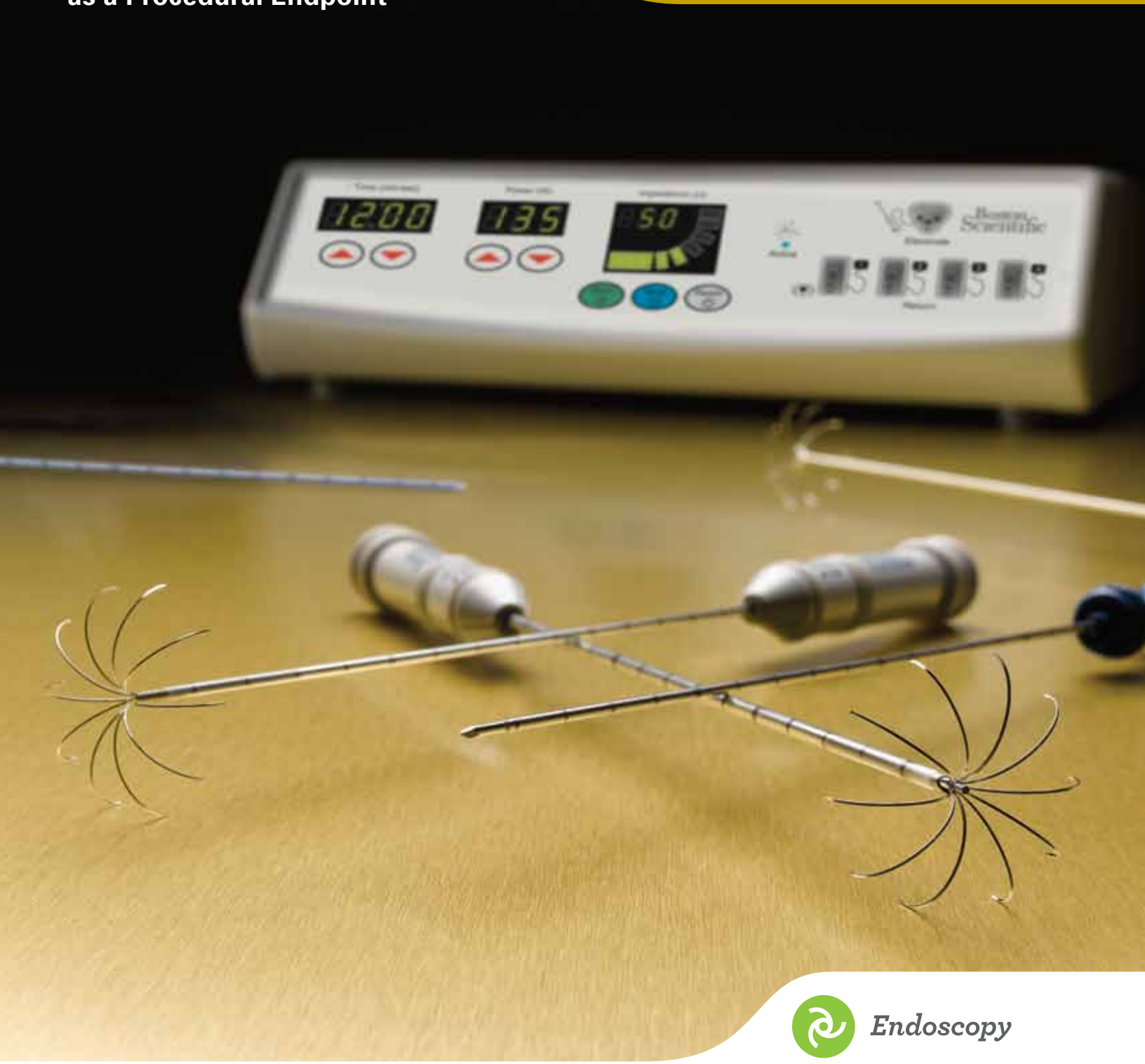
RF 3000®

Radiofrequency Ablation System

Boston Scientific

Use of Impedance as a Procedural Endpoint



Endoscopy

USE OF IMPEDANCE AS A PROCEDURAL ENDPOINT

RADIOFREQUENCY TISSUE ABLATION

Radiofrequency ablation (RFA) is caused by a high frequency alternating current (usually between 400,000 and 1,250,000 Hz) flowing from an uninsulated tip of an electrode into the surrounding targeted tissue. Ionic agitation occurs in the tissue as a result of the ions attempting to follow the directional changes of this alternating current; the ionic agitation results in frictional heating **(Figure 1)**.[1] This frictional heating phenomenon differentiates Radiofrequency ablation from other tissue ablation; with Radiofrequency heating, the tissue surrounding the electrode, rather than the electrode itself, becomes heated.

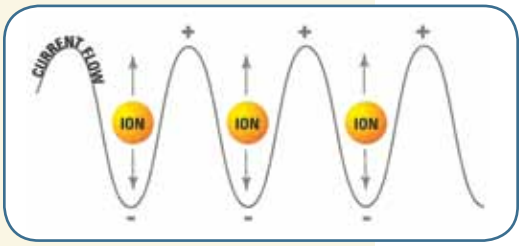


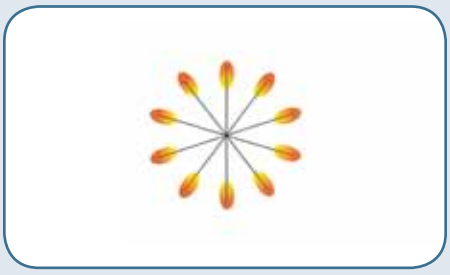
Figure 1
Ionic agitation from alternating current causes tissue coagulation through frictional heating. Tissue desiccation increases impedance which eventually decreases current flow.[4]

IMPEDANCE RISE IN ABLATED TISSUE

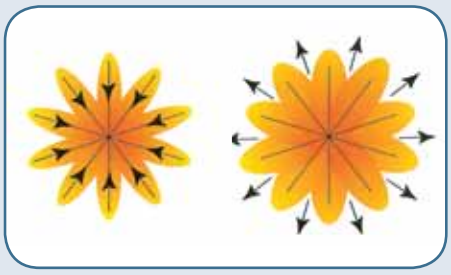
Application of electrical current can result in heating of soft tissue to above 50°C. This causes numerous changes at the cellular level, including protein denaturation and loss of intracellular fluids (desiccation). Both changes, denaturing of proteins and cellular desiccation, make the tissue more resistant to the passage of electrical current.[2] This resistance to electrical current is termed impedance which is measured in ohms. The ability to closely monitor changes in tissue impedance during the application of RF energy may be used to measure the completion of tissue ablation.

When the LeVeen® Needle electrode is used with the RF 3000® Radiofrequency Generator, a significant increase in impedance occurs when all the tissue surrounding the wire array becomes sufficiently desiccated and blocks the flow of current from the Needle array to the return electrode on the patient. The blocking of the current flow is indicated by a rise in impedance which is generally sufficient to signal completion of the thermal lesion.

Figure 2
LeVeen® Needle Electrode Thermal Lesion Creation



(A) The thermal lesion developed by the LeVeen Needle electrode begins at the tips of the array tines. The multiplicity of tines in the electrode allow the RF energy to shift away from any given tine as the adjacent tissue desiccates and increases in impedance.[5]



(B) As the tissue near the tips of the tines desiccates, the zone of ablation travels back along the tines toward the center of the array. The thermal lesion then moves outward and begins to fill in the gaps between the tines.

(C) A complete thermal lesion is achieved once tissue desiccation has occurred throughout the target tissue. The RF 3000 Radiofrequency Generator is designed to receive feedback from the target tissue to reduce power and signal a complete thermal lesion.

Only tissue within a certain distance from the Needle electrode is heated above a cytotoxic temperature.[3] The flow of RF current from the electrode creates a relatively uniform zone of heated tissue at the electrode/tissue interface. The temperature of the tissue eventually rises to cytotoxic levels. RF energy and conducted heat continue to spread throughout the tissue. If the tissue impedance is low, there is little resistance to the flow of electrical current and an expanding sphere of ablated tissue is created. Therefore, the Needle array first creates areas of necrosis close to the individual tines. Then, as the impedance of the tissue around those times increases (as the tissue desiccates), the RF energy shifts to the unablated tissue, which has lower impedance **(Figure 2)**.

MEASURING IMPEDANCE

An integral component of tissue ablation using the LeVeen® Needle electrode is the impedance-driven RF 3000® Radiofrequency Generator, which powers the electrode. This Generator is a 200W Radiofrequency power supply that has been designed to operate in a "constant voltage" mode. The output voltage of the Generator is constant once the power level has been set.

When using the LeVeen Needle electrode and the RF 3000 Radiofrequency Generator to ablate tissue, the principles of Ohm's Law dictate the course of the ablation. When an application of RF energy begins, the RF 3000 Radiofrequency Generator measures the initial impedance level of the target tissue. This is represented by three bars (typically 40 to 80 ohms) being illuminated on the RF 3000 Radiofrequency Generator bar graph located on the front panel **(Figure 3A)**. Then, instead of heating the tissue for a fixed amount of time and assuming that changes have taken place, impedance feedback to the Generator during application of RF energy is used to determine the extent of tissue desiccation.

As the areas around parts of the electrode heat and become ablated, local impedance rises causing current to flow to tissue with lower impedance. The impedance level changes only slightly because the Generator is still delivering constant voltage through the Needle electrode. As cellular destruction occurs in the targeted tissue, the impedance rises until all of the target tissue is desiccated by the RF energy. Tissue desiccation results in a rise of impedance because the desiccated target tissue has a high resistance to current flow to the return electrode (dispersive pad). The tissue impedance rises exponentially with the conclusion of the RF ablation. The RF 3000 Radiofrequency Generator is designed to measure this rise and illuminates the entire bar graph **(Figure 3B)**. Since the Generator is a constant voltage system, as the impedance in the tissue rises, the current delivered to the Needle electrode decreases. The power delivered by the Generator will fall below 10W, generally signaling the completion of the thermal lesion.

Figure 3

The RF 3000 Generator uses a direct measurement of impedance feedback from the target tissue to monitor the course of tissue ablation.

(A) Initial tissue impedance is measured prior to application of RF energy and is typically within the range of 40 to 80 ohms, illuminating three bars on the front panel of the RF 3000 Generator.

(B) Impedance rise is indicated by an increase in ohms and a sequential illumination of the bars on the front panel, signaling cellular destruction and the completion of a thermal lesion.

BIBLIOGRAPHY

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LeVeen® Electrode - Indications: The LeVeen Electrode is intended to be used in conjunction with a Boston Scientific Radiofrequency (RF) Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions. **Cautions:** The effectiveness of this device for the use in the treatment of liver cancer or liver disease (i.e., improved clinical outcomes) has not been established. The LeVeen Electrode is intended only for use with Boston Scientific RF Generators (peak voltage up to 200V max.) The power applied by the RF Generator should be kept to the minimum necessary to achieve the desired clinical effect. Larger arrays may require higher power.

RF 3000® Radiofrequency Generator - Cautions: The RF 3000 Generator is not MR compatible and should be kept outside the shielded MR scan room. The RF Generator emits signals that may interfere with MR imaging. Therefore, the Generator should be "OFF" when the MR scanner is acquiring image data. Ensure the Voltage Selector and the fuse block on the rear panel are set to the appropriate voltage before turning main power switch on. Boston Scientific strongly recommends the use of Valleylab® Polyhesive® Disposable Patient Return Electrodes (Pads) with Cord. Use four pads and connect the return pad plugs to the RF 3000 Generator return receptacles, placing tow pads on each leg. Be sure not to orient the pads improperly or to misalign the top edge of the pads.

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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