SPINERY

SPINE RECOVERY DEVICE

Instructions for use

SPINERY® RF Generator

Class IIb active medical device

CE 0051

Manufacturer:

AXON S.r.l.

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REVISIONS

DATE	REVISION	DESCRIPTION
14/06/2024	00	First release
28/06/2024	01	After the usability study, the following revisions were made: • Emphasized the importance of verifying the integrity of the sterile barrier prior to use in §10.2. • Stated and emphasized in §12.8 the timing and reason for the manual watering procedure.
31/07/2025	02	• Document divided into three separate IFUs: Spinery® RF Generator, Spinery® Kit and Spinery® Cooling Connection • Updated language for compliance with MDR Regulation (EU) 2017/745 and elimination of the term "Spinery system" • Purpose of use, up-to-date indications and warnings according to Annex I of the MDR Overhauled accessory sections to clarify sterility, single use, and compatibility • Added cross-references to dedicated IFUs for proper combined use

INDEX

1 DEVICE IDENTIFICATION

1.1 Device Name

Spinery® RadioFrequency Generator (REF: SPINE-GEN)

1.2 Device configurations/variants

The Spinery® RF Generator includes the following accessories:

1. Spinery® Kit (two REF variants: SP-BI0704EU, SP-BI1005EU):

- REF: SP-BI0704EU includes:
    - A bipolar cooled probe with an electrode length of 7 mm and an electrode spacing of 4 mm (active part 18mm)
    - Irrigation components
    - Bone Access Components (Cannula-Drill Coupling 22 mm)
- REF: SP-BI1005EU includes
    - A bipolar cooled probe with an electrode length of 10 mm and an electrode spacing of 5 mm (active part 25mm)
    - Irrigation components
    - Bone Access Components (Cannula-Drill Coupling 29mm)

Irrigation components are used to circulate saline through the probe during RF delivery, improving ablation control and thermal safety. Bone access components provide the necessary tools for percutaneous access to the vertebral body (e.g., cannula, stylet, bone drill). Both kit variants are supplied sterile and are intended for single use only. The sterilization method is ethylene oxide (EtO), validated according to ISO 11135:2014.

2. Spinery® Cooling Connections

These are sterile, single-use accessories that allow the connection of bipolar probes to an external cooling system. They ensure adequate temperature control during energy delivery. Operation is via the peristaltic pump integrated in the Spinery® RF Generator, which converts the mechanical energy of the generator into kinetic energy of the circulating fluid. The latter modifies the thermal profile of the probe through heat exchange, ensuring that the proximal rod maintains temperatures below critical thresholds. There are two configurations available:

- REF: SP-CDEU — Cooling connection for dual probe procedures (dual access)
- REF: SP-CSEU — Cooling connection for single-probe procedures (single access)

Spinery® Cooling Connections are sterilized with Ethylene Oxide and sterilization is validated in accordance with ISO 11135:2014. Spinery® RF Generator, used in combination with selected accessories, is indicated to provide thermal ablation treatment and pain relief in patients suffering from metastatic spinal tumors. The system supports both single-probe and dual-probe ablation techniques (in parallel or crossover configuration), depending on the size of the lesion, its location, and clinical strategy.

Under image guidance (e.g., CT or fluoroscopy), cooled bipolar probes are introduced percutaneously into the target vertebral area. RF energy is then applied for up to 20 minutes per treatment session.

2 MANUFACTURER'S INFORMATION

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3 SYMBOLS

3.1 Label Symbols

SYMBOL	DESCRIPTION	Spinery® RF Generator	Spinery® Kit (accessory)	Spinery® Cooling Coonecrtion (accessory)
	Medical device	X	X	X
	Serial Number: Indicates the serial number of the medical device.	X	-	-
	UDI: Indicates the UDI code of the medical device.	X	X	X
	Lot: Indicates the batch of the medical device.	-	X	X
	CE Mark: Identifier for CE mark	X	X	X
	Model: Indicates the model of the medical device.	X	X	X
	See the instructions for use: Indicates the need for the user to consult the operating instructions.	X	X	X
	Manufacturer: Indicates the manufacturer of the medical device	X	X	X
	Date of production	X	X	X
	Caution: Indicates that caution is required when using the device or control near where the symbol is placed, or that the current situation requires operator awareness or action to avoid unintended consequences	X	-	-

SYMBOL	DESCRIPTION	Spinery ® RF Generator	Spinery ® Kit (accessory)	Spinery® Cooling Coonecrtion (accessory)
	Expiry date: Indicate the date by which the medical device should be used.	-	X	X
	Ethylene oxide sterilized: Indicates a medical device that has been sterilized with ethylene oxide.	-	X	X
	Do not reuse A medical device intended to be used only once or on a single patient during a single procedure.	-	X	X
	Double Sterile Barrier System	-	x	x
	Double Sterile Barrier System with protective packaging outside	-	x	x
	Keep dry	-	X	X
	Keep away from sunlight	-	X	X
	Indicates the temperature range to which the medical device can be safely exposed.	X	X	X
	Humidity limitation Indicate acceptable upper and lower limits of relative humidity for transportation and storage	X	X	X
	Applied Part Type BF Identifies a Type BF applied part that complies with IEC 60601-1	X	X	X
	Non-ionizing electromagnetic radiation Indicates generally high, potentially hazardous, levels of non-ionizing radiation, or indicates equipment or systems that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	X	-	-
	Alternating current Indicate on the rating plate that the appliance is suitable for alternating current only; to identify the relevant terminals.	X	-	-
	Not safe in MRI environment Identifies a product that exposes the patient, medical personnel, or others to unacceptable risks in an MRI environment.	X	-	-
	Danger Risk of explosion when used with flammable anesthetics	X	-	-

SYMBOL	DESCRIPTION	Spinery ® RF Generator	Spinery ® Kit (accessory)	Spinery® Cooling Coonecrtion (accessory)
	Pedal	X	-	-
	USB port Indicates USB port	X	-	-
	WEEE Indicates that the device or component cannot be recycled.	X	-	-
	Attention: Fuse replacement as indicated	X	-	-

Table 1 – SPINERY® RF Generator label symbols

3.2 Generator on/off button

BUTTON	NAME	FUNCTION
	Power on/off	Allows generator power on/off
	ENABLE	Enables activation of generator probe connectors

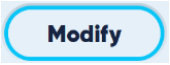
Table 2 – RF Generator Power Button

3.3 Symbols of the Spinery® RF Generator

SYMBOL	NAME	FUNCTION
	Probe connector 1 and 2	Allows the correct insertion of the probes.

Table 3 – RF Generator Symbols

3.4 Generator Display Screen Buttons

BUTTON	NAME	FUNCTION
	Settings	Allows management of generator settings
	Home	Allows you to start the ablation procedure from the beginning
	Modify	Allows you to go and change the identifiers of the hospital, the doctor and the patient

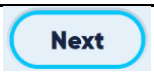
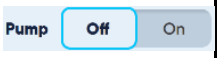
BUTTON	NAME	FUNCTION
	Confirmation	Allows you to confirm hospital, doctor, and patient identifiers
	Back	Allows you to return to the previous page
	Next	Allows you to go to the next page
	Ending	Allows you to terminate the ablation
	Storage of ablation parameters	Allows you to download the dedicated ablation log
	Increase	Allows you to increase the numbers
	Decrement	Allows you to decrement numbers
	Display of the target distal temperature	Allows you to display the target temperature
	Start	Allows you to start the ablation procedure
	Stop	Allows you to interrupt the ablation procedure
	Peristaltic pump management	Allows you to manage the activation of the peristaltic pump during the ablation setup. During ablation, the peristaltic pump is always running

Table 4 – Generator Display Screen Buttons

3.5 Generator Display Screen Symbols

SYMBOL	DESCRIPTION
	Work Output
	Exit blocked
	Hospital Property Identifier
	Patient ID
	Medical record
	Saline water for irrigation
	Peristaltic Pump
	Progress of the in-water primer

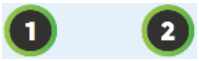
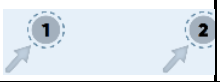
SYMBOL	DESCRIPTION
	Probe correctly connected
	Reporting of unconnected active probes
	USB flash drive
	Date and time
	QR code for downloading the manual

Table 5 – Generator Screen Symbols

3.6 Units of Measurement

SYMBOL	DEFINITION
°C	Degrees Celsius (Temperature)
Ω	Ohm (Impedance)
W	Watts (Power)

Table 6 – Screen Symbols

3.7 Guide to using the manual

This manual is the most comprehensive source of information for the safe, effective, and compliant use and/or maintenance of the SPINERY® RF Generator. This product is intended for trained and experienced healthcare professionals only.

Read and understand this manual before using the product or any component that is compatible with the product. Contact AXON for training if necessary. This manual is an integral part of the product. Keep this manual for future reference The following words may be used throughout this manual:

CAUTION:
Highlights a security issue. Always follow this information to prevent injury to patients and/or healthcare personnel.

ATTENTION:
Highlights a problem related to the reliability of the product. Always follow this information to prevent damage to the product.

NOTES:
Supplements and/or clarifies procedural information.

4 SAFETY GUIDELINES

4.1 General Security

⚠ ATTENTION

- Healthcare professionals should be fully familiarized with the instructions for use and operation of this product prior to use.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this product and the specific technique used for each patient. AXON, as a manufacturer, does not recommend surgical or technical procedures.
- Do not modify the equipment as this may compromise safety and effectiveness.
- Always store and transport the product within the specified environmental limits.
- Do not use the product after the expiration date printed on the packaging. The product may not be safe or effective after the expiration date.
- When the RF generator is activated, electric fields can interfere with other electrical medical devices.
- Appropriate measures should be taken to minimize exposure to X-rays during the use of fluoroscopy. This exposure can cause acute radiation injury and increase the risk of somatic and genetic effects.
- For information on how to attach and disconnect detachable parts and accessories, refer to the operating instructions of the corresponding parts and accessories.
- Carry out regular inspections of accessories and cables for damage caused by storage.
- Do not peel off the data label and/or keyboard from the device. If replacement is required, notify the manufacturer or the technical assistance service.
- Do not sterilize the generator, it may damage the appliance
- The correct and safe operation of the device is guaranteed by AXON only with the use of the accessories tested, approved and proposed in the previous sections.
- If there is any visible damage to the structure, unusual noise or vibration, or if you feel excessive temperatures, do not use the device and contact authorized technical support.

4.2 Electrical Safety

⚠ ATTENTION

- To avoid the risk of electric shock, always disconnect this product from the power supply before cleaning.
- To avoid the risk of electric shock, always plug this product directly into a hospital power outlet with protective ground.
- Do not wrap the power cord around metal objects. Wrapping cables around metal objects can cause a risk of currents. Be sure to fully extend the cables of the applied parts, avoiding wrapping.
- Use only the recommended wiring with the generator.
- Allow air to pass through the holes on the rear panel and place the generator on a level surface.

- Risk of radiofrequency burns to the patient: Avoid skin-to-skin contact (e.g., between the patient's arms and body) by inserting dry gauze.
- Always position the product so that the power cord can be easily unplugged.
- When the Generator is activated, electric fields can interfere with other electrical medical devices. If the emission of RF energy were to cause disturbances to equipment located in the immediate vicinity (malfunctions or abnormal behavior that occur exclusively with the SPINERY® RF Generator equipment in operation), such equipment should be moved as far away as possible or, if this is not sufficient, relocated to other rooms; all appropriate controls must also be carried out to prevent their operation from being compromised by the emission of RF energy.
- This device, while complying with current electromagnetic compatibility regulations and having passed all relevant tests, intentionally applies RF energy for therapeutic indications, therefore the energy emission must be used for the time strictly necessary for the operation. In any case, keep electronic devices at a distance of more than 50 cm while using the SPINERY® RF Generator.
- Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no less than 50 cm away from the Generator. Failure to do so may result in impaired Generator performance.
- Report the incident to our technical department who will carry out the appropriate checks and provide advice.
- Replace fuses only with those of the same type 1.6A 250V 5mmx20mm (2 fuses).
- When administering energy, the patient should not be allowed to come into contact with earthed metal surfaces. For this purpose, the use of an antistatic coating is recommended.
- Do not turn on the RF power while touching the electrodes. RF energy can cause burns.
- Do not remove the probe while the energy for ablation of lesions is applied.
- Use standard electrosurgical precautions when using the subject device ablation system in the vicinity of nerves and nerve roots.
- Take special precautions regarding electromagnetic compatibility (EMC) when using this product. Install and/or commission this product according to the EMC information contained in this manual. Portable and mobile RF devices may affect the function of this product.
- Do not put any equipment on or next to the generator. Failure to do so may cause electromagnetic interference and reduce performance.
- The Generator is manufactured in compliance with the regulations with reference to electromagnetic compatibility aspects (Group 1, Class A according to the provisions of the 60601-1-2 standard). However, it is possible that the activation of the Noise Generator, or that the Generator itself is disturbed by other devices in the immediate vicinity.
- Disturbances manifest themselves as an altered response to Generator commands, visual distortions, or similar malfunctions of nearby equipment. Interference caused by the activation of medical electrical equipment near the Generator can be reduced by increasing the distances between the devices themselves when they are used simultaneously.
- When high-frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, any monitoring electrodes should be placed as far away from the surgical electrodes as possible. The use of "Probe" monitoring electrodes is strongly discouraged.

- The SPINERY Generator (including cables) is intended for use in an electromagnetic environment where RF radiated interference is controlled. The customer or user of the Generator (including cables) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Generator, including cables, as recommended below, based on the maximum output power of the communication equipment.
- For transmitters with a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = [1.17]\sqrt{P}$	80 kHz to 800 MHz $d = [1.17]\sqrt{P}$	800 kHz to 2.5 GHz $d = [2.33]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3

Table 7 - Separation distance according to transmitter frequency (m)

4.3 Fire Hazards

⚠ ATTENTION

- Do not use in the presence of flammable anesthetics, other flammable gases, flammable liquids (such as skin preparation agents and dyes), flammable objects, or objects with oxidizing agents. Always observe proper fire precautions
- Do not use this equipment in the presence of cotton, wool, or gauze that is saturated with oxygen.
- Do not use the device in environments rich in oxygen, nitrogen oxide (N2O), or in the presence of other oxidizing agents.
- Care should be taken to avoid the danger of ignition of endogenous gases.

Failure to follow these instructions may result in fire or explosion and result in burns or property damage.

4.4 Magnetic Resonance Imaging (MRI) Safety

⚠ ATTENTION

- This product is not MRI safe. Do not use the product in an MRI environment. Use of the product outside the specified environmental conditions could result in death or serious injury.
- SPINERY® RF Generator is restricted to professional use within a professional healthcare facility, excluding the inside of RF shielded chambers of ME MRI systems.

5 DEVICE DESCRIPTION

SPINERY® RF Generator is an active medical device intended for radiofrequency thermal ablation of metastatic tumors of the spine. It is a surgically invasive device intended for transient use, as the accessory catheter percutaneously penetrates the human body into the target bone through a surgical incision, assisted by other accessories (see Bone Access Components), and remains in the body for the treatment time, estimated to be approximately 20 minutes as the maximum duration.

It is an active therapeutic device as it is intended to provide treatment and pain relief in tumor modifications of human bone. It is not intended to be used in the central nervous system

SPINERY® RF Generator includes the following components:

1. Spinery® RF Generator

REF	COMPONENT
SPINE-GEN	• Radio Frequency Generator • Metal support bracket for saline solution • Pedal

2. Spinery® Kit (Accessory):

The kit consists of:

- RF Probe
- Bone Access Components
- Manual Irrigation Components

Spinery® Kit	
REF	COMPONENT
SP-BI0704EU	• Bipolar probe cooled with 7 mm long electrodes and 4 mm intra-electrode length (active part 18mm) • Drill with Cannula-Drill coupling 22 mm • Trocar with oblique tip • Trocar with diamond tip • Syringe • Insulating and Irrigating Cannula
SP-BI1005EU	• Cooled bipolar probe with 10 mm long electrodes and 5 mm intra-electrode length (active part 25mm) • Drill with Cannula-Drill coupling 29 mm • Trocar with oblique tip • Trocar with diamond tip • Syringe • Insulating and Irrigating Cannula

3. Spinery® Cooling Connections (Accessory):

REF	COMPONENT
SP-CSEU	Cooling system connection hose for a single probe approach
SP-CDEU	Cooling system connection pipe for a dual probe approach

Spinery® Kit and Spinery® Cooling Connections are accessories supplied sterile; the sterilization method is Ethylene Oxide and is validated according to ISO 11135:2014 "*Sterilization of health products — Ethylene Oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*".

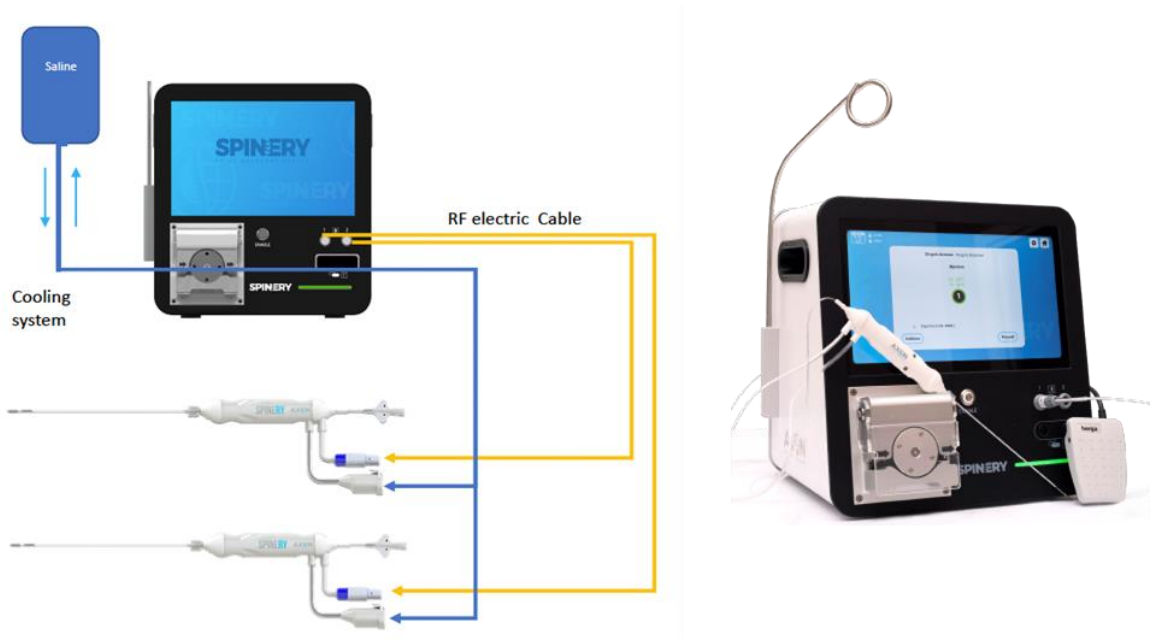


Figure 1 - SPINERY® RF Generator and its accessories

6 PURPOSE OF USE

The Spinery® RF Generator is a RadioFrequency ablation device intended for the palliative treatment of patients with metastatic bone tumors involving the vertebral bodies, sacrum, iliac bone, and acetabulum.

The generator is designed to deliver controlled bipolar radiofrequency (RF) energy to ablate target bone tissue and alleviate pain in patients who have failed or are not eligible for standard therapies. Clinical applications include:

- Pain relief associated with metastatic lesions of the vertebral bodies, sacrum, iliac bone, and acetabulum.
- Coagulation and thermal ablation of bone tissue during image-guided interventional procedures.

The generator operates exclusively in combination with specific sterile single-use accessories Spinery® Kit and the Spinery® Cooling Connection, which are essential for enabling the intended function of the device. Without these accessories, the Spinery® RF Generator cannot perform the clinical task for which it is designed.

6.1 Clinical Benefits

Radiofrequency ablation of bone metastases, particularly those located in the spine, can contribute to improving the patient's quality of life by reducing intractable pain and managing complications such as pathological fractures or nerve compression.

This palliative treatment is frequently followed by the application of bone cement (vertebroplasty or cementoplasty), in order to further stabilize the bone structure.

7 INDICATIONS, CONTRAINDICATIONS AND WARNINGS

7.1 Indications for Use

SPINERY® RF Generator is a radiofrequency generator intended for the palliative treatment of patients suffering from bone metastases.
In particular, the SPINERY® RF Generator is suitable for:

- To relieve pain associated with metastatic lesions located in the vertebral bodies, sacrum, ileum, and acetabulum, in patients who have not responded to or are not candidates for standard therapies.
- Coagulate and ablate bone tissue during interventional procedures aimed at reducing pain associated with bone metastases, in patients who have not responded or are not candidates for standard therapies.

7.2 Contraindications

The use of the SPINERY® RF Generator is contraindicated in the following cases:

- Presence of cardiac pacemakers or other implantable electronic devices.
- Presence of previous bone stabilization devices in the target area.
- Use in vertebral levels C1–C7.
- Systemic infections, bacterial or otherwise, involving the site of entry or anatomical region of interest.
- Presumed or confirmed pregnancy.
- Patients eligible for defibrillation.
- Paediatric population.
- Congenital or post-surgical anatomical alterations that prevent safe access to the treatment site.
- Patients being treated with steroids, biologics, or other immunosuppressive agents.
- Bleeding disorders or taking anticoagulants.
- Pre-existing neurological deficits in the area to be treated.

7.3 Warnings

- The delivery of RF energy to a vertebral segment cannot be repeated. If treatment has not been completed (e.g., due to failed access), a reattempt may be made as ablation has not been initiated.
- Particular care should be taken in patients with bleeding disorders, on anticoagulant therapy, with neurological deficits or systemic/localized infections.
- Perform the procedure preferably with minimal or moderate sedation to obtain patient feedback.
- Limit X-ray exposure during fluoroscopy to prevent acute radiation damage and minimize somatic and genetic risks.
- Do not alter the equipment, including accessory components, in any way.
- Activation of the generator may interfere with other medical electrical devices.
- When delivering RF energy, avoid patient contact with metal surfaces on the ground.

- Do not use in the presence of prostate cancer fractures or other vertebral osteoblastic metastases.
- Do not use in sclerotic bone or high-energy traumatic fractures – this may damage the device and cause injury.
- Do not touch the electrode while dispensing power.
- Do not remove the probe during active ablation.
- Use the typical precautions of elective surgery when working near nerve structures.
- Ablation should always be performed under fluoroscopic guidance.
- Place the probe inside the vertebral body, ensuring that nerves and nerve roots are outside the ablation area provided by the thermal tables.
- Failure to comply with the thermal distribution tables may result in serious injury to the patient.
- Use caution when ablating near organic surfaces or vascular structures, where anatomy may alter the thermal form of the ablation.
- Closely monitor any factors that may change tissue perfusion or temperature rise.
- Using high-power settings may cause tissue drying, reducing the effectiveness of ablation. Use the minimum effective power and observe the recommended time and temperature parameters.
- Carefully evaluate each patient for possible impending vertebral fractures: do not perform ablation if there is such a risk.
- Check the proximity of the target to critical structures: Place the probe at least 1 cm away from non-target structures. Injury to these structures can cause serious effects, including incontinence.

7.4 Precautions

- Please read these Operating Instructions and the User Manual carefully before use.
- The device should only be used by medical personnel trained and experienced in radiofrequency ablation.
- Do not modify the components of the device, including the insulation, in any way.
- Use caution when handling the generator and its accessories.
- Sterile techniques should be used when handling components and filling the saline infusion syringe.

7.5 Adverse reactions

The use of the Spinery® RF generator in combination with its sterile disposable accessories (Spinery® Kit and Spinery® Cooling Connection) may result in the occurrence of the following adverse events.
Such events are associated with imaging-guided radiofrequency ablation procedures, the specific anatomy of the patient, or the percutaneous nature of the intervention. Although this is generally safe and well-tolerated, the following side effects may occur:

<u>General Procedural Risks</u>

- Pain or discomfort during or after the procedure at the insertion site
- Local bleeding or hematoma formation at the point of access
- Superficial or deep wound infections (local or systemic), particularly in immunocompromised patients
- Accidental perforations of vascular or dural structures

- Skin burns at the access site due to incorrect electrode placement or thermal diffusion
- Allergic or hypersensitivity reactions to accessory materials (e.g., tubes, connectors) or medications

Neurological complications

- Iatrogenic nerve injury due to thermal diffusion or needle malpositioning
- Radiculopathy, paresthesias, transient or permanent motor or sensory deficits
- Injuries to the spinal cord or nerve roots (e.g. perforation or burn), with possible onset of paresis or paralysis
- Neuropathic pain from nerve irritation or incomplete ablation

Bone and Structural Complications

- Post-ablation vertebral fracture, particularly in structurally compromised bones or areas under load
- Partial or incomplete ablation due to technical or anatomical limitations of the patient
- Intra-abdominal fluid collections
- Pulmonary embolism, pneumonia, respiratory failure
- Hemothorax or pneumothorax
- Thermal damage to adjacent structures or organs (e.g. intestines, bladder, large vessels)

7.6 Limitation of Use

The SPINERY® RF Generator is intended for use by professional healthcare professionals only, in properly controlled clinical environments.
The device is prohibited for use in RF shielded rooms dedicated to magnetic resonance imaging (MRI) medical systems, due to the risk of electromagnetic interference.

8 PATIENT PROFILE

Metastatic bone disease is a common condition in advanced cancer patients.
Radiofrequency ablation of bone metastases, particularly in the spine, can significantly improve the patient's quality of life by controlling intractable pain, preventing pathological fractures, and reducing the risk of nerve compression. This palliative procedure is frequently followed by bone cement injection (vertebroplasty/cementoplasty) to stabilize the bone structure.
The SPINERY® RF Generator can be used on patients who meet the following criteria:

- Presence of painful bone metastatic lesions;
- Presence of pain localized in no more than two symptomatic sites (Note: "two symptomatic sites" means a maximum of two vertebrae to be treated in a single operation. There is no direct correlation between tumor volume and the number of treatable metastases);
- Absence of radiological or clinical signs of impending vertebral fracture;
- Patients eligible for standard therapies, in whom radiofrequency treatment can be combined with systemic or radiotherapy treatments, according to the assessment of the treating physician;
- Patients who do not respond or are not candidates for standard therapies (Note: treatment is palliative and is not aimed at direct control of metastatic progression);

9 INTENDED USERS

The SPINERY® RF Generator is intended for use by qualified healthcare professionals only, in accordance with local regulations.
The use of the device during surgery or interventional procedures is reserved for medical specialists who are legally authorized to perform such procedures, in particular interventional neurosurgeons and neuroradiologists. These operators can be assisted by qualified health personnel, such as operating room nurses and radiology technicians.

User training

The user must have completed specific training on the use of the device, provided by authorized personnel of AXON S.r.l., according to the manufacturer's training protocols.

- Training is necessary to ensure:
- The correct technical and operational management of the equipment;
- The interpretation of the device's screens and signals;
- The adoption of the correct precautions for use;
- Recognition and resolution of problems during clinical use.

Note:Not it is specific training required for the'bone access, which is presumed to have already been acquired by specialized medical personnel.

Mandatory training

- The training program is developed according to the following steps:
- Explanation of the technical characteristics of the device, including the structure, components, package contents, and description of sterile accessories;
- Presentation of how to prepare the device for clinical use, with interpretation of the instructions for use;
- Simulations or hands-on sessions on the use of the generator, when provided.

10 PRODUCT OVERVIEW

10.1 Principles of operation of the device and its mode of action

RF ablation is an invasive technique that involves delivering RF energy to a target tissue (tumor metastases in the bone) in order to heat the tissue to cytotoxic levels and cause thermal ablation. The SPINERY® RF Generator includes a generator with disposable components, which delivers RF energy directly to the target tissue to cause acute necrosis due to overheating. Thermal ablation is completed by heating the target tissue to cytotoxic levels. Generally, a cytotoxic temperature above 60°°C causes complete necrosis in most tissues, although temperature sensitivity can vary depending on the cell type. Cancer cells are generally more sensitive to heating than normal cells due to variations in sensitivity to tissue hypoxia. Hyperthermic ablation is intended to cause acute coagulative necrosis within the target tissue. At temperatures of up to 41°°C, blood vessels dilate, blood flow increases, and the heat shock response is initiated. The heat shock response is a process of rapid gene expression that aims to combat thermally induced damage. This includes the production of heat shock proteins, which can confer greater thermal resistance in tissues that survive the initial thermal damage. From 42°C to 46°C, irreversible damage begins, and after 10 minutes, significant necrosis occurs.

From 46°C to 52°C, the time to cell death decreases due to a combination of microvascular thrombosis, ischemia, and hypoxia[1].

At sufficiently high temperatures (> 60°°C), proteins denature and the plasma membrane melts so that cell death is almost instantaneous. The energy is delivered to the patient in the form of RF currents, to achieve tissue ablation. The working frequency is fixed. The energy emitted is automatically controlled by the generator by setting the following flow parameters:

- Distal electrode temperature
- Selection of linear or three-stage temperature heating ramps
- Maximum output power.

The effect of RF emission on tissue can be measured by the following parameters at treatment sites:

- Tissue impedance (Ω)
- RF Needle Distal Electrode Temperature (°C)
- RF needle proximal electrode temperature (°C)
- Power (W)

The RF emission modes of the SPINERY® probes are described in the following table. The configured heating ramps provide similar ablation results even if they terminate at slightly different temperatures (85 °C for the linear ramp versus 90 °C for the three-step ramp).

	TEMPERATURE HEATING PROFILE	
	PRESET 1 – LINEAR RAMP	PRESET 2 – THREE-STEPS
HEATING MODE (T)	Heating up to 85°C and holding for 4 minutes	Heating up to 60°C and holding for 2 minutes
		Heating up to 75°C and holding for 2 minutes
		Heating up to 90°C and holding for 2 minutes
POWER (W)	Maximum power 15W* *Power automatically reduces to maintain the selected temperature for the set time	Maximum power 15W* *Power automatically reduces to maintain the selected temperature for the set time
MANUAL IRRIGATION	Irrigation: 0.1 mL (at distal and proximal irrigation sites) prior to initiating RF ablation	Irrigation: 0.1 mL (at distal and proximal irrigation sites) prior to initiating RF ablation
AUTOMATIC COOLING DURING ABLATION	Probe needle cooling (room temperature) to 30 ml/min for dual access	Probe needle cooling (room temperature) to 30 ml/min for dual access

[1] Evidence of this dynamic is provided in the following article: *Knavel EM, Brace CL. Tumor ablation: common modalities and general practices. Tech Vasc Interv Radiol. December 2013; 16(4):192-200. DOI: 10.1053/j.tvir.2013.08.002. PMID: 24238374; PMCID: PMC4281168.*

	TEMPERATURE HEATING PROFILE	
	PRESET 1 – LINEAR RAMP	PRESET 2 – THREE-STEPS
AUTOMATIC COOLING AFTER ABLATION	Automatic cooling of the probe needle for 30 seconds	Automatic cooling of the probe needle for 30 seconds
DURATION OF ABLATION	Average of 5-6 minutes	Average of 7-8 minutes

Table 8 - RF emission modes of the SPINERY® RF Generator probes

Small deviations on the setup parameters are allowed but always under the control of the Software, such as:

FIXED PARAMETERS	USER-SETTABLE PARAMETERS	AUTOMATICALLY MODULATED PARAMETERS
RF Frequency	• Maximum ablation power (40W) • Target distal temperature (85°C or 90°C)	• RF Power • RF voltage • Impedance

Table 9 – SPINERY® RF Generator Probes Parameters

This effect of RF emission on the fabric can be adjusted by selecting the factory presets of the Operating Instructions. The factory presets can be customized by the operator who can change the maximum RF power and two different heating ramps.

The Essential Performance of the device, as defined in the IEC 60601-1 *Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance*, are as follows: considering the intended use of the product, the essential performance of the device is its ability to generate heating of the patient's tissues in a controlled manner through RF energy:

- The ability of SPINERY® RF Generator to provide energy to the patient's body in a controlled manner;
- The ability of SPINERY® RF Generator to generate critical alarms and provide user information to the interface;
- The ability of the SPINERY® RF Generator to provide exactly the preset energy parameters required by the user for patient treatment;

In addition, the available variants of the ablation probes have the characteristics of internal cooling and irrigation through the needle tip. The solution (sterile saline solution at room temperature) flowing inside the needle lumen works by keeping the electrode surface cold to prevent charring of the surrounding tissue. The solution that irrigates the fabric around the needle tip is able to alter the electrical conduction of the tissue. Both the characteristics of cooling and irrigation have an action directly related to the prevention of carbonization of the surrounding tissue and the enlargement of the ablated area. One or two RF ablation probes can be connected to the RF generator, and the ablation area configurations, which can be obtained based on the possible combinations of probes, are shown in the table below.

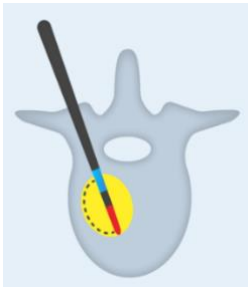
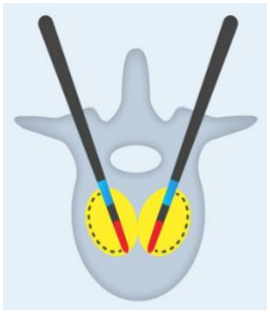
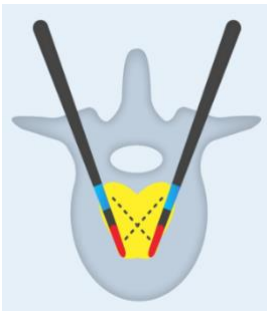
Configuration	Ablation zone configurations
Single sign-on: Bipolar (SP-BI0704EU) Or Bipolar 10-5-10 (SP-BI1005EU)	
Double bipolar access, parallel configuration: Bipolar (SP-BI0704EU) Bipolar (SP-BI0704EU) Or Bipolar (SP-BI1005EU) Bipolar (SP-BI1005EU)	
Double bipolar access, cross configuration: Bipolar (SP-BI0704EU) Bipolar (SP-BI0704EU) Or Bipolar (SP-BI1005EU) Bipolar (SP-BI1005EU)	

Table 10 - Ablation zone configurations

10.2 Operation of the medical device with its accessories

Access to the bone ablation site is facilitated by the use of a bone access cannula (Introducer), part of the Bone Access Components contained in the disposable Spinery® Kit.
Once the target site is reached, the single-use ablation probe (RF probe) is inserted, connected to the SPINERY® RF Generator (see Figure 2).
Radio frequency (RF) energy is delivered through the probe based on the settings selected on the generator, and the entire procedure is automatically monitored by the system, for each active channel.
The RF energy induces a localized thermal response in the bone tissue, creating an area of controlled ablation.
During the procedure, a slow infusion of sterile saline is delivered via the probe's built-in irrigation pathways, keeping the tissue hydrated.
This irrigation is essential to prevent impedance from rising and reduce the risk of tissue charring, events that could compromise the effectiveness or safety of the procedure.

⚠ The operating frequencies used by the generator do not generate ionizing radiation.
⚠ No high voltages are used inside the equipment during operation.

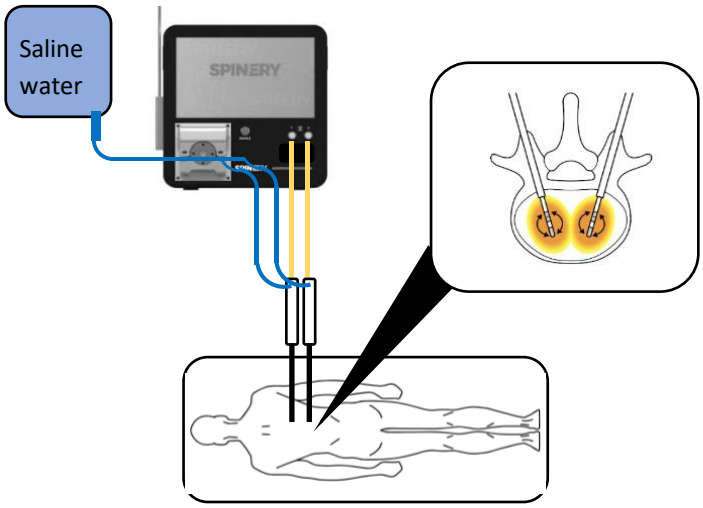


Figure 2 – SPINERY® RF Generator Overview

Important:

The use of the SPINERY® RF Generator requires the use of specific accessories supplied in sterile disposable packages:

- Spinery® Kit, containing the RF probe, the Bone Access Components and the infusion components;
- Spinery® Cooling Connection, dedicated connector for the management of irrigation and intra-procedural cooling.

Carefully consult the operating instructions for the Spinery® Kit and Spinery® Cooling Connection accessories before using them.
Each component must be used exclusively in accordance with the methods, warnings and technical specifications contained in the respective IFUs.

10.3 System components and user interface

The SPINERY® RF Generator consists of an RF generator connected directly to one or two disposable probes, a cooling component circuit that connects the probe needle with the salt bag, and bone access accessories. The irrigation system circuits are provided through the probe handle (Figure 1). The RF generator provides a controlled power source for ablation. The active probe tip (applied part) delivers targeted RF energy to the ablation site. The power interface provides the electrical connection between the generator and the power supply of the plant. The graphical user interface provides selective control over the operation of the generator. User interface elements (Figure 3) include an audio buzzer and a touch-sensitive screen to provide audible and visual status information. The touch screen allows you to select generator settings, adjust probe settings, and control ablation creation.

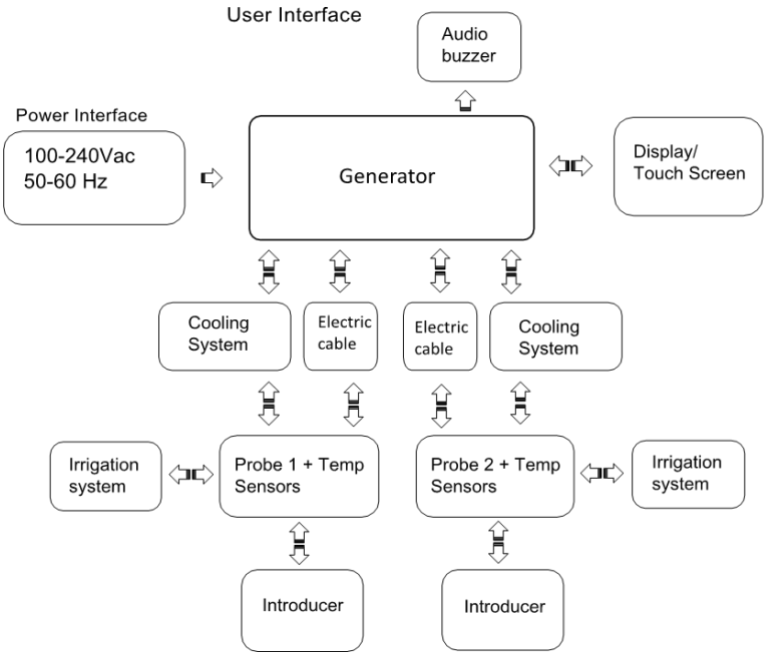


Figure 3 – User Interface Elements

10.4 To Be Used With

⚠ WARNING

- Use only components and accessories approved by AXON S.r.l. to ensure a safe and effective combination.

The use of unauthorized components can lead to an increase in electromagnetic emissions or a reduction in the immunity of the system, resulting in malfunctions.

- Do not reuse, reprocess, or repackage accessories intended for single use, such as:
- ablation probes, access cannulas, drills and irrigation components.
- Single-use products are not designed to withstand chemical reprocessing, high-temperature sterilization, or steam exposure.
- Reuse involves significant risks:
    - impairment of structural integrity,
    - contamination
    - fragmentation of the device during use,
    - loss of critical information (labelling, traceability, identification),
    - potential transmission of infections or cross-infection, with serious harm to patients and caregivers.
- The ablation probes and Bone Access Components included in the Spinery® Kit are sterilized with ethylene oxide (EtO).

Before use, check the integrity of the sterile package. Do not use the device if:

- the sterile barrier is damaged or accidentally opened,
- The package has been exposed to environmental conditions other than those specified

DESCRIPTION OF SPINERY COMPONENTS	REF	TYPE OF USE
SPINERY® Generator includes the foot pedal and its electrical cable and the metal rod for saline solution.	SPINE-GEN	Multiple use
SPINERY® Kit (accessory), includes a probe with 10 mm long electrodes, **bone access components** (cannula-drill coupling 29 cm), drill, introducer, oblique trocar and diamond tip), insulating and irrigation cannula and 1 ml syringe.	SP-BI1005EU	Single Use
SPINERY® Kit (accessory), includes a probe with 7 mm long electrodes, bone access components (22 cm cannula-drill coupling), drill, introducer, oblique trocar and diamond tip), insulating and irrigation cannula and 1 ml syringe.	SP-BI0704EU	Single Use
SPINERY® Cooling Connections (accessory) includes the single connection of cooling components for the use of a single bipolar probe.	SP-CSEU	Single Use
SPINERY® Cooling Connections (accessory) include dual connection of cooling components for the use of a dual bipolar probe.	SP-CDEU	Single Use

Table 11 - Description of the components of the SPINERY® RF Generator and its accessories

For the correct use of the Spinery® Kit and Spinery® Cooling Connection accessories, it is mandatory to consult the specific Instructions for Use, supplied with each component.

10.5 Features – Hardware

10.5.1 SPINERY® RF Generator

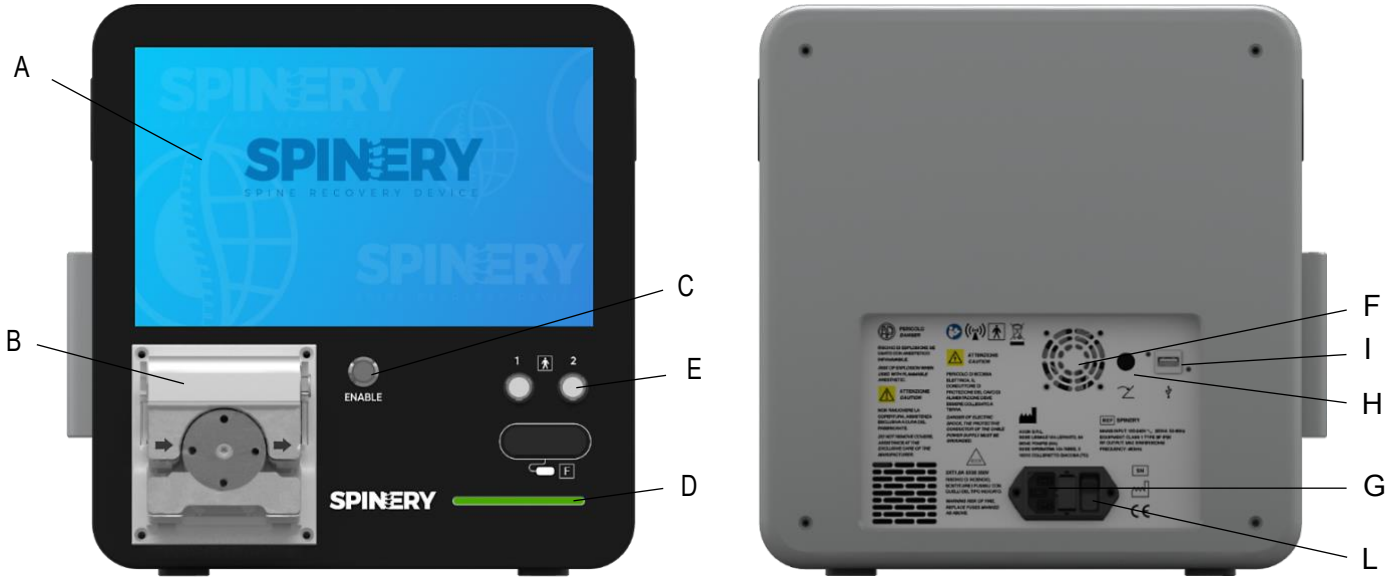


Figure 4 – SPINERY® RF Generator

Generator detail - front	
A	Touchscreen display: Displays messages (e.g., errors, faults, settings, current status, etc.) and allows the operator to interact with the device via the touchscreen. Each time you press a key, a beep appears. If a system error occurs, the generator fails. See Section 12.2 for more details on alarms and warnings
B	Peristaltic pump - Provides cooling of the probe(s) (24 mL/min if a single probe is used and 30 mL/min if a double probe is used)
C	Enable/Disable Button - Button to enable and disable radio frequency delivery.

Generator detail - front	
	This button, when pressed, disables the RF delivery of the Generator at any time
D	Led - Led indicating the status of the generator. It is always green; It turns red if an alarm is occurring.
E	Probe Port(s) – Provides the electrical connection of the probe(s) to the generator

Table 12 – Spinery RF Generator Features - Front

RF Generator Detail – Back	
F	Fan Ventilation Holes – Provides ventilation of the generator air.
G	Power Cord Receptacle - Allows installation of the power cord connector.
H	Switch pedal connection port. Note – Do not plug any device into this outlet.
I	USB Port – Use only if you need to download procedure data. Note – Do not plug any device into this outlet.
L	On/Off Button: Allows you to turn the generator on or off.

Table 13 - Features of the SPINERY® RF Generator - back

10.5.2 Generator power cable

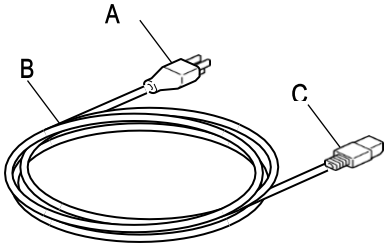


Figure 5 – RF Generator Power Cable

RF Generator Power Cable Features	
A	Power Cord Plug - Allows the power cord to be installed into a hospital-grade electrical power outlet.
B	Power Cord - Provides the electrical connection between the generator and the system power supply.
C	Power Cord Connector - Allows the power cord to be installed into the power cord receptacle.

Table 14 – RF Generator Power Cable Features

10.5.3 Pedal power cable

Figure 6 – Pedal Power Cord

Features of the RF Generator Pedal	
A	Pedal - Herga model 6225-BBBB-ZZZZ.
B	Pedal Cable - Provides the electrical connection between the generator and the pedal.

Table 15 – RF Generator Pedal Features

⚠ CAUTION - Condition of components at the time of delivery

The RF generator and foot pedal are not supplied sterile and should be placed in the operating room outside the sterile field. Both the RF generator and the foot pedal are reusable.

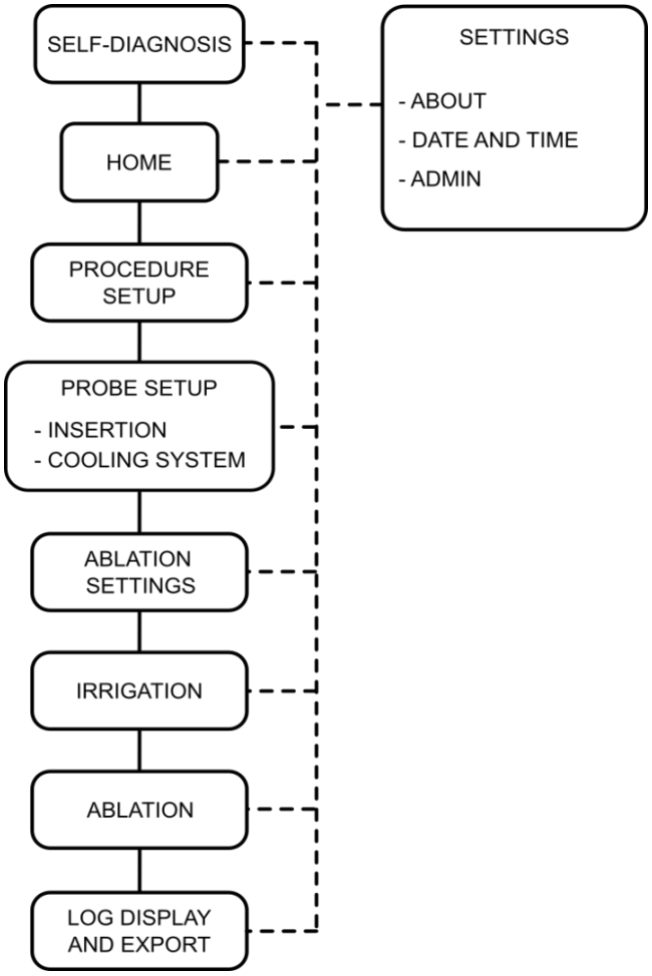


Figure 7 – Software Interface Flowchart

10.6 Features – Software Menu

The HOME screen provides a simple interface to enter identification codes for Hospital, Doctor and Patient. The primary purpose of the HOME screen is to provide reference IDs before accessing the procedural workflow and ablation settings. During all the procedural workflow screens, you can access the Home or Settings areas. The SPINERY software interface guides the operator in the preparation of the accessories and in the execution of the ablation. Figure 12 represents the workflow.

10.7 Features – Software Screen

Functional screen and pop-up windows that support the SPINERY® RF Generator's procedural workflow include patient and operator registration, selection of ablation parameters with entering and changing temperature and power values, initiating ablation creation, and downloading ablation data. During the guided procedural workflow, pop-ups ensure proper operation with warning messages and error messages.

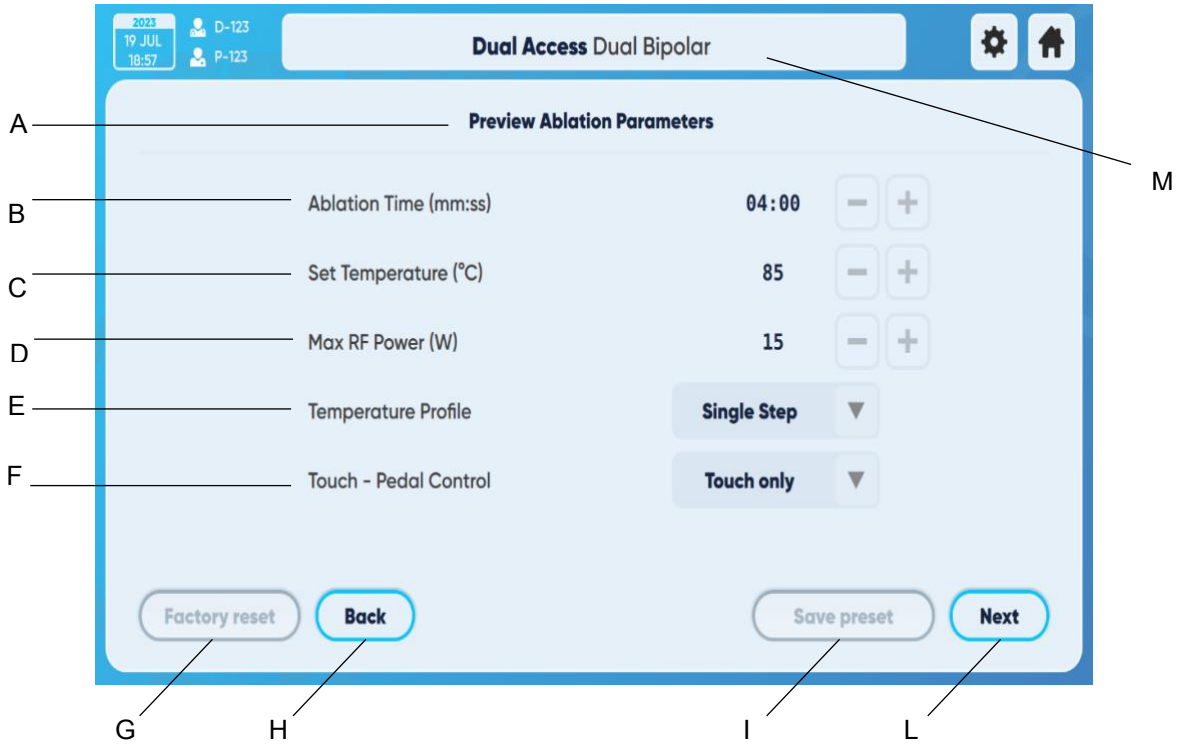


Figure 8 - Ablation Preparation Screen

A	Screen Title
B	Setting the Ablation Time
C	Setting the Ablation Temperature
D	Setting the Maximum RF Power
E	Setting the Temperature Profile
F	Setting the Control Mode
G	Factory reset button: Provides factory reset ablation parameters
H	Back button
I	Save Preset Button – Allows you to save your personal ablation parameters
L	Next button
M	Selected ablation mode

Table 16 – Software Screen Features

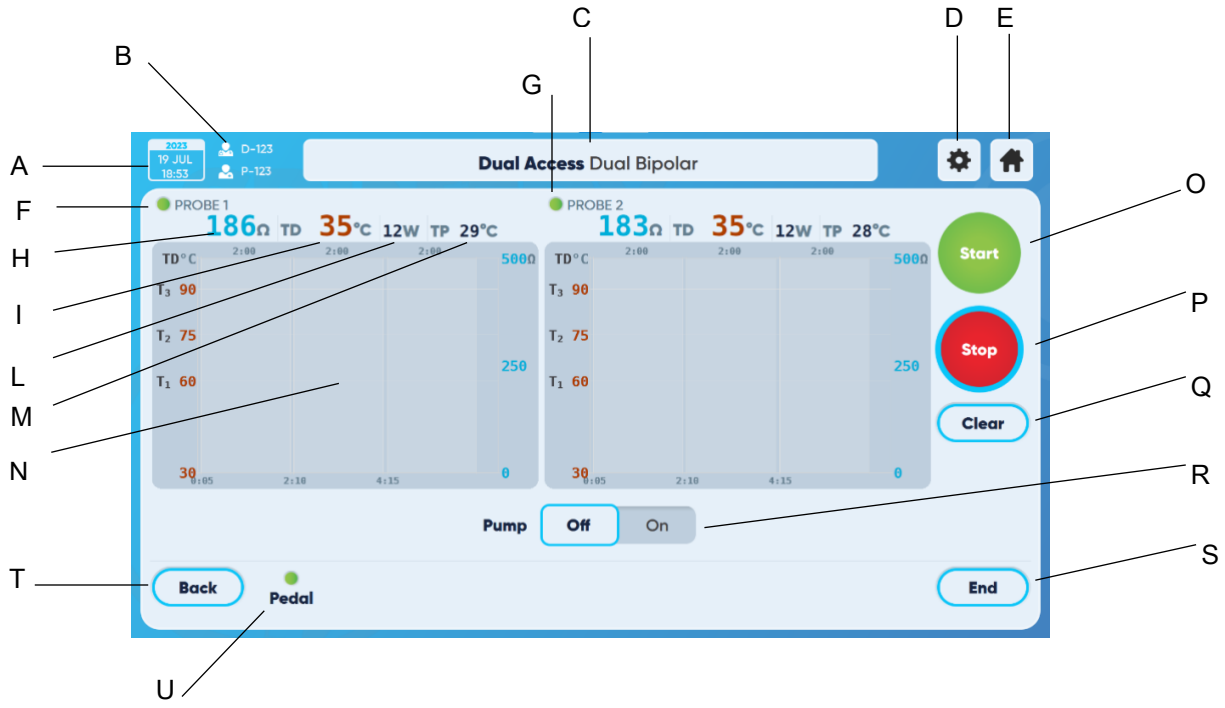


Figure 9 - Ablation screen

A	Date of procedure
B	Code entered by the patient and the doctor
C	Selected ablation mode
D	Settings
	Home
F	Connected probe 1
G	Connected probe 2
H	Impedance (Ω)
I	Distal Temperature (degrees Celsius) – Temperature monitored within the ablation area
L	Power (W) – Allows you to monitor power during ablation

M	Proximal Temperature – Temperature (degrees Celsius) monitored at the edge of the ablation area
N	Graph – Allows the operator to constantly monitor distal temperature and impedance during the procedure
O	START – Allows you to start the procedure
P	STOP – Allows you to interrupt the procedure
Q	Clear – Allows you to cancel the displayed temperature-impedance diagram
R	Peristaltic Pump – Allows the pump to start and stop during ablation preparation if necessary. During ablation, the pump automatically activates in the Sync position and cannot be stopped.
S	Finish – Allows you to follow along on the log export screen when the ablation procedure is complete.
T	Back – Allows you to return to the ablation parameters screen
U	Pedal - Allows you to understand when the pedal is connected and available for starting and stopping ablation

Table 17 - Ablation Screen

The following table summarizes the number of temperature and impedance values displayed continuously during the ablation procedure depending on the probes connected.

Connected probe(s)	Displayed temperatures	Impedances displayed
Single bipolar (SP-BI0704EU or SP-BI1005EU)	2	1
Dual bipolar (SP-BI0704EU + SP-BI0704EU)	4	2
Dual Bipolar (SP-BI1005EU + SP-BI1005EU)	4	2

Table 18 - Number of parameters displayed by type of connected probe

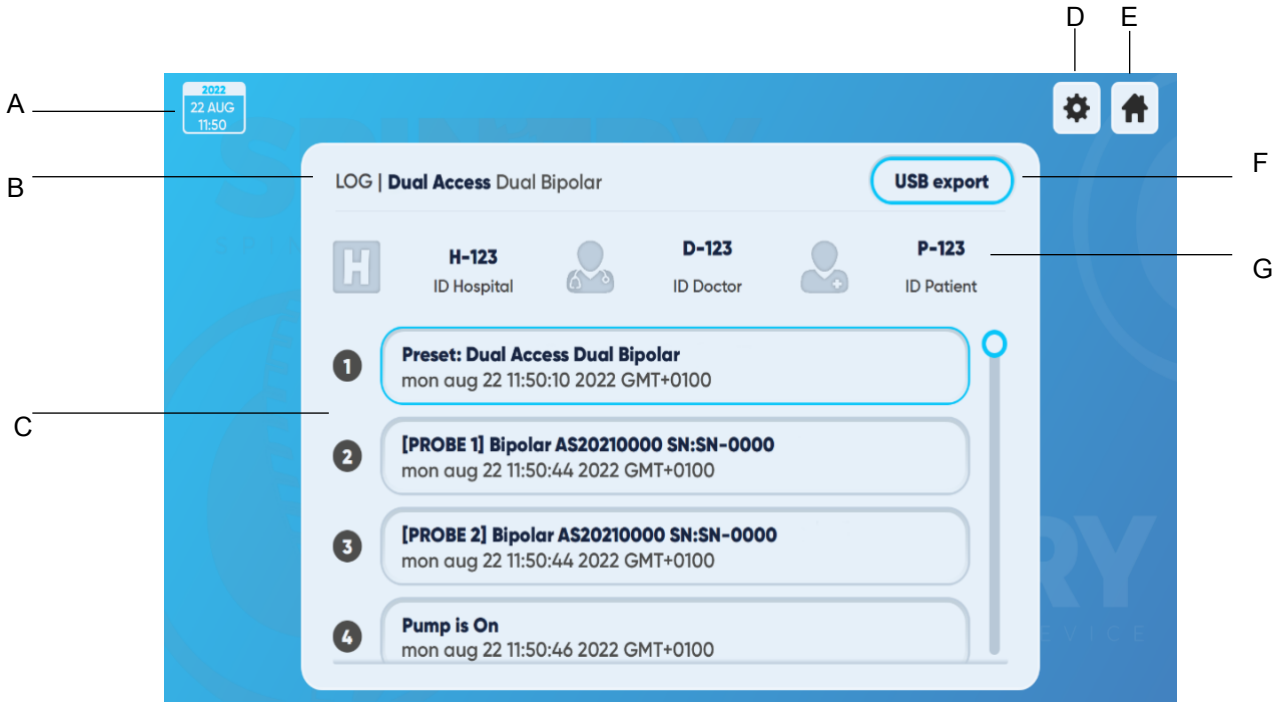


Figure 10 - Export of ablation data screen

A	Date of procedure
B	LOG List
C	Summary data
D	Settings

E	Home
F	USB export button
G	Hospital-Doctor-Patient ID

Table 19 - LOG Screen

10.8 Features – Accessories

For the correct operation of the Spinery® RF Generator, it is necessary to use compatible disposable and sterile accessories, namely:

- Spinery® Kit, containing the cooled bipolar probe, irrigation components and Bone Access Components
- Spinery® Cooling Connection, for connecting the external cooling system to the probe

However, this IFU refers only to the **Spinery® RF Generator**.

For a detailed description of the accessories mentioned above, including their technical characteristics, how to use them, safety requirements and specific precautions, please refer to the IFUs dedicated to accessories:

- IFU Spinery® Kit
- IFU Spinery® Cooling Connection

The aforementioned IFUs are provided separately from this document and must be consulted in full before the joint use of the generator.

11 START OF THE PROCEDURE

11.1 Unpack the generator

⚠ WARNING:

- Always inspect the product and all system components for damage upon initial receipt and before each use. Do not use the product if damage is evident.

CAUTION – Always keep the original packaging container for reuse. Failure to do so may result in damage during transportation to the Axon Customer Service Center.

Open and remove all components from the RF generator packaging (Pelican Luggage)

Make sure all components are supplied with the RF generator. Also check the power cord, metal stand, and foot pedal. If any of the components are missing or damaged, please contact AXON customer service (contact information at §17).

DESCRIPTION
Axon RF Generator
Power cord
Instructions for use
Foot pedal with power cord

11.2 Prepare the generator

⚠ WARNING

- To avoid the risk of electric shock, always plug this product directly into a protective grounded hospital-grade facility power outlet.
- Always position the product so that the power cord can be easily unplugged.

To prepare the generator:

1. Place the generator on a flat surface, outside the sterile field and near a hospital-grade power outlet with protective grounding.
2. Position the generator so that the power cord socket is easily accessible.
3. Connect the power cord to the generator power outlet and to a hospital-grade power outlet with protective grounding (Figure 11).
4. Press the power button on the rear panel to power the generator.

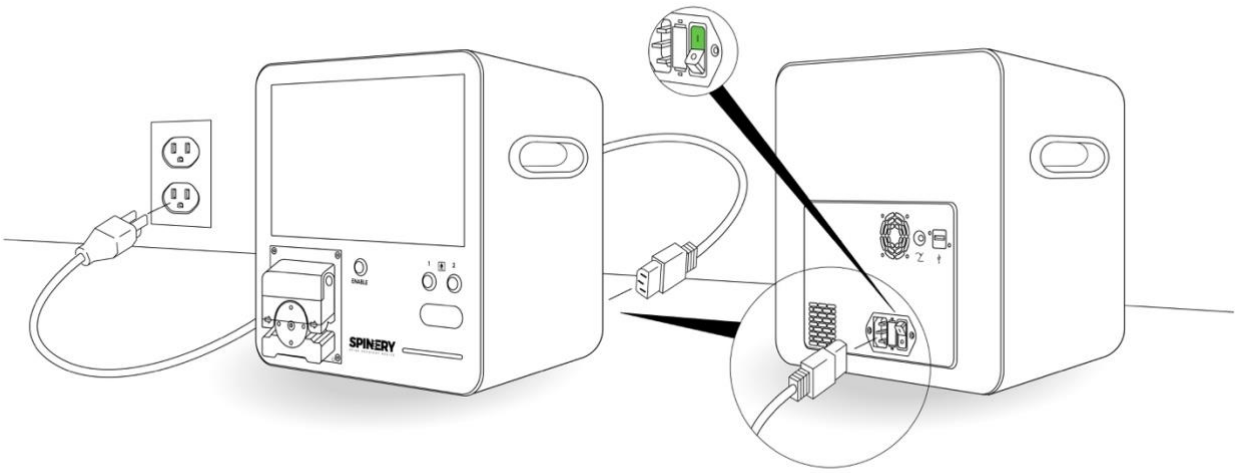


Figure 11 – Main Power Connection

ⓘ Note: For more information on equipotential grounding, refer to the 60601 Series Standard Requirements for Medical Electrical Systems.

1) Initially, a temporary start-up page is displayed and a subsequent automatic self-diagnosis procedure is initiated with an audible sound and a front status LED colored red and then green (Figure 12).

2) When the self-diagnosis is complete, a green dot and a "Start" button will appear in the middle of the screen. Press the "EANBLE" button on the front panel and press the "Start" button to open the home page.

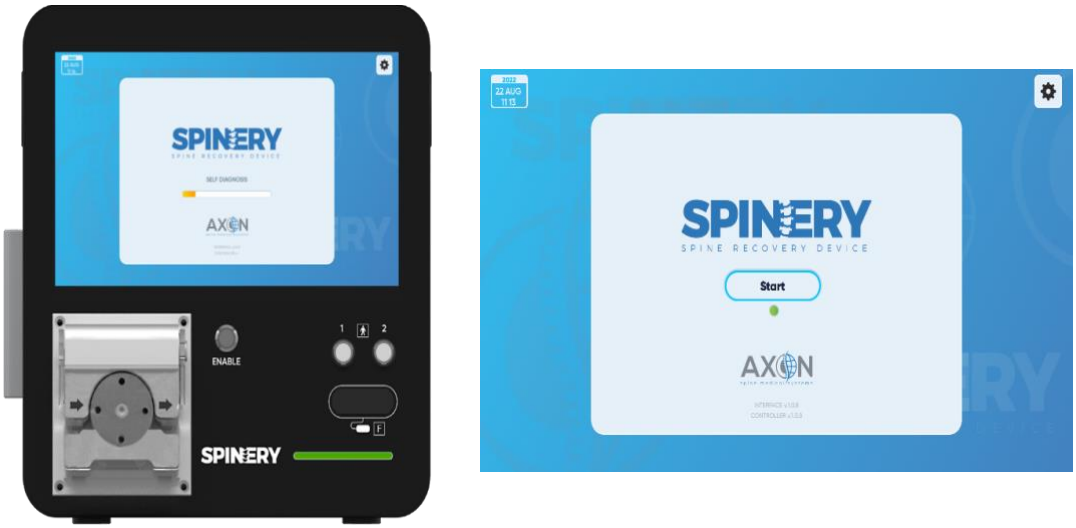


Figure 12 - Front LED status

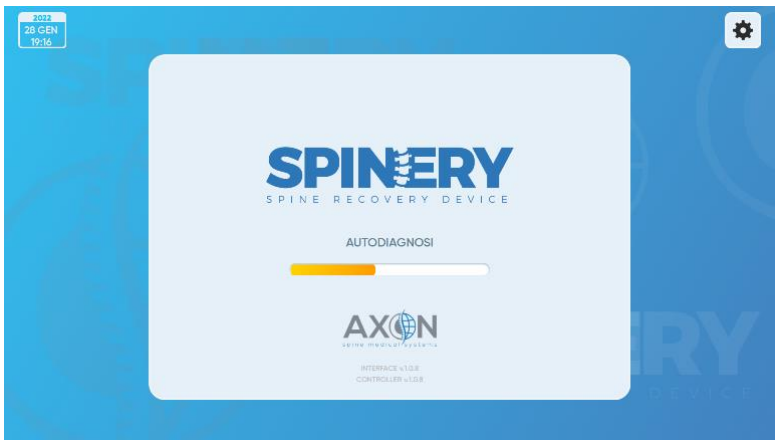


Figure 13 – Self-diagnosis screen

11.3 Accessing Generator Settings

Note – Before first use, you may need to review and adjust the generator settings.

1. After the automatic self-diagnosis procedure, tap the SETTINGS button on the right side of the screen to access the desired setting or information.

Note - Pressing the set button during ablation stops the ablation.

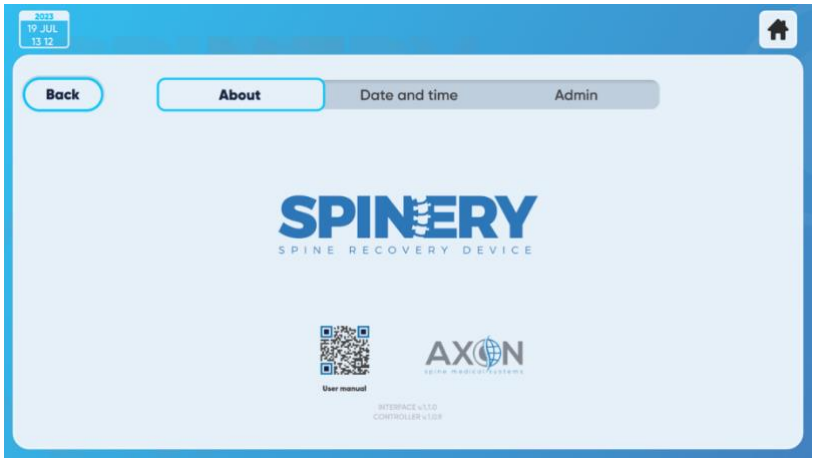


Figure 14 - Setting Screen

The SETUP screen includes:

- **Information**: logos, links to the user manual and information on software versions;
- **Date & Time**: Current date and time settings
- **Administrator**: Login page for Axon authorized technicians (login credentials required)

1. See the "About" settings page to access the SPINERY® RF Generator's operating instructions via the QR code (Figure 14).
2. See the "Date and Time" setting page to update the date and time.
3. See the "Admin" settings page to access the factory settings. Access requires dedicated credentials and is reserved for Axon technicians only

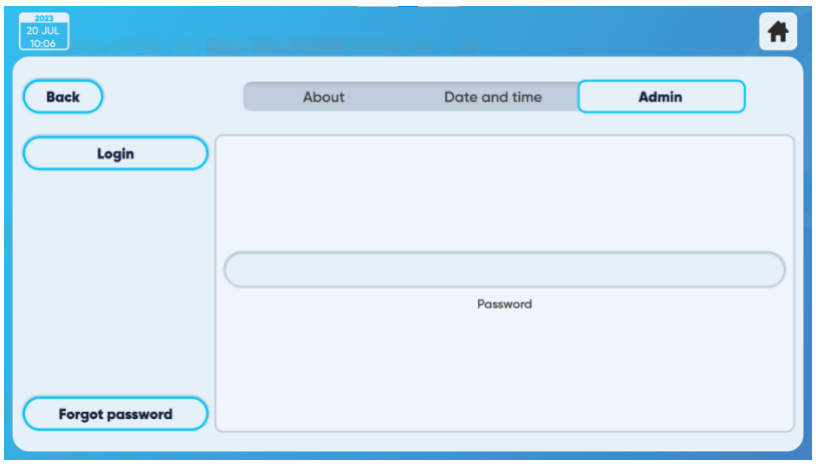


Figure 15 - Administrator Settings Screen

12 USING THE PRODUCT

12.1 Operator authentication

Note

- – Before starting any ablation procedure, the Home page allows you to enter your Hospital ID, Medical ID, and Patient ID.

The illustrated instructions always ask you to confirm or change the last indicative ID of the Hospital, Doctor and Patient, as shown in Figure 16 below.

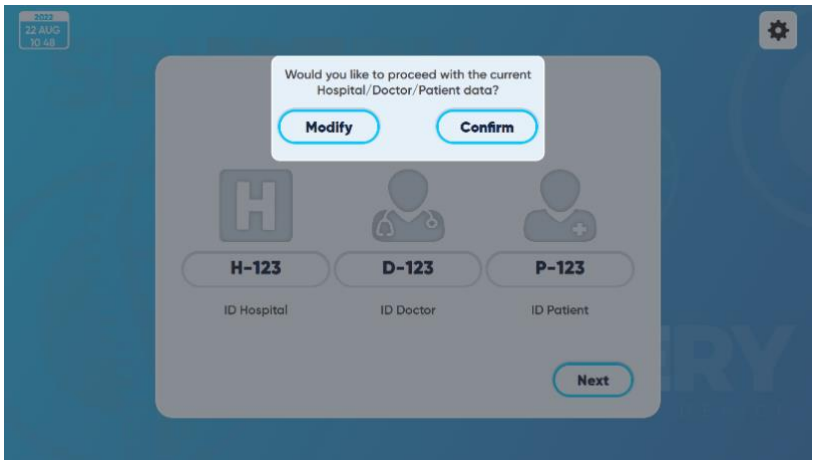


Figure 16 - Splash screen

Pressing the "Confirm" button takes you directly to selecting the ablation mode, while pressing the "Edit" button gives you the option to enter new data.

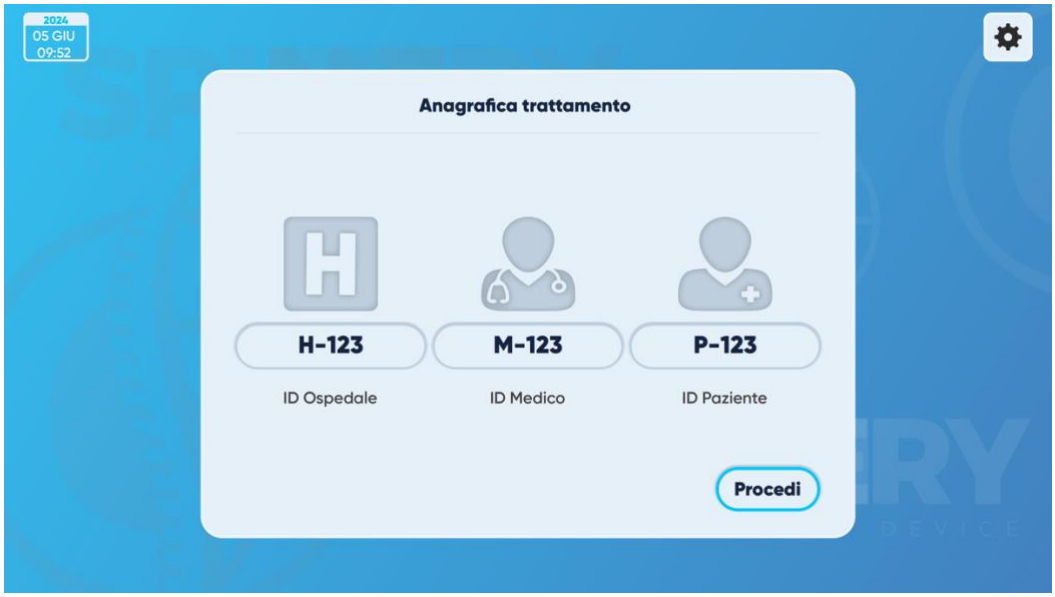


Figure 17 - Procedure reference screen

Pressing the "Proceed" button takes you to the next step of selecting the ablation mode.

The entered ID of the Doctor and Patient is displayed on all subsequent screens at the top left next to the current date and time.

12.2 Select ablation mode

⚠ WARNING

- Use only components and accessories approved by AXON to ensure a safe and effective combination. Failure to comply may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.
- Traditional surgical instruments including a surgical hammer and sterile saline water are required during the procedure.
- Upon initial receipt and prior to use, visually inspect the package for damage to confirm the integrity of the sterile barrier. Do not use the product if damage is evident, if the sterile barrier is compromised, or if the package is opened unintentionally.
- Do not use the product after the expiration date printed on the packaging. The product may not be safe or effective after the expiration date.
- Upon initial receipt and before each use, always clean and disinfect the generator and splitter cable.

1. Open the package in a sterile field using appropriate aseptic techniques. Remove and remove all protective plastic conduits on metal components.
2. Visually check all components of the device to ensure that there are no damaged parts. Do not use if parts are damaged.

🛈 Note

- The Axon generator allows the creation of ablation tissues using up to two probes. RF energy is delivered in short, timed bursts to allow all probes to heat up at the same time.
- RF energy is delivered through one or a maximum of two probes connected directly to the generator. The generator can support two combinations of probe configurations.

Select the appropriate procedure configuration. See Procedure Configurations.

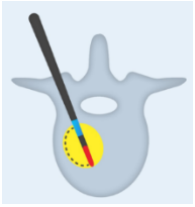
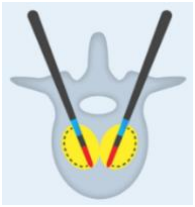
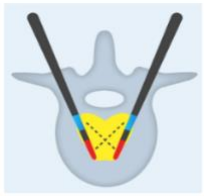
DIRECT CONNECTION TO THE GENERATOR	NUMBER OF PROBE(S)	PROBE MODEL TO USE	NUMBER OF TEMPERATURE SENSORS
YES	1 Probe – Single Access 	1 SP-BI0704EU bipolar or 1 x SP-BI1005EU bipolar	2 (distal and proximal)
YES	2 probes – double access – parallel ablation 	2 SP-BI0704EU bipolar or 2 x SP-BI1005EU bipolar	4 (distal and proximal) (2 for each probe)
YES	2 Probes – Double Access – Cross Ablation 	2 SP-BI0704EU bipolar or 2 x SP-BI1005EU bipolar	4 (distal and proximal) (2 for each probe)

Table 20 - Possible probe connections to the generator

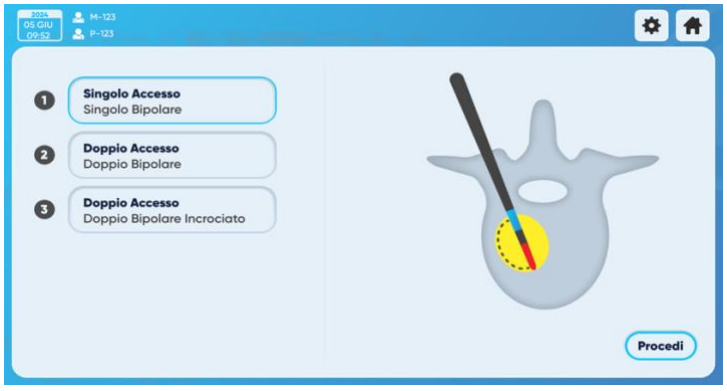


Figure 18 – Ablation Mode Selection: Single Access (Single Bipolar)

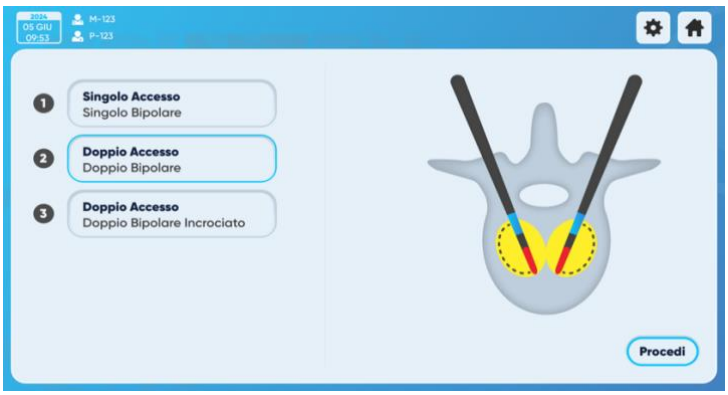


Figure 19 – Ablation Mode Selection: Dual Parallel Access

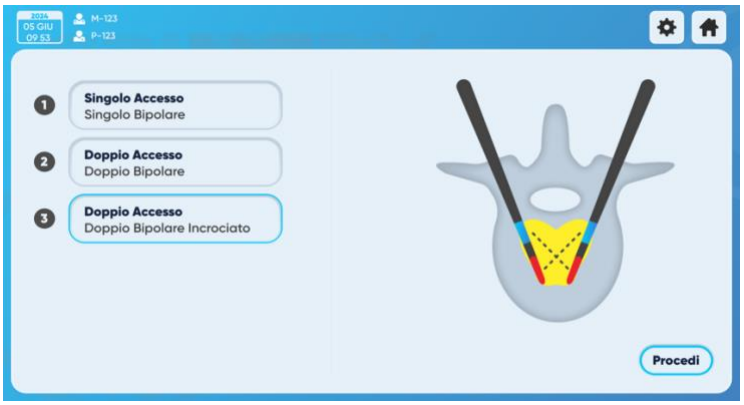


Figure 20 – Ablation Mode Selection: Dual Bipolar Cross Access

Note

- - You cannot use the dual bipolar probe ablation configuration using an SP-BI0704EU bipolar probe and an SP-BI1005EU bipolar probe.

12.3 Accessory Connection - Spinery® Kit and Spinery® Cooling Connection

The correct use of the Spinery® RF Generator to achieve its intended use requires connection with compatible and dedicated accessories: Spinery® Kit and Spinery® Cooling Connection, both sterile and disposable.
As these accessories are not covered by this IFU, all specific information regarding their connection, configuration and handling is set out in the respective operating instructions documents. Therefore, before using the generator in a clinical setting, it is mandatory for the operator:

- See the IFU of the Spinery® Kit device for detailed instructions on connecting the probe, irrigation components, and Bone Access Components
- Consult the IFU of the Spinery® Cooling Connection device for proper installation and connection of the cooling circuit to the probe and external system

Improper use or incorrect connection of accessories may compromise the performance and safety of the treatment

CAUTION:

- When connecting or disconnecting a cable, always grasp the cable by the connector or plug when installing or removing.

Note

- Make sure the generator is properly positioned outside the sterile field, powered on, and ready for use.

- The generator display screen will provide illustrated instructions regarding the proper connection of the probe(s) and accessories (cooling system).
- The generator will only recognize AXON-approved components and accessories.

1. Connect the probe to the generator (Figure 26).

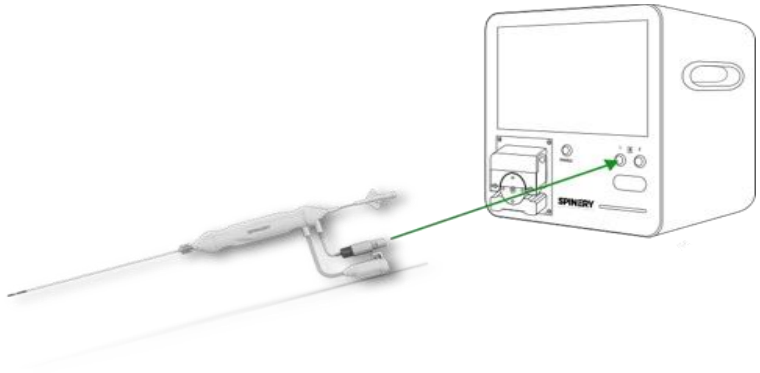


Figure 26 – Connecting the Probe to the RF Generator

2. Once the probes have been connected to the RF Generator, the display indicates the probe lot and the recognized serial number and shows the temperatures detected by the distal (TD) and proximal (TP) thermocouples

Figure 27 - Single probe recognition screen

Figure 28 - Dual probe recognition screen

3. Select the Next button to proceed with initializing the peristaltic pump.

Note: Depending on whether one or two probes (code SP-BI0704EU or SP-BI1005EU) have been connected to the Generator, the single cooling connection (code SP-CSEU) or the double cooling connection (code SP-CDEU) must be connected, respectively. The single or double connection circuit should be connected to the room temperature saline bag at one end and the probe(s) at the other end.

4. The illustrated instructions (Figure 29/30) ask you to connect the cooling connection tip to the saline bag from one end to the probe at the other end and to place the propulsion tube in the peristaltic pump.

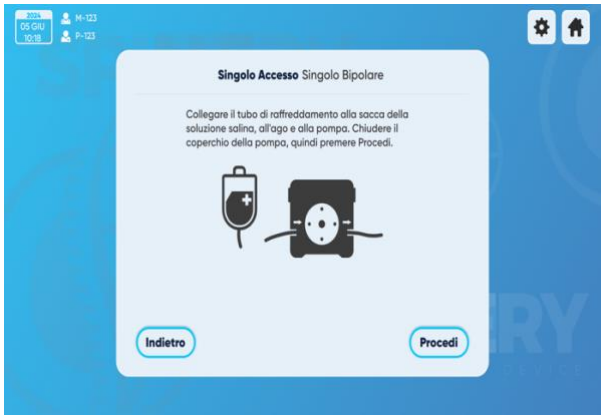


Figure 29 – Single Access Cooling Connection Screen

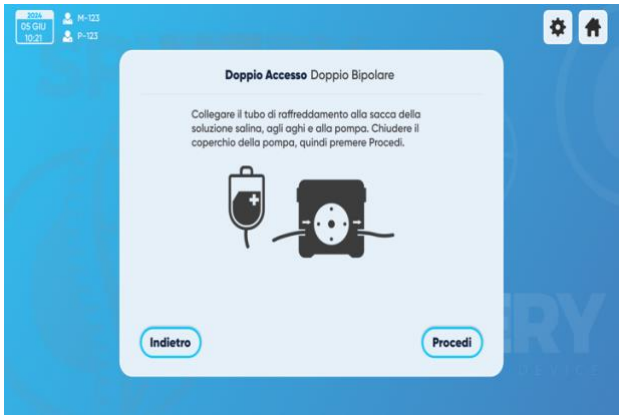


Figure 30 – Dual-Access Cooling Connection Screen

5. To complete the preparation of the cooling components, the following steps must be performed:
   A. Open the plastic door of the peristaltic pump (Figure 31);
   B. Insert the propulsion tube into the appropriate seat, checking the correct direction of travel of the liquid indicated on the pump and on the propulsion tube;

Figure 31 - Peristaltic pump

   C. Close the plastic door of the pump checking that the hose is correctly in place. If this were not the case, the correct functioning of the cooling of the needle probe would be precluded;
   D. Be careful to leave the return hose free;
   E. Insert the tip into the saline bag previously inserted vertically into the appropriate slot on the generator;
   F. Finally, connect the cooling connection port to the probe to close the cooling circuit.

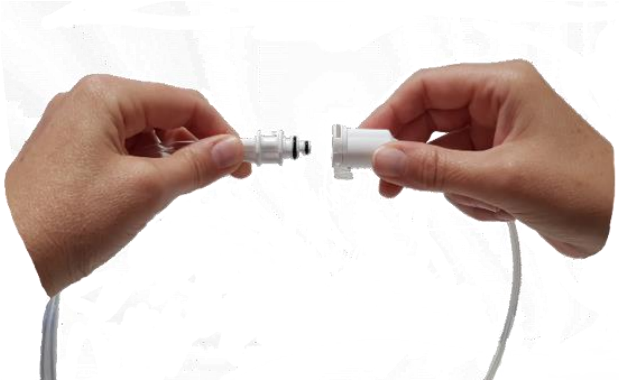


Figure 32 – Cooling Connection Ports

6. When the tubing is inserted and the pump door is closed, you can select the "Next" button.
7. The illustrated instructions (Figure 33/34) inform you that the saline water is recirculated into the closed cooling system to ensure total de-bubbling of the pipes.

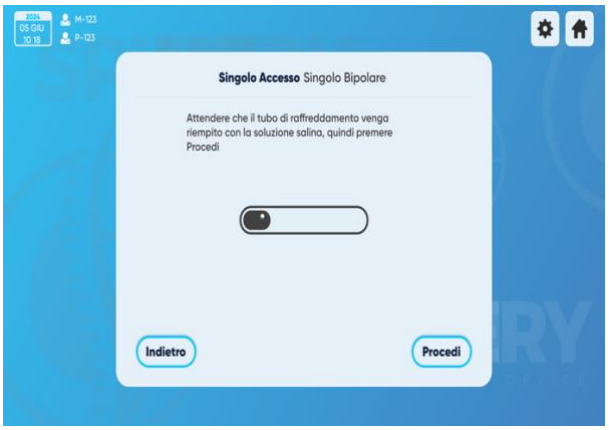


Figure 33 – Single Access De-Bubbling Screen

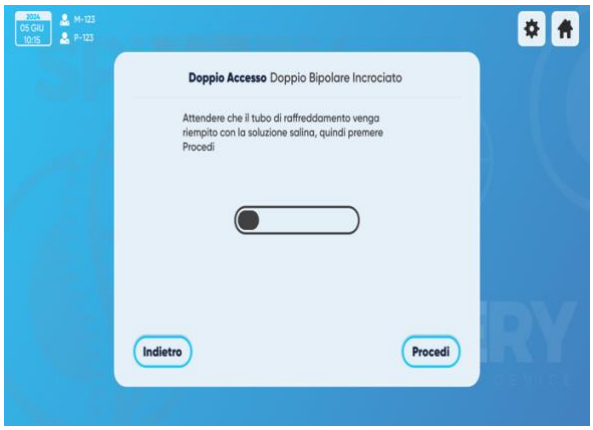


Figure 34 – Dual-access de-bubbling screen

- At the end of the de-bubbling procedure, the operator must verify that the cooling tube is filled with saline. By selecting the "Next" button, you can continue with the procedure.

12.4 Patient Preparation

WARNING

- Do not touch any exposed metal parts of the generator and the patient at the same time. Failure to comply may result in electric shock.
- Do not allow the patient to come into contact with metal parts, such as an operating table or stands that are grounded or have an appreciable capacity with respect to ground. Always use anti-static covers. Failure to comply may result in burns to the patient.
- Always clean any potentially flammable solutions under the patient's body, or in recesses or body cavities, BEFORE using the equipment. Failure to comply may result in burns to the patient.
- Apply dry gauze between the patient's arms and body if necessary to avoid skin-to-skin contact. Failure to comply may result in burns to the patient.
- Always reduce patient contact with any probe, temperature sensor, or electrical cable (probe cable, temperature sensor cable, splitter cable) as much as possible. Place temporarily unused temperature probes or sensors connected to the generator in a sterile, electrically insulated container.

Note

- Orient the patient in the prone position on a surgical table.
- Establish a sterile field on a previously selected patient surface treatment area.
- Transfer the sterile disposable introducer, sterile disposable probe(s) with insulating and irrigation cannula, 1 mL syringe, and the sterile disposable hand drill and trocars into the sterile field as needed.
-

12.5 Access to the vertebra using the bone access components

The vertebral access phase is a critical component of the ablative procedure. It is performed through the use of dedicated tools — introducer, trocar and bone drill — included in the Spinery® Kit disposable accessory device.
These devices are not covered by this IFU, as they belong to a sterile accessory, packaged separately. Access to the vertebra must be performed by a healthcare professional experienced in percutaneous interventional techniques and under fluoroscopic or tomographic (CT) guidance, according to standard clinical practice.
For detailed information on the composition of the set, bone access technique, how to use it and specific precautions, it is mandatory to consult the IFU of the Spinery® Kit device before use.
Inappropriate or non-compliant use of access tools can compromise the entire ablative procedure, increase patient risk, and damage generator components.

12.6 Preparing for Ablation

⚠ WARNING

- Do not perform ablation in painful osteoporotic vertebrae without tumor evidence: SPINERY® RF Generator is indicated only for metastatic lesions.
- Do not pull out the probe while RF energy delivery is active: possible uncontrolled tissue damage.
- Once the START button is pressed, the delivery of RF energy is fully automated and modulated by the generator, depending on the selected temperature and time values.
- In the event of a technical failure of the generator, an abnormal RF power delivery may occur: stop use immediately and contact the AXON technical service.

Trigger Sequence with SPINERY® RF Generator

Before proceeding with ablation using the SPINERY® RF Generator, all accessory components must be properly prepared and positioned.
IMPORTANT: To correctly carry out the procedures for positioning, mechanical preparation and irrigation of the probe and dedicated accessories, it is mandatory to consult and scrupulously follow the instructions contained in the respective specific IFUs:

- Instructions for Use – SPINERY® Kit (RF probe, cannulas, bone access and irrigation)
- Operating Instructions – SPINERY® Cooling Connection (cooling and irrigation management)

The following are only the steps that are directly related to managing energy through the generator:

1. After preparing and positioning the ablation probe as described in the Spinery® Kit IFUs, insert the probe fully into the introducer and lock it using the introducer's Luer Lock port (Figure 41).
2. Perform a slow initial infusion of sterile saline (as described in the Spinery® Kit IFUs and Spinery® Cooling Connection) to ensure tissue hydration and prevent high impedance events.
3. After verifying the correct preparation, activate the SPINERY® RF Generator by pressing the START button, starting the automated delivery of RF energy according to the previously selected settings (time/temperature).

12.7 Selection of ablation parameters

On the Ablation Parameters screen, set the temperature heating profile (single pass or three pass). The table below shows the heating profile of the preset temperature.

Temperature heating profile	PRESET 1 – SINGLE STEP	PRESET 2 – THREE STEPS
HEATING MODE (T)	Heating up to 85°C and holding for 4 minutes	Heating up to 60°C and holding for 2 minutes
		Heating up to 75°C and holding for 2 minutes
		Heating up to 90°C and holding for 2 minutes
POWER (W)	Maximum power 15W* **Power automatically reduces to maintain the selected temperature for the set time*	Maximum power 15W* **Power automatically reduces to maintain the selected temperature for the set time*
MANUAL IRRIGATION	Irrigation: 0.1 mL (at distal and proximal irrigation sites) prior to initiating RF ablation	Irrigation: 0.1 mL (at distal and proximal irrigation sites) prior to initiating RF ablation
AUTOMATIC COOLING DURING ABLATION	Probe needle cooling (room temperature) to 24 mL/min for single access and 30 mL/min for double access	Probe needle cooling (room temperature) to 24 mL/min for single access and 30 mL/min for double access
AUTOMATIC COOLING AFTER ABLATION	Automatic cooling of the probe needle for 30 seconds	Automatic cooling of the probe needle for 30 seconds
DURATION OF ABLATION	Average of 5-6 minutes	Average of 7-8 minutes

Table 21 – Preset Ablation Parameters

Note

- Manual irrigation is always recommended before ablation procedures. Hydration prevents an increase in impedance or a high-impedance phenomenon that could cause the tissue to char.
- The automatic cooling process is always activated by the RF generator depending on the type of access: using a single probe the flow rate of the peristaltic pump is 24 ml/min, using a double probe the flow rate of the peristaltic pump is 30 ml/min.
- Alternatively, set the desired Temperature (up to max 90°C) and set the desired Power (the standard and automatic maximum applied Power is always 15W, the maximum value of the Maximum Power that can be set is 40W) as shown in Figure 21. The ablation time can never be set differently from the preset time.

Figure 21 – Ablation Setting Screen/Temperature Setting

Figure 22 - Ablation Setting Screen

Note

- If you use two probes, the parameters you choose apply to both probes.
- The ablation time cannot be set.
- When you open the Ablation Parameters screen, the factory parameters are always displayed.
- The heating gradient cannot be set and is set at 2°C/second.
- Setting the highest maximum power value (40W) does not affect the values and maintenance times of the target temperatures.

1. The Temperature Profile drop-down menu allows you to choose the two preset heating ramps: single-step or three-level (Figure 23).

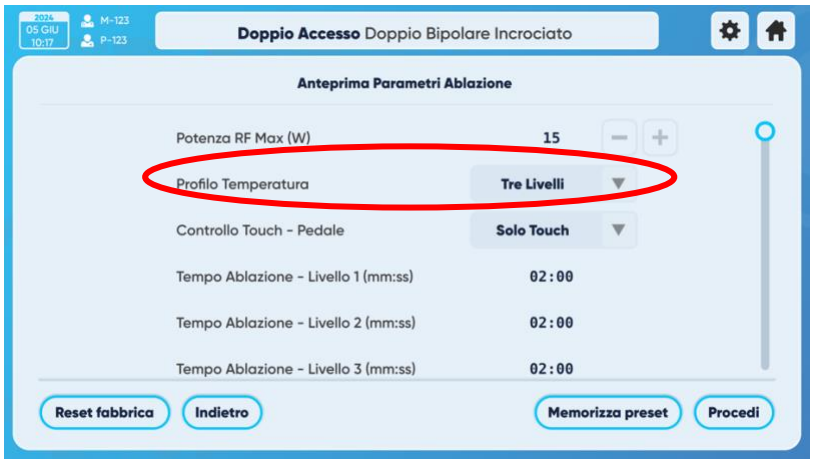


Figure 23 – Temperature Profile Selection

2. The Touch – Pedal Control drop-down menu allows you to choose whether to control the Start and Stop of the ablation only with the Touch Screen or with both the Touch Screen and the pedal.

Figure 24 - Touch Setting - Foot Control

3. In case you selected the foot pedal or Touch + foot pedal, connect the foot pedal connector to the rear panel port of the generator (Figure 25). If the control pedal is selected, a green LED ensures the connection, while the red LED indicates that it is not connected.

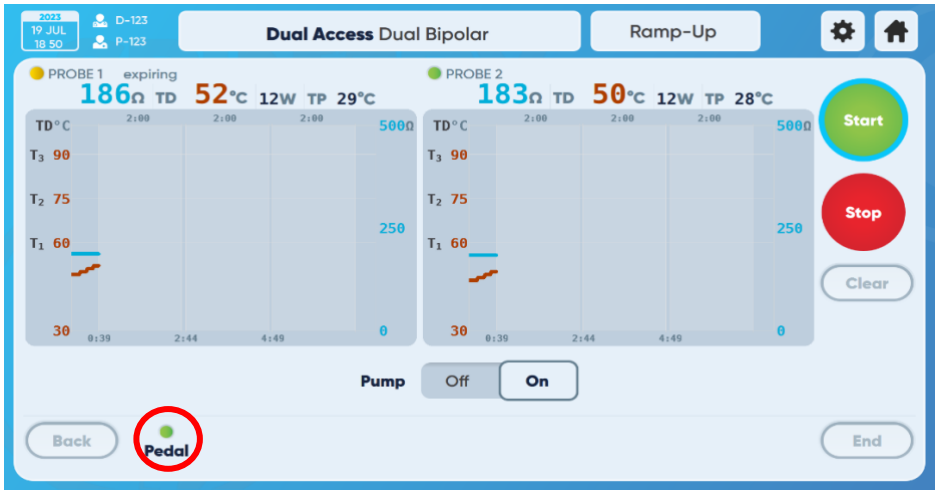


Figure 25 – Pedal symbol on generator screen

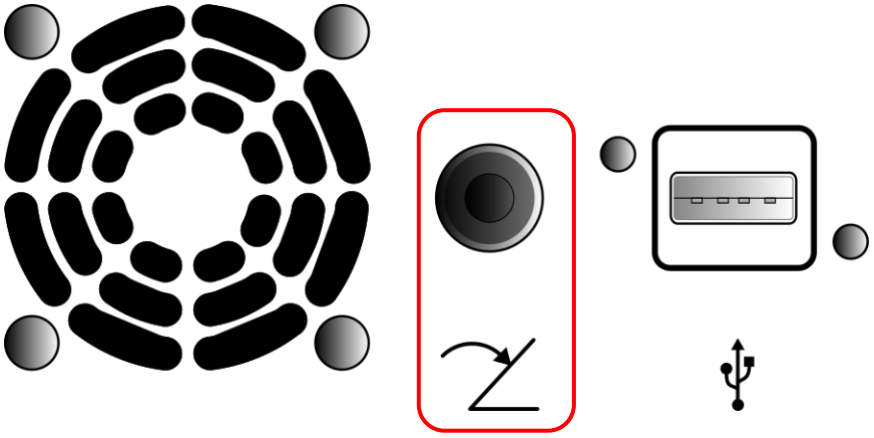


Figure 26 - Pedal connection port

4. In case you are asked to save the procedure parameter for a second ablation, press the "Save Preset" button, before pressing the "Next" button. In case you are asked to reset the previously saved parameter; press the "Factory Reset" button.

5. Press the "Next" button to open the irrigation screen, asking to provide irrigation from both distal and proximal irrigation sites (Figure 27).

Figure 27 - Watering Screen

6. The device is now in standby mode, ready for ablation to start.

12.8 Ablation creation

⚠ WARNING

- Ablation cannot be performed until the "Enable" button is activated.

ⓘ Note

- RF energy can be delivered to multiple probes simultaneously (simultaneous/simultaneous) or to a single probe one at a time.
- Ablation settings are selected before energy is applied to create an ablation.
- Make sure one or two probes are plugged into the generator outlets to have access to the START button.

12.8.1 Radio Frequency energy supply

⚠ WARNING

- Before beginning an ablation, verify that the probe(s) are reading a body temperature of approximately 37°C If the temperature reading appears incorrect or fluctuates from what was expected, contact your Axon sales representative or customer service.
- Before activating the "START" button, make sure that the "ENABLE" button on the generator is activated correctly. Activation is indicated by a white LED lighting around the ENABLE button.
- When activating the "START" button, do not touch other buttons on the screen unless necessary.
- Before starting ablation, the peristaltic pump can be activated/stopped by pressing the "On/Off" button. During ablation, the peristaltic pump is automatically activated by showing the "Sync" button.

1. Make sure the probe(s) is reading a body temperature of approximately 37°C. If the temperature reading appears incorrect or fluctuating, DO NOT begin ablation. Contact your Axon sales representative or customer service.

2. Tap the "START" button or press the connected foot pedal for a few seconds to start ablation. If the foot pedal configuration is set with Touch + Pedal mode, both the foot pedal and the touch screen can initiate ablation (Figure 28 and 29). An intermittent sound is activated throughout the ablation procedure (including cooling of the needle probe after the RF emission has stopped).

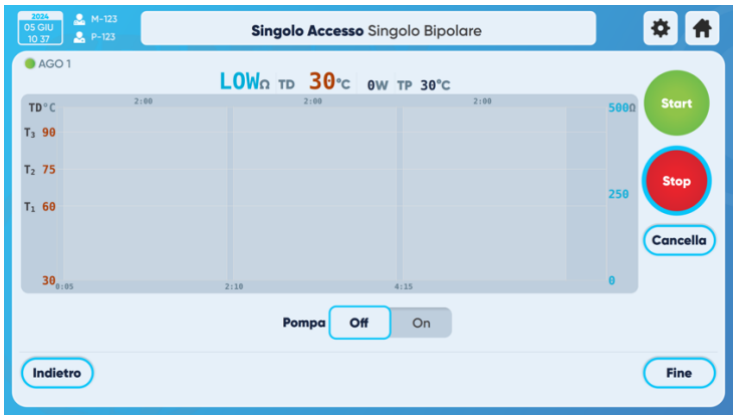


Figure 28 - Ablation screen for the single sign-on procedure

Figure 29 - Ablation screen for the double access procedure

Note

- During RF energy transfer and ablation creation, the active probe number is placed near the green dot. An audible indicator (slow, low-pitched beep) will also occur indicating active energy. The generator emits only one (1) sound regardless of the number of probes connected and the probes in use.
- The red line in the graph corresponds to the distal temperature (°C), the blue line in the graph corresponds to the impedance (Ω) with respect to the ablation time.

- If the foot pedal is plugged in, a green light appears on the button on the left of the screen

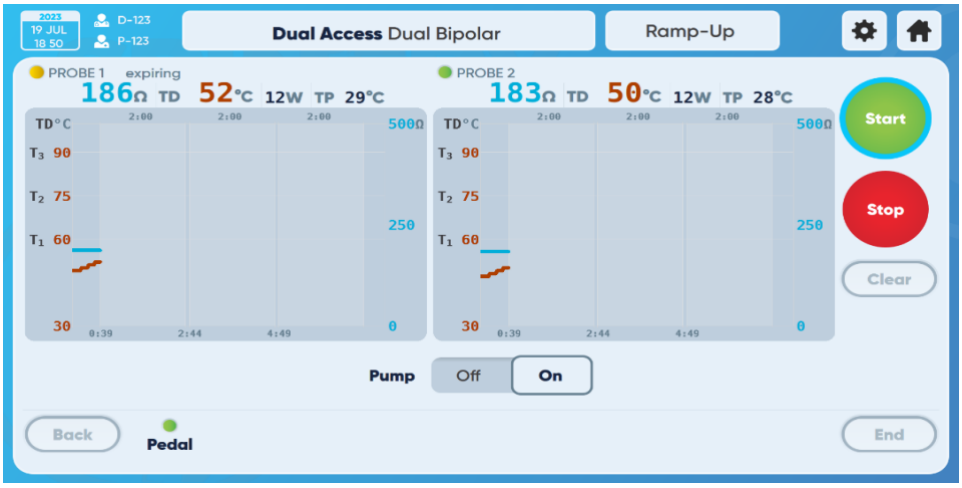


Figure 30 - Ablation procedure start screen

3. To remove RF energy before the ablation time is complete, tap the "STOP" button.

Note: With the STOP button, or by pressing the pedal, you can stop the ablation, while the Clear button resets the timer and allows you to repeat the ablation starting from the preset time on the ablation setting screen.

4. When the ablation creation process is complete, the Completed Procedure screen will be displayed (Figure 31)

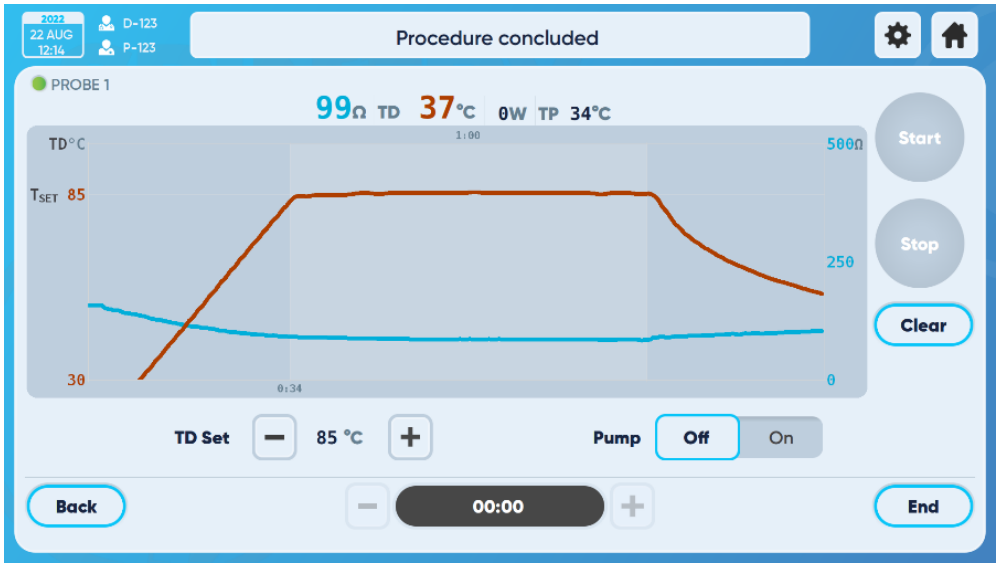


Figure 31 - Completed procedure screen

5. Remove the probe(s) from the seated introducer(s).

Note

- If applicable, hold the introducer(s) in place to apply bone cement. If using the AXON VV+ Spinal Cement System (Ref. T040333K), follow the VV+ Spinal Cement System instructions for use.
- After the injection of the bone cement, proceed with the extraction of the Introducer from the bone, inserting the appropriate Trocar inside the Introducer. Hook the two handpieces making sure that they are locked.

6. Pull the introducer/trocar out of the bone.

Note

- It is important to perform the extraction of the introducer/trocar by applying an axial force.

12.9 Export Ablation Data

After the ablation procedure is complete, you can view the LOG screen as follows (Figure 32).

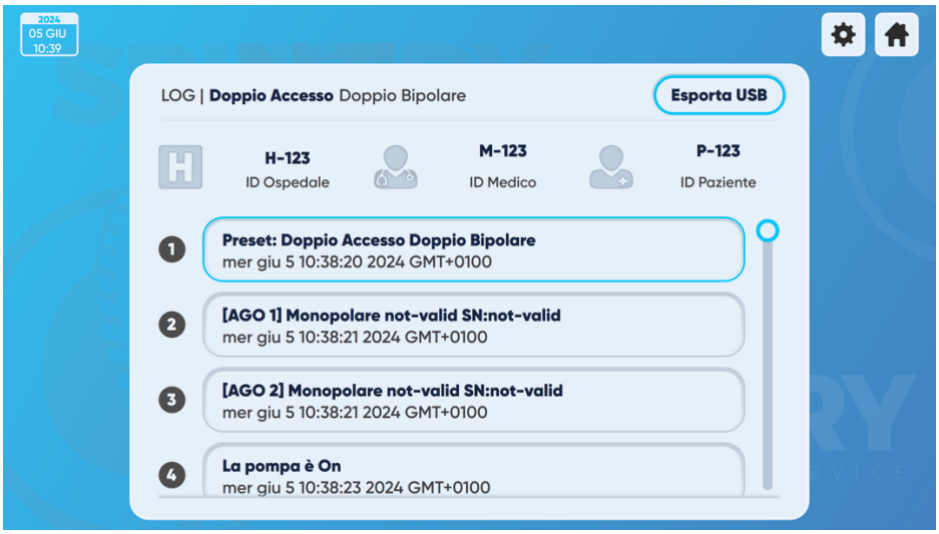


Figure 32 - Export of ablation data screen

1. Plugging in the USB stick for downloading data and then pressing the "USB Export" button will bring up a pop-up window to enter the required export code. Enter the code (ask Axon Customer Support) and press OK to allow the LOG to be saved to the USB stick.

Note

- Insert only compatible USB flash drive to download the data from the last ablation.
- Only use USB points with these characteristics: Formatting: FAT32 and USB Class: Storage Device
- The following devices have been tested with SPINERY: SanDisk Ultra USB 3.0 32GB and SanDisk Ultra USB 3.0 16GB.

13 AFTER USE

13.1 Removing components

WARNING

- Always follow current local regulations and procedures governing biohazardous waste to safely handle and dispose of surgical waste.
- Always follow current local regulations and procedures governing the handling and disposal of sharps.
- Press the power button on the back side of the generator to turn off the generator.
- Disconnect the disposable probes and irrigation connection ports.

13.2 Removing Power

⚠ WARNING

- To remove power, disconnect the power cord from the generator power outlet (Figure 33) and the hospital-grade power outlet with protective ground (ground). Make sure the display is turned off.

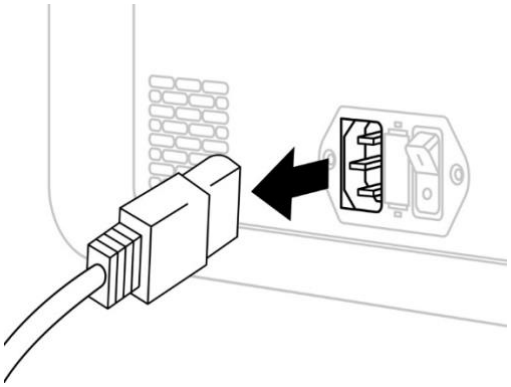


Figure 33 – Disconnecting the RF Generator Power Cord

13.3 Cleaning

Clean and disinfect the generator. See Cleaning and Disinfection Section §14.2

14 ROUTINE MAINTENANCE

14.1 Equipment inspection

⚠ WARNING

- Always inspect the product and all system components for damage upon initial receipt and before each use. Do not use the product if damage is evident.

ⓘ Note

- Routine and careful inspection of the equipment is the best method to determine the service life of the equipment. See the Inspection Policies and Actions table.
- If a component is to be rejected, see §18 "Environmental Specifications for Disposal"

INSPECTION CRITERIA AND ACTIONS:		
Interval	Policy	Action
Before initial use	Inspect system components for damage or missing parts.	If damage is evident, replace the component.
	Make sure the generator is working properly.	See §11 For Proper Generator Use
Before each use and after each cleaning and disinfection.	Inspect system components for damage or missing parts.	If damage is evident, replace the equipment. See section §11
	Inspect components for corrosion, discoloration, pitting, cracked materials, or unacceptable deterioration on any exterior surface, including labels.	
	Inspect the power cord for cuts and the cord plug for bent pins.	
	Inspect the pedal cable.	

INSPECTION CRITERIA AND ACTIONS:		
Interval	Policy	Action
	Inspect the power cord socket for damage.	

Table 22 - Inspection criteria and actions

14.2 Periodic cleaning and disinfection operations

⚠ WARNING

- It is advisable to follow the routine cleaning schedule scrupulously. Activities should not be performed when the device is in use on a patient.
- Always provide personal protective equipment (PPE) for treatment personnel according to the instructions and safety data sheets (SDS) provided with the disinfectant. Always wear PPE when working.
- Upon initial receipt and before each use, always clean and disinfect the generator and power cord.
- The generator and its power cord cannot be sterilized. Do not allow liquids to get inside the generator.
- Do not spray or pour liquids directly onto the generator.
- Non-flammable agents should be used for cleaning and disinfection where possible.
- Flammable agents used for cleaning or disinfection, or as solvents or adhesives, should be allowed to evaporate prior to the application of high-frequency surgery.
- Do not reuse, refurbish or repackage a product intended for single use only.
- A single-use product may not withstand chemical reprocessing, chemical steam, or high-temperature sterilization.

Use a solution of 70% isopropyl alcohol (IPA) and 30% deionized water and a cloth to clean the generator container, display, and power cord. The generator can be disinfected using a standard hospital alcohol solution applied with a cloth.

Note

- Failure to comply with these requirements may void the Manufacturer's liability for any damage or malfunction of the equipment.

15 ERROR MESSAGES AND ALARMS

15.1 Error messages and corrective actions

Note

- If an error message appears, respond as prompted.
- If service is required, the pop-up will remain on the screen until the error is resolved.

The generator handles several anomalies with error messages. Any evidence of alarm is identified by an error code as shown in the table below (Table 23). When an **alarm condition** occurs, the dialog box is surrounded by a red frame, a red window appears in the center of the display describing the alarm, and a beep sounds at the same time.

Figure 34- Alarm Screen

When a **warning condition** occurs, the dialog box is surrounded by a yellow frame, a yellow window appears in the center of the display showing the warning message, and a beep sounds at the same time. Alert states are automatically restored.

Figure 35 - Warning screens

ERROR CODE	MESSAGE	CORRECTIVE ACTION
E01	Self-diagnosis error	An error detected during self-diagnosis implies a problem with the correct functioning of the device. The user interface keys are disabled. The message "Self-diagnosis error" (red banner) appears on the display and a high-priority alarm tone sounds. In this case, turn the machine off and on again, but if the problem persists, contact Axon for assistance.
E02	Probe/needle not connected or faulty	If it does not occur during ablation, the Spinery® RF Generator generates an alarm message (red banner), emitting a high-priority tone and presenting the message "Probe not connected or defective" indicating which probe is not working. During ablation, the treatment is automatically stopped. In this case, it is necessary to reconnect or replace the probe(s) and wait for the system to perform automatic recognition. Pressing on the red alert message directs you to the probe arming screen. If it occurs on the probe insertion screen, the red alert message "Probe not connected or defective" is displayed, and when a recognized probe is connected, the alarm automatically disappears.

ERROR CODE	MESSAGE	CORRECTIVE ACTION
E04	Distal overtemperature	During ablation, if the maximum distal temperature threshold (in the center of the ablation area) (95°C) is exceeded, a red "Distal Overtemperature" alarm message is displayed and a high-priority alarm tone is emitted. The message is preceded by an indication of the probe that has exceeded the maximum temperature. If ablation is in progress, it is stopped. Wait for the temperature to drop below the threshold and press on the error message to continue ablation. If there are no treatments in progress, the alarm message disappears when the temperature has dropped below the threshold.
E05	Proximal overtemperature	During ablation, if the maximum proximal temperature threshold (at the limit of the ablation area) (50°C) is exceeded, a red "Proximal Overtemperature" alarm message is displayed and a high-priority alarm tone is sounded. The message is preceded by an indication of the probe that has exceeded the maximum temperature. If ablation is in progress, it is stopped. Wait for the temperature to drop below the threshold and press on the error message to continue ablation. If there are no treatments in progress, the alarm message disappears when the temperature has dropped below the threshold.
E06	Impedance beyond the maximum limit	During ablation, the generator calculates the base impedance value. If the measured increment exceeds the baseline value of 200 Ω, a red "Impedance Beyond Maximum Limit" warning message appears on the display, a high-priority audio tone is generated, and ablation is stopped. The message is preceded by the indication of the probe that generated the alarm. To continue with the procedure, wait for the measured impedance values to return to the allowed values, and then click the error message to clear it.
E07	Internal communication error	If there is no internal electronic communication within the generator, a red "Internal Communication Error" alarm message is displayed and a high-priority beep is generated. When communication is restored (for example, after transient internal communication failures), the ablation parameters can be initialized. If the message does not disappear automatically, click the error message. If it occurs during ablation, treatment is immediately stopped. You can start a new ablation only after internal communication has been restored and after clicking on the alarm message. In either situation, if the alarm does not stop, you should contact Axon for assistance.
E08	Disabled outputs	If you press the ENABLE button during ablation, ablation is stopped, the "Outputs disabled" alarm is displayed, and a high-priority tone is generated. To continue with the ablation, click the ENABLE button again and then click the error message to delete it. If you press the ENABLE button when operating on the ablation screen, but ablation does not start, the "Outputs disabled" alarm is displayed and a high-priority tone is generated.

ERROR CODE	MESSAGE	CORRECTIVE ACTION
		To clear the error, click the ENABLE button again, if you press the ENABLE button during operation on all other screens, the "Outputs disabled" alarm is displayed with a yellow frame and automatically disappears when you press the ENABLE button again.
E09	Radio frequency generator anomaly	If the "Radio Frequency Generator Abnormality" alarm is displayed during ablation, the ablation is immediately stopped and a high-priority beep is generated. If the fault is resolved, click on the error message to restart the ablation, otherwise call the Axon service for assistance. If the "Radio Frequency Generator Anomaly" alarm does not occur at the same time as ablation, a medium-priority tone is generated. If the fault is resolved, click on the error message to continue, otherwise call Axon Support for assistance.
E10	Cooling ventilation system	If the "Cooling System" alarm message is displayed during ablation, ablation is immediately stopped and a high-priority tone is generated. If the problem is resolved, restart the ablation by clicking on the error message. If the error does not go away, contact Axon Support for assistance. If ablation is not in progress, a high-priority tone is generated and the alarm message appears on the display; The message and tone will automatically disappear if the cooling ventilation problem is resolved.
E11	Pump failure	If a peristaltic pump malfunction occurs when the pump is in motion but not during ablation, a red "Pump Failure" alert message is displayed and a medium priority tone is generated. If the alarm is displayed during ablation, a red "Pump Failure" alarm message is displayed and a high-priority tone is generated, and ablation is immediately stopped. Check the correct pump configuration and click on the error message to resolve the alarm. If the error message persists, contact Axon Support for assistance.
E12	Close the cover of the peristaltic pump	If the peristaltic pump cover is open but not during ablation, a red "Close the peristaltic pump cover" alarm message is displayed and a medium priority tone is generated. If the alarm occurs during ablation, a red alarm message "Close the cover of the peristaltic pump" is displayed and a high-priority beep is generated, and the ablation is immediately stopped. Check that the pump cover is properly closed and click on the error message to resolve the alarm. If the error message persists, contact Axon Support for assistance.
E13	Pedal disconnected	If the foot pedal selected on the ablation preparation screen is not working properly, the foot pedal indicator LED will turn red on the ablation screen. Check the pedal cable and connector and plug it back in (you can always use the touch panel to continue). If the pedal cable is securely connected, but the problem persists, contact Axon Support for assistance.
E14	Incorrect probe connected	If incorrect probes are connected to the Generator (probes that do not match the selected model or probes that are not authorized by the manufacturer) a red warning message "Incorrect probe connected" is displayed in the event that an Axon probe is not connected or the probe does not match the selected treatment (highlighted in red). Check the probe(s) or replace to continue.

ERROR CODE	MESSAGE	CORRECTIVE ACTION
E15	Expired probe connected	If already used probes are connected to the Generator (probes whose first start-up was carried out for a time longer than the timing threshold or if their shelf-life has expired), a red warning message "Expired probe connected" is displayed in case an Axon probe is not connected or the probe does not correspond to the selected treatment (highlighted in red). Check the probe(s) or replace to continue.
E16	After 110 minutes from the start of the first treatment	A warning message on the status bar, emphasized by the yellow LED and an "*expiring*" text next to the probe number that is about to expire, is displayed 110 minutes after the start of the first treatment with the same probe. Only an additional 10 minutes are allowed for operation with that probe.
E17	After 120 minutes from the start of the first treatment	After 120 minutes from the start of the first treatment with the same probe, *an error message appears on the status bar, emphasized by the red LED and an "*expired" text next to the expired probe number. If ablation is in progress, it will be completed and the probe will no longer be reusable. When the probe expires, or when the ablation in progress with the expired probe is complete, the error message "Timeout: 120 minutes from the first treatment" is displayed. A new ablation can only be performed after replacing the probe and clicking on the error message; The display will now show the probe selection screen.
E18	USB stick not usable	In the event that an incompatible USB stick is inserted into the USB port of the generator, the copy of the ablation data is not authorized, the virtual "USB export" button is obscured and cannot be used. Remove the USB and insert a compatible one to continue exporting the ablation data.
E19	Export failed	If there is an error while exporting USB ablation data, the "Export USB" button on the display is replaced by the message "Export failed". Remove the USB and insert a new one to continue exporting the ablation data.
E20	Radiofrequency parameter anomaly	If, during ablation, a current or voltage value is detected outside the permissible operating ranges, the red alarm message "Radio Frequency Parameter Abnormality" is displayed, a high-priority alarm tone sounds, and the ablation is immediately stopped. To initiate a new ablation, the abnormal current and/or voltage value must return to normal operating values.
E21	Impedance outside the permissible threshold	If, during ablation, an impedance value is detected outside the permissible operating range, a red error message "Impedance out of threshold allowed" is displayed, a high priority audio tone is heard. When the measured impedance value is within the permissible operating range, the alarm state disappears. You can now continue or start with ablation. Alarm status E21 takes precedence over alarm status E06.

Table 23 - Error Messages and Corrective Actions

15.2 Beeps

Error messages are always accompanied by audible signals generated during alarms, warnings, and in normal generator operation.

⚠ WARNING

- The beep and activation light are important safety features.
- Do not obstruct the activation light.
- Do not disable the activation tone file.

TYPE OF REPORT	BUZZER	VOLUME
Beep	Single BEEP	Low
Ablation Tone	BEEP every 2.5 s	Medium
Procedure completion tone	Continuous beep duration 2 s	Medium
Medium Priority Tone	BEEP every 1 s	Medium
High Priority Tone	Continuous BEEP	High

Table 24 - Generator beeps

16 INCIDENT ALERT

The user and/or patient must report any serious incident that has occurred in relation to the device to both the manufacturer and the competent authority of the European Member State in which the user and/or patient is established.

17 CORRECTIVE MAINTENANCE, CUSTOMER SERVICE AND TECHNICAL SUPPORT

In case of abnormal behavior or malfunction, turn off the device and stop treatment immediately; then contact Axon srl's customer service and technical assistance to report the problem.

⚠ WARNING

- Only authorized personnel may carry out maintenance and/or repair operations.
- No constructive modifications to the device are permitted.
- Do not disassemble, modify, or repair any component of this system without the manufacturer's authorization. Contact Axon for assistance.
- Use only Axon-approved components and accessories to ensure a safe and effective combination. Failure to comply may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.
- Failure to comply with these requirements may void the Manufacturer's liability for any damage or malfunction of the equipment.
- Annual general checks: operation of the buttons and ignition controls, lights on the control panel, status of the cables and handpiece to be carried out annually by the user himself.

For any need for assistance, technical support and/or replacement of defective parts, please contact:

Customer service and technical assistance Axon S.r.l.


AXON Srl, Via Lepanto I Traversa 18, 80045 Pompei (NA) - Italy


Tel. +39 081 229 0044


info@axonmedicalsystems.com


https://www.axon.productions

Note

- Contact the Axon service center to obtain a repair purchase order BEFORE submitting a product return directly to the center.
- To expedite processing, ALWAYS include the following information with your product return:
    - Contact name
    - Contact address
    - Contact phone number
    - Repair purchase order number
    - Part Number(s)
    - Serial number(s)
    - Detailed reason for return
    - Precise information on the problem encountered
- Always recondition (clean, disinfect, sterilize if necessary) all potentially contaminated equipment BEFORE returning it to AXON. AXON will not accept or treat any potentially contaminated equipment.

17.1 Limitations of the warranty

WARNING

- Removing the screws and opening the generator will void the warranty.

Axon warrants to the original purchaser of the RF Surgical Generator that it will be free from defects in materials and workmanship for a period of one year from the date of purchase, when used in the manner intended under normal operating conditions and in accordance with the operating and maintenance instructions.

This warranty is in lieu of all other warranties, express, implied, or statutory, including, but not limited to, the implied warranties of merchantability and fitness for a particular purpose and any other obligations and liabilities on the part of Axon.

Axon neither assumes nor authorizes any other person to assume any other liability on its behalf in connection with the sale of the generator. This warranty is invalid if the device or parts of it have been subjected to accident, neglect, alteration, incorrect or improper use.

17.2 Periodic checks on the generator

- Pre-use checks: Before each use, the user must visually check the correct functioning of the interface, connections and mechanical parts.

- Annual General Checks: Operation of power and control buttons, control panel lights, status of cables and connections to be performed annually by the user
- **Electrical safety verification according to IEC 62353:** Safety checks must be performed at the intervals required by the local regulations in force. In the absence of specific instructions, the **manufacturer suggests a check at least every 2 years after the first use**. A safety test is carried out by AXON after each repair/upgrade work on the electrical parts to which the mains voltage is applied;
- Spinery® Kit and Spinery® Cooling Connection are disposable accessories that do not require maintenance and periodic checks.

17.3 Software update

Software updates can only be carried out by authorised personnel of the Manufacturer, after authentication on the machine's Maintenance Panel.

18 SPECIFICATIONS FOR ENVIRONMENTAL DISPOSAL

⚠ WARNING

- Always follow current local recommendations and/or regulations governing environmental protection and risks associated with recycling or disposing of the product at the end of its useful life.

SPINERY® RF Generator is subject to national and European legislation regulating the disposal of waste such as electrical/electronic equipment.

The graphic symbol (crossed-out box) shown in the figure, applied to the outside of the appliance, indicates the obligation to collect and dispose of electrical and electronic equipment separately at the end of its useful life.

INFORMATION FOR DISPOSAL AT THE END OF ITS LIFE pursuant to Legislative Decree no. 27 of 04/03/2014 "Implementation of the Directives Implementation of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment" and pursuant to Legislative Decree no. 49 of 14/03/, no. 49 "Implementation of Directive 2012/19/EU on waste electrical and electronic equipment"

The device you have purchased requires the use of special materials and substances for its production. It may also contain hazardous substances with potential harmful effects on the environment and human health, if improperly released into the environment. In order to prevent the release of hazardous substances into the environment and to promote the conservation of natural resources, the manufacturer, in the event that the user wishes to dispose of the used appliance at the end of its useful life, facilitates the possibility of its reuse and the recovery and recycling of the materials contained therein. The public administration shall take appropriate measures to ensure that users, distributors and manufacturers contribute to the collection of electrical and electronic equipment and shall oblige its reuse, recovery or recycling. If the device is to be disposed of, it must be considered that there are precise provisions of European and national laws in force, which prescribe to: not dispose of it as municipal waste, but carry out a separate collection, contacting a company specialized in the disposal of electrical/electronic equipment or the local administrations responsible for waste; if a new device is purchased from the same manufacturer to replace used equipment placed on the market before 13 August 2005 of an equivalent type and used for the same functions as the new equipment, the distributor or the manufacturer himself is required to take back the old equipment; if the user intends to dispose of a used device placed on the market after August 13, 2005, the distributor or manufacturer is required to take it back.

The manufacturer will transport, treat, recover and/or dispose of the used appliance collected and will bear the related costs; take into account the potentially harmful effects on the environment and human health due to the possible presence of hazardous substances or the improper use of electrical and electronic equipment or parts thereof. The device covered by this user manual consists of metal and plastic mechanical parts, electrical components and electronic boards. The manufacturer is available to users to provide all the information on the hazardous substances contained in the appliance and on how to recover and recycle it or on the possibilities of reusing the used appliance.

The SPINERY® RF generator is subject to national and European legislation regulating the disposal of waste such as electrical/electronic equipment.

19 SPECIFICATIONS

IMPEDANCE MEASUREMENTS (Low Power Mode)	
Range	40 ÷ 500 Ω with 1 Ω resolution
Frequency	480 kHz ± 1%,[2]
Power	< 10 mW (average over a one-second period)
Accuracy	< ± 20% in the 40 ÷ 500 Ω range
CHARACTERISTICS OF RADIO FREQUENCY	
Frequency	480 kHz ± 1%
Maximum power	40 W with 100 Ω rated resistive load.[3]
Maximum RF voltage	90 Vrms (software limit) 100 Vrms (hardware limit)
Maximum RF Current	650mArms (software limit) 1000 mArms (hardware limit)
Accuracy (power measurement)	The greater of ± 20% or ± resolution of 1W, 1W
Accuracy (impedance measurement)	< ± 20% in the range of 40 ÷ 500 Ω, 1 Ω resolution
TEMPERATURE	
Target Ablation Temperature	37 ÷ 90 °C
Measured temperature	20 ÷ 110 °C
Accuracy	± resolution 3°C, 1°C
HOURS[4]	
Setting	0:00 to each selected preset duration
Resolution	1 second
Accuracy	± 1%
WORKING CONDITIONS	
Temperature[5]	20°C to 35°C

[2] Near-sine waveform with harmonic content <15dBc

[3] Outside of this value, the output power is automatically reduced according to the imposed limits of the maximum voltage and current

[4] The selectable time is the part related to maintaining the temperature, excludes the docking and cooling time

[5] To operate within safety and performance specifications, an acclimatization period of 25°C ± 3°C is required for at least two hours after being moved from the warehouse or warehouse.

Relative humidity	30 to 70%, non-condensing
Maximum height	Up to 3000m
STORAGE AND TRANSPORT CONDITIONS	
Generator	
Temperature	-20°C to +60°C
Relative humidity	20 to 90%, non-condensing
Pressure	600 to 1060 hPa
Probes, connections, Components bone access	
The probes, connections, and the Bone Access Components should be stored at room temperature, away from heat and moisture.	
POWER SUPPLY	
Mains voltage	100 ÷ 240Vac, 50/60Hz
Fuse	2 x 1.6 A/250 V, type T, 5 x 20 mm
MECHANICAL SPECIFICATIONS	
Generator size	320 x 340 x 340 mm (W x H x D)
Saline solution rod	500 mm (length)
Weight	10 kg
CLASSIFICATION	
IEC protection class	CLASS I
Applied parts	BF
IP Grade	IP20 rating

Table 25 - Generator Technical Specifications

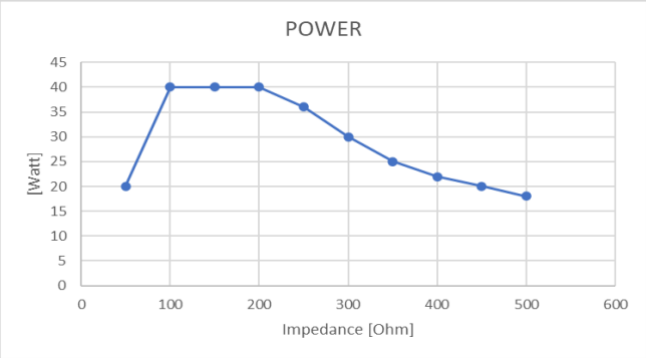


Figure 36 – Output Power Graph: Power vs. Load Impedance

20 ELECTROMAGNETIC COMPATIBILITY

PROOF	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT - GUIDE
Electrostatic IEC 61000-4-2	±8 kV contact in download ±2 kV, ±4 kV, ±8 kV, ±15 kV air discharge	The floors must be made of wood, concrete or ceramic tiles. If the floor is made of non-conductive plastic, the relative humidity of the air must be at least 30 %

PROOF	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT - GUIDE
Rapid and transient perturbations/bursts per IEC 61000-4-4	± 2 kV for grid lines	The quality of the supply voltage must be that of a typical hospital or commercial environment
Voltage spikes according to IEC 61000-4-5	Common Mode: ± 0.5 kV; ± 1 kV ± 2 kV Differential Mode: ± 0.5 kV; ± 1 kV	The quality of the supply voltage must be that of a typical hospital or commercial environment
Voltage drops, short interruptions, and fluctuations in supply voltage based on IEC 61000-4-11	Vn=240 VAC 0% Vn - 10ms 0% Vn - 20ms 70% Vn - 500ms 0% Vn - 5000ms Vn=100 VAC 0% Vn - 10ms 0% Vn - 20ms 70% Vn - 500ms 0% Vn - 5000ms	The quality of the supply voltage must be that of a typical hospital or commercial environment. If the user needs continuous operation even during the mains voltage interruption, it is recommended to supply the appliance with an uninterruptible power supply
Heart failure disorders conducted according to IEC 61000-4-6	3 V/m AM 80% 80 MHz – 2.7 GHz 27 V/m PM 50% 380 MHz – 390 MHz 28 V/m PM 50% 430 MHz – 2.57 GHz 9 V/m PM 50% 704 MHz – 5.8 GHz	The field strength of fixed radio transmitters, conducted as part of an on-site survey, should be below the compliance level for all frequencies[(b)]. In environments where devices bearing the following symbol are installed, noise may occur. 
High-frequency electromagnetic fields radiated according to IEC 61000-4-3 Certification	AC Power: 3 V 150 kHz to 80 MHz 6 V from 6.765 MHz to 40.70 MHz RF Probe Output 1: 3 V 150 kHz to 80 MHz 6 V from 6.765 MHz to 40.70 MHz RF Probe Output 2: 3 V 150 kHz to 80 MHz 6 V from 6.765 MHz to 40.70 MHz Reference plate cable: 3 V 150 kHz to 80 MHz 6 V from 6.765 MHz to 40.70 MHz	
Magnetic field at the power supply frequency (50/60Hz) based on IEC 61000-4-8	30 A/m	The magnetic fields at the mains frequency must correspond to the characteristic values found in a hospital or commercial environment.
a) The ISM bands between 150 kHz and 80 MHz range from 6.765 MHz to 6.795 MHz, from 13.553 MHz to 13.567 MHz, from 26.957 MHz to 27.283 MHz and from 40.66 MHz to 40.7 MHz.		

PROOF	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT - GUIDE
(b) The field strength of fixed transmitters, such as base stations for terrestrial telephones and mobile radio services, amateur stations, AM-FM and television broadcasters, cannot theoretically be precisely predefined. To determine the electromagnetic environment caused by fixed transmitters, an on-site electromagnetic survey must be considered. If the electromagnetic field strength measured at the location where the appliance is used exceeds the above level of compliance, it is advisable to Keep the device under observation to verify its correct operation. If there is abnormal performance, you may need to take additional measures, such as changing the orientation or changing the position of the device		

Table 26 – Guidance and manufacturer's declaration – electromagnetic emissions

20.1.1 Guidance and manufacturer's declaration – electromagnetic emissions

The SPINERY RF generator is intended for use in the electromagnetic environment specified below. The customer or user of the SPINERY RF generator must ensure that it is used in such an environment.

The SPINERY® RF Generator device is designed to operate in the electromagnetic environment specified below. The customer or user of the SPINERY® RF Generator appliance must ensure that it is used in that environment.		
EMISSION TEST	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT
RF Emissions CISPR 11	Group 1	The SPINERY® appliance uses high-frequency energy exclusively for its internal operation.
RF Emissions CISPR 11	Class A	The SPINERY® device can be used in any environment except in the home. This device/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or disrupt the operation of nearby equipment. You may need to take steps, such as changing the orientation or position of the SPINERY® device, or shielding the installation site.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation/flicker emissions IEC 61000-3-3	Compliant	

Table 27 – Guidance and Manufacturer's Declaration – Electromagnetic Immunity

21 ACRONYMS

ACRONYM	DEFINITION
RF	Radio frequency
DPI	Personal Protective Equipment
SDS	System Board
RM	Magnetic Resonance Imaging

Table 28 – Glossary Acronyms

22 IFU IN OTHER LANGUAGES

The Instructions for Use (IFU) for the Spinery® RF Generator and its single use accessories are available in multiple languages.

For the most up-to-date versions and for IFUs in languages other than English, please visit the manufacturer's official website or scan the QR code provided below.

Accessing the online version ensures consultation of the latest approved revision of the Instructions for Use.

Manufacturer website:

https://www.axon.productions

QR code: