-60Hz/280 - 140mA

ENVIRONMENT:
Temperature: Operation at 10 to 35°C / 50 to 95°F.
Storage and transportation at -20 to 50°C / -4 to 122°F.
Altitude: Operation in 0-3000 m.
Storage and transportation: no restrictions.
Humidity: Operation, storage and transportation: 10-95%.

Classification: Council directive 93/42/EEC, Class IIa. Internally powered equipment, Class IIa battery charger, type b applied part, ipx 7 foot control, suitable for continuous operation.

Standards: EN60601-1

Disposal: Separate collection of electronic waste.

TROUBLESHOOTING			
Problem	**Cause**	**Solution**	**Future remedy**
Unstable function	Damaged handpiece cord.	If any visible damages on plug or cord -> send it in for repair.	Read instructions for correct connection / removal of plug. Avoid squeezing damages and sharp bending of the cord.
	Damaged foot switch cable.	If any visible damages on plug or cable -> send it in for repair.	Avoid passing over the cable with your chair. Avoid squeezing damages and sharp bending of the cable.
	Loose connection in wires, plugs, terminals or foot switch.	Visual inspection not possible. Check the function by using another CALAJECT™ foot switch. Send in for repair.	Read instructions for correct connection / removal of plug. Avoid squeezing damages and sharp bending of cables.
Premature illumination of pressure indicator.	Blocked needle.	Change the needle.	
Automatic stop happens often.	Piston moves slowly – too much friction between the moving parts inside the handpiece.	Send in for repair.	
Piston does not retract	Piston O-ring has become dry.	Lubricate the O-ring with PTFE grease according to “Maintenance by User”.	Lubricate regulary as advised in “Maintenance by User”.
Leakage	The needle was screwed onto the barrel after insertion of the cartridge. That can cause an uneven perforation of the membrane, which leaves a hole in the membrane that is too big.	Mount the needle first to the empty cartridge barrel. Hereafter insert the cartridge and push it forward. This ensures a straight and clean cut of the cartridge membrane.	
	The rear part of the needle cannula is relatively long. (rear cannula length varies among needle brands).	In such case, the opposite sequence is recommended: Insert cartridge first after which you mount the needle.	
	The membrane of the applied cartridge is relatively small – a risk that the needle will penetrate at the edge of the membrane and loosen the membrane at the metal cap.	Change cartridge brand. The diameter of the membrane must be bigger.	

TROUBLESHOOTING			
Problem	**Cause**	**Solution**	**Future remedy**
The cartridge broke during injection.	Piston O-ring has been damaged.	Change the O-ring and apply a thin layer of PTFE grease as described under “Maintenance by User”.	
	This specific cartridge was weak and did not withstand the higher injection pressure required for intraligamental injections. A rare, but well-known risk at intraligamental injections.	Disconnect the cartridge barrel and remove the fragments of glass very carefully. Check if liquid has leaked at the piston rod opening. Clean it by using a cotton stick moistened with a surface disinfectant. Blow it dry with clean air. If leakage is extensive, send the handpiece in for cleaning and repair.	
Battery level does not improve at charging	Charger is defective.	Try another CALAJECT™ charger (Other chargers may not be used).	
	The built-in Li-Ion battery is defective or worn out.	Send in CALAJECT™ for battery change.	Extend battery lifetime by charging regularly. Avoid draining the battery completely several times.

CONTRA-INDICATIONS AND PHYSIOLOGICAL HAZARDS

Contra-indications: No specific for CALAJECT™ beyond the contra-indications described in the product page and package insert of the applied analgesic solution purchased separately.

Possible physiological hazards: In the event of the most serious technical failure that can be foreseen, the dental cartridge will be emptied in 30 seconds at maximum speed. Injection of 1.8 ml local analgesic at this speed may cause the following physiological complications:

Nerve block analgesia and infiltrations: No known. Discomfort and after pain may occur.

Intraligamentary and palatal injections: No known, but injection at this high speed level may be associated with discomfort and pain, and the patient will react.

Intravascular injection: By accidental intravascular injection of 1.8 ml local analgesic containing adrenaline as a vaso-constricting agent, the patient may feel heart palpitations and discomfort. Patients with heart and cardiovascular diseases may risk more serious complications - therefore, please study the package insert of the applied local analgesic solution.

EMC Technical Information

Table 1 Electromagnetic emissions

The “CALAJECT™” is intended for use in the electromagnetic environment specified below. The customer or the user of the “CALAJECT™” should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR11 IEC 60601-1-2 EN55011	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR11 IEC 60601-1-2 EN55011	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 60601-1-2 IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 60601-1-2 IEC 61000-3-3	Complies	

Table 2 Electromagnetic immunity

The “CALAJECT™” is intended for use in the electromagnetic environment specified below. The customer or the user of the “CALAJECT™” should assure that it is used in such an environment.

Immunity test	IEC 60601-1 Test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 60601-1-2 IEC61000-4-2	±6KV contact ±8KV air ±15KV air	±6KV contact ±8KV air ±15KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 40%.
Electrical fast transient/ burst IEC 60601-1-2 IEC61000-4-4	±2KV for power supply lines ±1KV for input/output lines	±2KV for power supply lines ±1KV for input/output lines	Mains power supply quality should be that of typical residential area.
Surge IEC 60601-1-2 IEC61000-4-5	±1KV differential mode	±1KV differential mode	
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 60601-1-2 IEC61000-4-11	<5% UT for 0.5 cycle 40%UT for 5 cycles 70%UT for 25 cycles <5%UT for 250 cycles	<5% UT for 0.5 cycle 40%UT for 5 cycles 70%UT for 25 cycles <5%UT for 250 cycles	Mains power supply quality should be that of typical residential area.
Power frequency (50-60Hz) magnetic field. IEC 60601-1-2 IEC61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be that of typical residential area.

Table 3	Electromagnetic immunity		
The “CALAJECT™” is intended for use in the electromagnetic environment specified below. The customer or the user of the “CALAJECT™” should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1 Test level**	**Compliance level**	**Electromagnetic environment guidance**
Conducted RF IEC 60601-1-2 IEC61000-4-6 Radiated RF IEC 60601-1-2 IEC61000-4-3	10Vrms 150KHz to 80 MHz 3V/can 80MHz to 2,5GHz	10Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz to Hz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 4	Recommended separation distances between portable and mobile RF communications equipment and the “CALAJECT™”		
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output of transmitter (W)	Separation distance according to frequency of transmitter m		
	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	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Explanation of symbols used in CALAJECT™ labelling.

CE 2460	CE mark with ID no. of notified body.
	Type B applied part.
	Interference may occur in the vicinity of equipment marked with this symbol.
	To be disposed of as electronic waste according to WEEE Directive 2012/19/EU.
SN	Serial number.
	Manufacturing company.
	Read the instructions
	Standby key

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CE 2460