Instructions For Use

ALCIS
Connecting box 2069-BC3
for 2069-EPC

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The use of ALCIS connecting box needs to take note of the following elements:

Coagulation	**Instructions for coagulation IFU**	Ref. 2069-EPC-IFC
	Connecting box IFU	Ref. 2069-BC3-IFU
	RF generator	See manufacturer manual
	EEG recording device	See manufacturer manual

1. Products description

Description

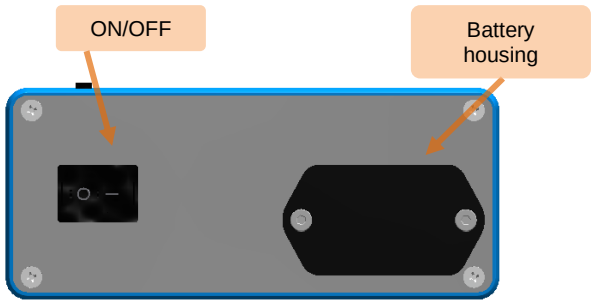
- Portable switch box self-power supplied with several connectors and buttons.
- 2 functioning modes are available: COAG and EEG.
- Possibility to connect any Alcis depth electrode Range 2069-EPC from 5 to 18 contacts.

The device is provided alone (2069-BC3) or in a suitcase presentation (kit 2069-BC3-KIT1) including:

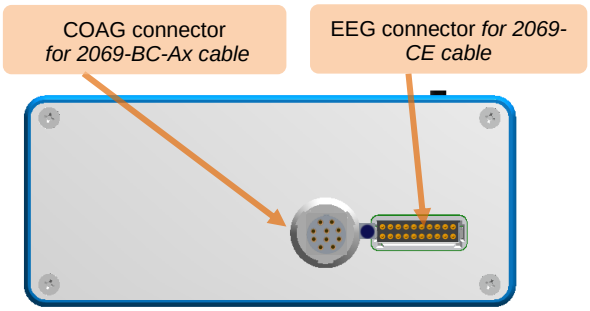
- A cable to connect the box with a RF generator (specific cable could be provided on request),
- A braided extension cable for EEG,
- A testing device Ref 2069-BC-TD to check device condition,
- A fast battery charger,
- Two rechargeable batteries.

Note: Alcis depth electrodes are used as bipolar electrodes for coagulation (2 contiguous contacts of the same electrode).

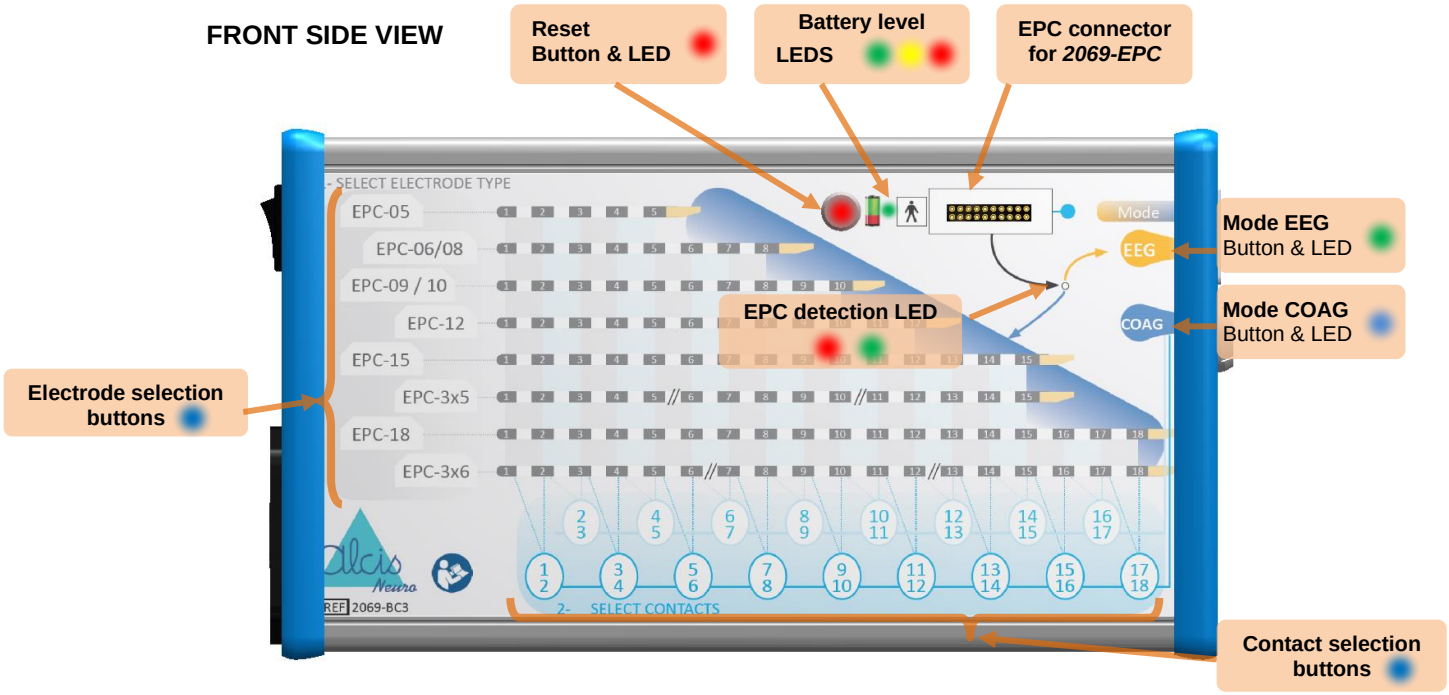
LEFT SIDE VIEW



RIGHT SIDE VIEW



FRONT SIDE VIEW



Instructions For Use
ALCIS Connecting box 2069-BC3
For 2069-EPC

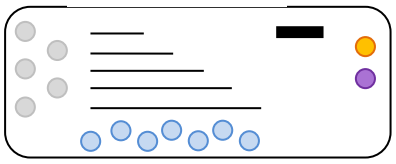
Intended use
The connecting box is an interface of connection between an EPC (ALCIS depth electrode from range 2069-EPC), any compatible RF generator, and any compatible EEG monitor.

Performances
- **Connecting Box REF 2069-BCX**
  - Ability to transmit electric current with minimal alteration from the RF generator to 2 contiguous contacts of a depth electrode for coagulation.
  - Ability to allow the quick and efficient selection of the 2 contiguous contacts between which the coagulation is due.
  - Ability to transmit the EEG signal with a minimum of change from the 2069-EPC connector to the EEG output connector (the RF signal should not be transmitted to the 2069-EPC output).
- **Connection cable REF 2069-BC-AX**
  - Ability to connect and transmit electrical signals with minimal alteration between the RF generator and the Connecting Box.

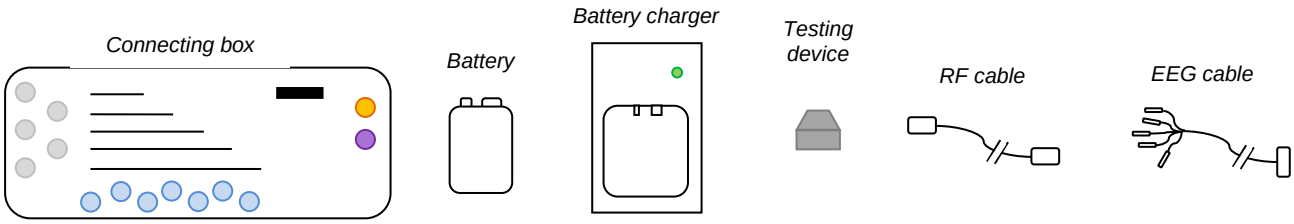
Contents of the packaging
As specified in “description” paragraph, device is available in two different presentations:

- **Alone device presentation, including these instructions for use**

Connecting box



- **Suitcase kit presentation including these instructions for use**



2069-BC3 *2069-BCX-BAT* *2069-BCX-FBC* *2069-BCX-TD* *2069-BC-AX* *2069-CE*

2. Indications
The connecting box is used in the context of thermo-coagulation further to an SEEG (Stereo-Electro-Encephalography) involving Alcis Depth Electrode Range 2069-EPC (applied part BF type).
The bipolar thermo-coagulation between two contiguous contacts is indicated for the therapeutic treatment of epilepsy, especially for patients for who conventional surgery is excluded.

3. Contraindications
- Any other use of connecting box than those described in this document is contraindicated.
- The contraindications related to RF thermo coagulation techniques are applicable.
  - **Do not coagulate on a patient carrying a cardiac pacemaker or a neuro-stimulator.** Indeed the reaction of stimulator to the electromagnetic interferences caused by the use of these techniques or by the use of the electrodes for stimulation can result in dysfunctions or the brutal stop of the stimulator.
  - **Do not coagulate, given the state-of-the-art, if the size of the maximal lesion area to achieve is greater than the size of the area which should be treated by conventional surgery.**
- **The use of other electrotherapy techniques than RF thermo-coagulation is formally contraindicated on a patient carrying neurological electrodes.**
  - The use of other techniques using the electromagnetic waves on a patient carrying neurological electrode must be submitted to the agreement of the doctor responsible for the implantation and/or of the patient follow-up (AFSSAPS note, 2001/06/18).
- The neurosurgeon must verify the relevance to thermo coagulate in the selected brain area:
  - **Do not thermo-coagulate between contacts which have caused functional signs during stimulation phases.**
  - **Do not thermo-coagulate when vessels are close to the lesion area,** they can alter the shape of the lesion due to cooling effect or be damaged (risk of hemorrhage, hematoma, thrombosis or stenosis).
  - **Do not thermo-coagulate with electrodes if brain functional areas are close to the lesion.**

4. Recommendations / Warnings

The implantation, the stimulation and the coagulation with ALCIS electrodes must be carried out by an experienced neurosurgeon and according to a controlled stereotactic procedure. The choice of the model and the number of electrodes to be established, as well as the type of coagulations to create are responsibility for the neurosurgeon. The patient must be placed under a continuous surveillance and in an adapted environment to avoid every risk of incidents.

General recommendations:

- No modification of any device or equipment covered by this IFU is allowed.
- If box or other devices performances change, contact technical/biomedical department and stop using the box.
- It's advised to remove the battery after each use.

Checking to be made before the use:

- Always read both these IFU and electrode IFU (ref. 2069-EPC-001) before use.
- Always check the box with testing device (2069-BCX-TD) before use.
- Check battery before use, change battery if charge level indicator is red or yellow.
- Check the integrity and the good state of electrodes and all accessories before use. Do not use a product in case of wear and / or damage of any kind.

Electrical safety main considerations to be observed:

- Check before use the good state of RF generator, EEG recording system and cables.
- Checks that the equipment connected to depth electrodes are functioning and compliant with international safety standards. In particular devices such as recorders used with 2069-EPC electrodes must be compliant with IEC/EN 60601-1 and associated relevant standards.
- The equipment must be used with temperature between -20°C and +40°C.
- Do not coagulate patients with a cardiac pacemaker or other active implants.
- Do not monitor EEG signal while using RF coagulation signal. Connecting box allows switching from COAG to EEG mode for the connected electrode.
- Do not touch at the same time the patient and devices ensuring coagulation or recording (connecting box, cables, RF Generator, EEG recording).
- Temporarily unused electrodes should be stored in a location that is isolated from the patient.
- The recording of EEG signals from Alcis depth electrode, the short stimulation and the coagulation with these electrodes must be carried out by an experienced neurosurgeon or neurologist.
-  After linking (extension cables and recording system) the distal part of electrode becomes an applied part type BF.
- Do not twist the cables on themselves.
- Do not use a neutral electrode.
- The connecting box must be connected with compatibles accessories and a compatible RF generator (see §10).
- The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to hearth.
- After introduction into the brain, the depth electrode establishes a direct conductive link with patient, avoid any contact with any powered device or any device that could be powered.
- The use of flammable anesthetics or oxidizing gazes such as nitrous oxide (N_2O) and oxygen should be avoided unless these agents are sucked away.
- It is recommended to avoid skin- to-skin contact (for example between the arms and body of the patient).
- When RF generator and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.
- It is recommended to place the patient's contacts in a way to avoid a contact with the patient or with other conductors.

  For information, note that EEG signal is transmitted even when connecting box is switch off.

Warnings in relation with thermo-lesion performing:

- Connect all the cables and the electrode before switching on the connecting box.
- Always select the appropriate electrode on the keypad.
- Ensure before a coagulation that the potential maximal lesion size is compatible with the presence of nearby vessels and the risk of injuring an important functional area. After thermo coagulation it is recommended to present a safe distance of at least 10mm between the lesion and a vessel or a functional area (*refer to §**Lesions Dimension** to know the lesion feasible size by thermo coagulation between two contiguous contacts).*

- The choice of electrodes, contacts and the number of lesions to achieve, the management of thermo-coagulation and post-operative monitoring are under the responsibility of the neurosurgeon.
- The output power selected should be as low as possible for the intended purpose (see §.Lesions Dimension).
- See *Recommendations and limitations on the parameters* for the key parameters of the coagulation procedure in 2069-IFC document.
- Stop immediately coagulation, in case of heat sensation by the patient. The coagulation leads to a warm on the electrode (see abacus for thermo-coagulation with the ALCIS depth electrodes for coagulation).
- Do not use more than 10W to coagulate.
- Do not coagulate more than 60 seconds four times for each contact configuration.
- Do not use more than 2 consecutive hours without interruption.
- The interference produced by the use of a HF electrosurgical equipment may have a harmful influence on other electronical equipment functioning.

Incompatibility with other techniques

- To date, the absence of burns risks in the during MRI or MEG imaging haven't been clearly establish. So the decision to carry out MRI or MEG imaging to a patient with neurological electrode is under neurosurgeon responsibility. We advise to use Scanner or X-ray imaging.
- During the MRI imaging, to reduce the risks of induced current in the device:
- Avoid forming loops with the not-implanted part of the electrode,
- Disconnect the extension cable and the electrode.

Accessories associated / Compatible combinations

- Only products listed in table 1 are compatible. The use for other products could be dangerous for the patient and Alcis could not be hold as responsible. The verification of the compatibility of products used is under practitioner responsibility. In the event of use of other equipment, it is the responsibility of user to ensure himself of the mutual compatibility of the products.
- The connecting box associated with RF generator can affect other medical electrical equipment.

Cleaning, Disinfection and Sterilization

- Nonflammable agents should be used for cleaning and disinfection wherever possible.
- Reusable device, clean before and after use.
- Do not sterilize.
- Clean and disinfect using a cloth dampened with alcohol before and after use, avoiding any introduction of liquid into the Connecting Box
- Dry connectors after cleaning.
- Do not bring the connecting box, extension and connection cables on the operative field as they not sterile.
- Given the nature of the act (action affecting the central nervous system), respect the laws in force for the prevention of infectious risks include transmission of prions

Storage and maintenance

- Store in a dry, dark and cool place.
- Temperature: -20°C - +40°C
- Avoid projection or introduction of liquid on or in the connecting box. Protect it against any potential projection.
- Handle with care.

Maintenance considerations:

- Each year a maintenance is required, this maintenance have to be performed by qualified staff like a biomedical technician or an engineer. You can refer to the manual service ref: 2069-BC3-MAS. If needed, contact your local retailer for Alcis support or "1st level maintenance" realization.
- After 3 years a "2nd level maintenance" performed by Alcis is required. Contact your local retailer to plan and perform the conditions of this maintenance.

Lifetime expectation:

- The expected lifetime of the connecting box is 6 years starting from product putting into service to perform a maximum of 60 000 coagulations*.

  **60 000 coagulations between 2 contiguous contacts for 6 years represent an average of 10 000 coagulations per year. With the worst case hypothesis of 100 couple of contacts coagulated per patient this represent a potential of 100 patients per year.*

Disposal parts

According to WHO, electronic devices as connection cable shall be disinfected with common disinfectant, prior be disposed by providing it to companies specialized in electronic waste disposal.
At the end of life, the connecting box should be sent back to Alcis for recycling.

Patient monitoring
To avoid any risk of incidents, the patient must be placed under medical supervision during the phases of recording, stimulation and coagulation.

5. Adverse events / main complications

Any serious incident that as occurred in relation to the device should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

No adverse event was identified specifically linked to the connecting box use.

However, it is recommended to consult the ALCIS depth electrode IFU (ref. 2069-EPC-001) for potential adverse events in relation with ALCIS depth electrodes stereotactic implantation and use.

List of known side effects due to the electro-coagulation technique:

The main complications and possible side effects of the RF coagulation are:

- A neurological deficit linked to a deterioration of functional tissue when a coagulation have reached an important brain area,
- An arterial thrombosis.

The first results from the RF coagulation techniques guided by SEEG showed that no neurological complication is occurred at terms. However, transient side effects were observed:

- Heat sensation in the head which required to stop immediately the coagulation (sensation correlated to the coagulation site), headache felt after coagulation but which stops quickly after a few minutes,
- In the short term (< 3 months): oral dysesthesy (paresthesic intra-oral sensations)
- In the long term (>3 months): motor apraxia of the hand contralateral to the thermo-coagulation in the supplementary motor zone. Intraoral paresthesic sensations lasting several months have been reported together with temporary benign motor apraxia.

6. Electrical safety and EMC

The connecting box has been tested to and meets the requirements of the following Electrical Safety standards:
NF EN 60601-1: Medical electrical equipment – General requirements for safety
IEC 60601-2-2: Medical electrical equipment – Particular requirements for safety of high frequency surgical equipment

The connecting box has been tested to and meets the requirements of the following EMC standards:

IEC 60601-1-2: Collateral standard: Electromagnetic compatibility — Requirements and tests

Guidance and manufacturer's declaration – electromagnetic emissions

The connecting box is intended for use in the electromagnetic environment specified below.
The customer or the user of the connecting box should assure that it is used in such an environment

Emission test	Compliance	Electromagnetic environment - guidance
Radiated electric emission CISPR11	**Class B**	**WARNING: This equipment is intended/system is intended for use by healthcare professionals only. This equipment/system (with RF generator) may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system or shielding the location.**
Measure of human exposure to electromagnetic field	See table below	

Probe position	Measured level	
	COAG mode	EEG mode
Front	0.5G 95nT 1.0V/m	0.5G 93nT 1.3V/m
Back	0.4G 89nT 1.4V/m	0.5G 88nT 1.6V/m
Left	0.3G 68nT 1.3V/m	0.2G 67nT 1.3V/m
Right	0.4G 120nT 0.9V/m	0.4G 118nT 1.3V/m
Top	0.8G 95nT 1.9V/m	0.9G 95nT 1.8V/m

Guidance and manufacturer's declaration – electromagnetic immunity

The connecting box is intended for use in the electromagnetic environment specified below.
The customer or the user of the connecting box should assure that it is used in such an environment

IMMUNITY TEST	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharges (ESD) IEC 61000-4-2:2008	± 2kV ± 4kV ± 8kV ± 15kV	Compliant with standard	**Floors should be wood, concrete or ceramic tile. If the floors are covered with synthetic material the humidity relative should be at least 30%**
Power frequency (50/60Hz) magnetic field IEC 61000-4-8: 2009	30A/m	Compliant with standard	**Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment**
Radiated RF IEC 61000-4-3:2006/ A1:2007/A2:2010	See table below	Compliant with standard	**Nothing to report – this part is explained in IFU of RF generator.**
Conducted RF IEC 61000-4-6:2013	See table below	Compliant with standard	

Tested side	Frequencies band	level
Front (sweep)	80MHz – 1GHz	3V/m
Front (spot freq.)	200MHz – 1GHz	9V/m
Front (sweep)	1GHz – 2.7GHz	28V/m
Front (spot freq.)	3GHz – 6GHz	9V/m
Left (sweep)	80MHz – 1GHz	3V/m
Left (spot freq.)	200MHz – 1GHz	9V/m
Left (sweep)	1GHz – 2.7GHz	28V/m
Left (spot freq.)	3GHz – 6GHz	9V/m

Tested cable	Frequencies band	level
COAG cable, coag mode	150KHz – 80MHz	3Vrms
COAG cable, coag mode	150KHz – 80MHz	6Vrms
EEG cable, eeg mode	150KHz – 80MHz	3Vrms
EEG cable, eeg mode	150KHz – 80MHz	6Vrms

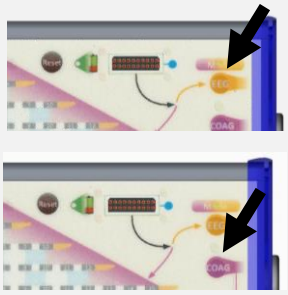
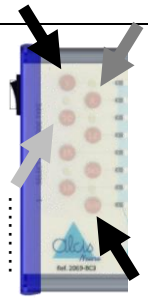
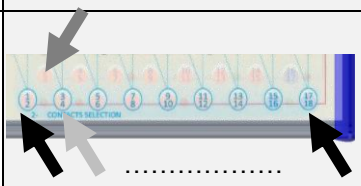
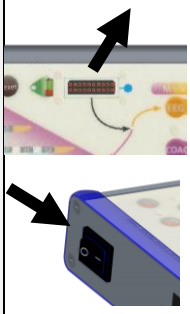
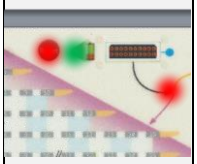
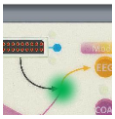
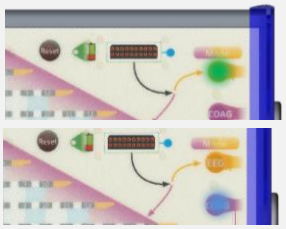
7. Recommended use steps

WARNING

The **EEG signal** can pass through the connecting box **even if the box is switched off** or if it has **no battery**.

- **EEG signal transmission is activated** if: EEG mode is activated, the box is switched off while EEG mode was the last mode activated before switching off.
- **EEG signal transmission is not activated** if: COAG mode is activated

7.1 Prepare and check the integrity and functionality of RF generator, connecting Box and connection cables.

Action1	Action2	Action3	Action4	Action5	Action6
Switch on the box	Connect testing device on EPC connector	Select EEG mode, then COAG mode	Select each type of electrode	Switch to each contact combination *(with 18 contacts selected)*	Remove testing device and switch off the box
					
Checking1	**Checking2**	**Checking3**	**Checking4**	**Checking5**	
 Battery level indicator must light green (if not, change the battery), reset button & EPC indicator red.	 EPC indicator must light green, if not, do not use the box	 EEG button must light green, **then** COAG button must light blue.	 EPC type buttons must light blue	 Buttons must light blue. Check impedance value on RF generator. ⚠ Target value: **500 ±50Ω**.	

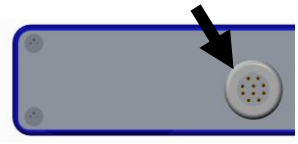
If at least one of the checking steps is not satisfying, do not use the box. Contact your technical/biomedical department**.**

Check preliminary to coagulate that the electrode contacts are functional & the absence of short circuit.

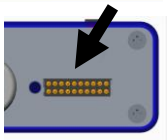
Note: *the loss of some contacts may occur during violent epilepsy seizures*.

7.2 Use the box.

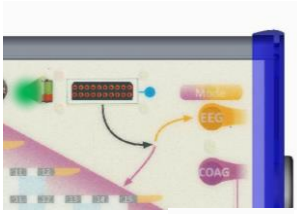
- Connect the box to the generator with the appropriated cable (2069-BC-Ax cable on COAG connector).



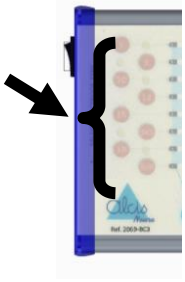
- Connect the EEG cable (2069-CE cable on EEG connector) to EEG monitor.



- Switch **ON** the box. Check that battery level indicator is green (if yellow or red, change battery).

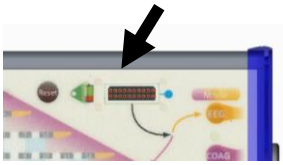



- Select the type of electrode connected (check label on electrode connector before connect the electrode).
  Example: press "3x5 contacts" for a 3x5 contacts electrode.



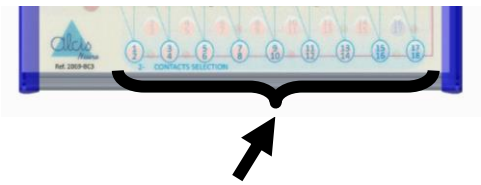
- Select the COAG mode.

- Setup RF generator (see RF generator IFU).
- Connect the Electrode to the box (EPC detection led must be green).



- Select the contacts.

Example: press 7-8 to coagulate between contact 7 and 8.
Depending on the therapeutic objective, it may be necessary to achieve several contiguous coagulations. For example: between contacts 1 and 2 and 3 and 4, 5 and 6, and so on. The choice of contacts and the number of lesions to achieve are under the responsibility of the neurosurgeon.



- Check impedance value on RF generator

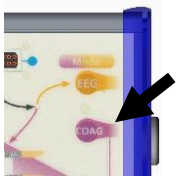
Use steps of coagulation, refer to the instructions for coagulation (2069-IFC)

Switch to EEG mode

- Select the EEG mode.
  ➔ EEG signal is transmitted to EEG monitor.
  ➔ EEG LED light up.

Switch to COAG mode

- Select the COAG mode.
  ➔ EEG LED light up.
- Select the contacts (check impedance on the generator).
- Proceed to thermo-coagulation *via* RF generator interface.



System shut down

- Switch **OFF** the box.
  ➔ All LEDs light down.

8. Technical data

- Power supply: 9V battery / 6HR61 / 900mAh
- Battery lifetime: 2hours for a 356mAh Battery
- IP 20
- Electrical safety class (electrode):  (BF) when connected to connecting box and RF generator.
- Device lifetime: 6 years from first use.
- Working limits:
  - Temperature -20°C / +40°C.
  - Humidity 65% +/- 20%.

Contents of the packaging

- 1 connecting box (ref 2069-BCx).
- 1 RF cable (to connect the box with the RF generator - ref 2069-BC-Ax).
- 1 EEG cable (to connect the box with the EEG monitor - ref 2069-CE).
- 1 testing device (ref 2069-BCx-TD).
- 1 battery charger (ref 2069-BCx-FBC).
- 3 batteries (ref 2069-BCx-BAT)

9. Warranty

ALCIS products are submitted to control tests at the various stages of manufacture to ensure compliance with specifications. ALCIS can never be held responsible for any expenses or damages directly or indirectly resulting from:

- The non-respect of instructions, recommendations and warnings of the instruction of use,
- The purchase, the use, the implantation, the ex-plantation or replacement of depth electrodes for coagulation or their accessories,
- The use of accessories or apparatuses unsuited or defective.

10. Compatible accessories and generators (table 1)

Products		Range / product	Characteristics / accessories compatibility
Connecting box	NON STERILE	**2069-BCX** CE 1014 Year of CE marking : 2016	**Use exclusively with the depth electrodes for coagulation - Range 2069-EPC** **Main characteristics:** • Internally powered by a 9V battery • 2hours battery expected lifetime for a 356mAh Battery • IP 20 • Service voltage: $50V_{RMS}$ / $71V_{PEAK}$ • Device lifetime: 6 years from first use. **Device inputs/outputs:** • 1 Depth electrode connector • 1 EEG connector • 1 COAG connector Depth electrode electrical class when connected to the connecting box and the RF generator is BF type The connecting box device is reusable and can be cleaned with alcohol.
Testing device	NON STERILE	**2069-BCX-TD** CE Year of CE marking : 2016	**Use exclusively with connecting box - 2069-BCX**
Battery charger	NON STERILE	**2069-BCX-FBC**	**Use exclusively with batteries - Range 2069-BCX-BAT** • For 9V rechargeable batteries • Power supply input 230V 50Hz
Battery	NON STERILE	**2069-BCX-BAT**	**Use exclusively with the connecting box - Range 2069-BCX-BAT & battery charger.** • 9V rechargeable batteries • Minimal capacity 356mAh for an autonomy of 2 hours
Connection cable	NON STERILE	**2069-BC-A*X*** CE Year of CE marking : 2008	**Use exclusively with devices from Alcis range 2069** • Electric resistance ≤ 0,5 Ohms • Dedicated connector for connection to connecting box • Dedicated connector for connection to RF generator • Reusable and non-sterilizable Cleaning with alcohol
Extension cable *Technical form 2069-CE-FT*	NON STERILE	Range **2069-CE** CE Year of CE marking : 2008	**Use exclusively products from ALCIS range 2069** • Specific 2069 product range connector • Female isolated banana plugs Ø1,5mm
Depth electrode *Technical form 2069-EPC-FT*	STERILE EO	Range **2069-EPC** CE 1014 Year of CE marking : 2010	**Refer to ALCIS depth electrodes IFU (ref. 2069-EPC-001)**

Compatible SEEG Recorder

Specification
A Neurological Recorder; adapted for **SEEG** recording. ***Safety requirements:*** EEG recorder have to be CE mark (Class IIb or Class III) and an applied part type BF which induce compliance to the following: - IEC 62304 (software life cycle) - IEC 60601-1 (electrical safety) - IEC 60601-2 (electromagnetic disturbances) - IEC 62366 (usability) - IEC 60601-1-8 (guidance for alarm system)

Compatible RF generator

Specification
A RF Generator with an applied part type BF; adapted for **bipolar** RF brain coagulation. Possibility to operate **bipolar RF Lesion without temperature control** (no temperature probe in Alcis Depth Electrodes) Generator designed for at least an input impedance range of 300Ω up to 1 500Ω
Output Voltage: Generator output voltage up to $71V_{PEAK}$ / $50V_{RMS}$
Output Power: Generator output power capacity from $3W_{RMS}$ up to $10W_{RMS}$ (with a resolution of 0.5W maximum).
Lesion duration: Lesion time should be adjustable up to 60s minimum (with a resolution of 1 second).
Coagulation management: The user should have the ability to optimize the applied power / voltage and the duration of coagulation to impedance variations of tissues. Two techniques can be implemented: • Impedance direct measure. Surer but depending on generator available options. Optimization could be automatic by using a pre-defined function of the generator. Management consist in measuring continuously the tissue impedance during the thermo-lesion (through either display of a real time impedance curve or values) • Use of an adapted clinical procedure for the monitoring of micro-bubbles appearance[1] Whatever the choice for coagulation management in place, continuous monitoring display has to be observed during the thermo-lesion: • The in progress lesion duration • Output RF Power
Safety requirements: - Generator has to be CE mark (Class IIb or Class III) which induce compliance to the following standards: - ISO 62304 (software life cycle) - IEC 60601-1 (electrical safety) - IEC 60601-2 (electromagnetic disturbances) - IEC 60601-2-2 (high frequency surgical equipment) - ISO 62366 (usability) - IEC 60601-1-8 (guidance for alarm system) User should be able to stop the coagulation at any time.

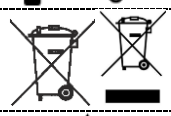
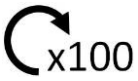
Compatible battery charger

Specification
- Operating voltage 230 V/AC, 50Hz or 110/115V - Battery type 9V - Charging current max. 70mA

[1] Detection of microbubble formation during radiofrequency ablation (…/…) - Wood et al - February 2006

11. Miscellaneous

See Abacus for thermocoagulation in appendix1.

Significations of symbols on labels			
	Humidity limits		Warning, refer to instruction for use
	Use before		Warning
	Manufacturer's catalogue reference		Read Instructions for Use
	Batch No.		Store in a dark and dry place
	Manufacturer		Must be recycled as per the European Directive 2002/96/EEC
	Applied part type BF		Non sterile device
	Reusable device validated for x nn use cycles (here 100).		Do not use if damaged
	Period of use After Opening (here 71 months)		Temperature limit
	Superior temperature limit		Medical Device
	Manufacture date		

Light color		Meaning
	Green	normal functioning mode (battery level high, electrode connected, EEG mode activated)
	Red	device not ready for normal functioning (change battery, electrode not connected, reset mode)
	Yellow	battery level low
	Blue	coagulation mode activated

Mode	Meaning
COAG	Press to activate "Coagulation mode "
EEG	Press to activate "EEG recording mode "
RESET	Press to reset connecting box settings

1. Troubleshooting

Connecting box can't be started

- Check the battery
- Change the battery

Impossibility to change mode (EEG/COAG) on connecting box

- Change the battery (open battery housing, change battery, close battery housing)

Coagulation doesn't works

- Check electrode connection
- Check cable connection
- Check impedance on the generator display.
- Check connecting box setup (see **Use steps §7**)
- Check generator setup (refer to **Generator IFU**)
- Check connecting box with testing device (**2069-BCx-TD**)

If trouble remains, contact your technical/biomedical department for servicing.

Notes

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