

White Paper: Technical Overview and Pre-Clinical Data

gi4000 electrosurgery generator

March 2014

US Endoscopy acquired Genii, Inc. on April 7th, 2017

Product Overview

The **gi4000 electrosurgery generator (ESU)** has been designed for use exclusively in flexible endoscopy and priced to make true **standardization** possible-- a key component of all Six Sigma and Lean strategies to efficiency. Genii recognized a need for endoscopy centers to be able to end throughput disruptions while patients and physicians are kept waiting mid procedure for specially equipped generators to be moved from room to room. The **gi4000** can 'do it all' to become the only ESU and lavage pump needed for flexible endoscopy, and it easily fits onto booms, room shelves, scope, travel or bleed carts. No separate cart is needed to carry large argon tanks and external pressure regulators because the patented miniature gas canister and regulation elements are all contained within the generator unit itself. The **gi4000** makes argon treatment more readily available and improves standardization of care available to all patients.



The unit supports all usual therapies common to flexible endoscopy including: lavage washing, polypectomy, bipolar hemostasis, sphincterotomy (with two pulse cut modes), EMR (endoscopic mucosal resection), ESD (endoscopic submucosal dissection), POEM procedures, argon coagulation, and monopolar contact coagulation using a full range of electrosurgery accessories from all main US suppliers.

The unit was extensively studied prior to FDA clearance and has been successfully used in thousands of patient procedures since it was FDA cleared in 2012. It is owned by many dozens of endoscopy centers located in the U.S. including many prestigious teaching and opinion leading centers.

Certifications

The **gi4000** received US FDA clearance March 22, 2012 (K113265). It bears the ETL Mark (Intertek authorization to mark control number 4003941) and is manufactured in the United States. It is designed and tested to the highest standards including ISO 14971 2007 and 10993-1 2009; IEC 60601-1:1995, IEC60601-2: 2007, and IEC 60601-2-2: 2009. The **gi4000** is protected by US patent numbers 8,083,735 B2 and 13/296,811. Other applicable patents have been filed. It is believed to be the first ESU FDA cleared to the highest “major” level of safety concern for software validation and verification.

Standardization Benefits

There is an urgent medical need for an easier to use, argon capable electrosurgery unit compact and inexpensive enough to be placed in every treatment room of a therapeutic endoscopy center and on any and all travel carts. This allows the flexible endoscopy specialty to comply with demands for standardization (having all of the ESUs in a center exactly the same) which saves time by ending throughput disruption, training and retraining of staff, and time lost moving equipment from place to place. Biomedical engineering prefers to learn and maintain fewer ESUs.¹ Physicians prefer continuity in procedure and tissue effect expectations. Best physician competence is promoted when hospital and free standing endoscopy centers are standardized with the same generators. Standardization clearly promotes better patient outcomes and reduces user errors.² Currently available, bulky, argon capable units do not meet this need. Simply having the same brand of ESU in all rooms may not be true standardization. True standardization is having every standard therapy available in in each treatment area in the same ESU. Many companies make several models of ESUs, many of which have significantly different output characteristics.³

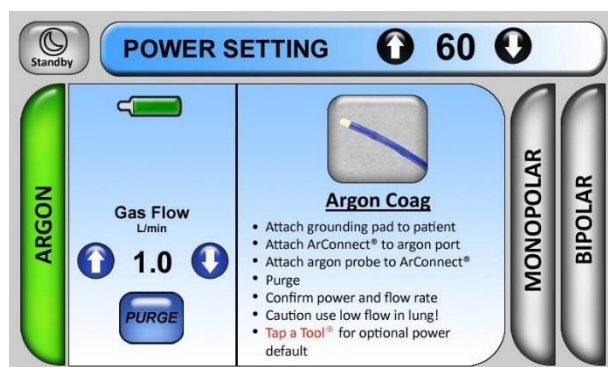
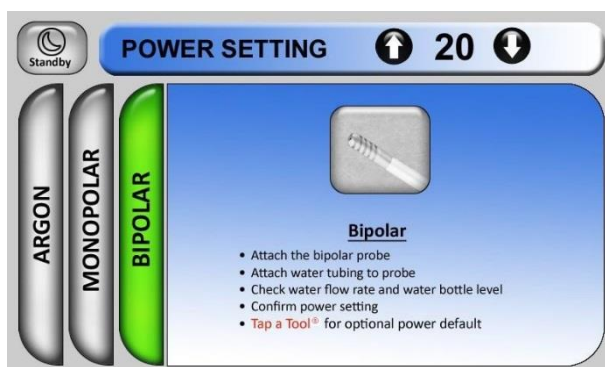
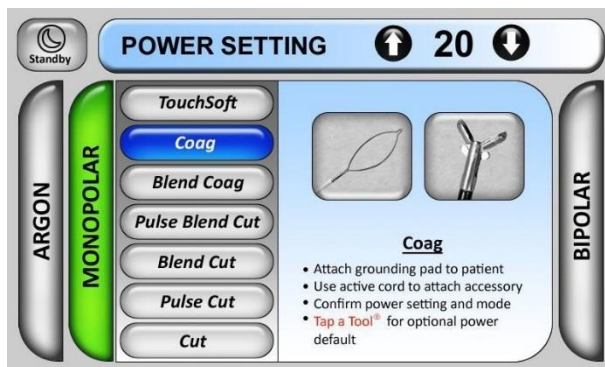
Pricing for the **gi4000** complete unit (which includes argon capability and a lavage pump) has removed the cost barrier to having all therapies easily available wherever endoscopic treatment is done; free standing Endo center, ASC or hospital based department.

Unique User Interface

Current ESUs are confusing to operate and require unacceptable levels of training and maintenance. Nearly all ESUs currently in endoscopy centers were designed primarily for the operating room and have open surgical (OR) types of connectors and features that add confusion which can increase operator errors.

The user interface touch screen, and the “Irrigation or Power” footswitch of the **gi4000** are so innovative that the impact is often compared to the advent of the iPhone. In controlled testing, GI nurses and technicians were able to more correctly set up the unit after only five minutes of *group* training than they were after 45 minutes of *individual* training on an ERBE VIO®.⁴ Many users are quickly able to train someone else. Constant training and retraining on the use of equipment adds cost to endoscopic practices. The foot pedal on the **gi4000** has one pedal for operating the incorporated lavage pump, labeled ‘irrigation’ and a second pedal for ‘power’ to eliminate confusion over “which color of pedal do I use?” It also eliminates multiple pedals, and allows for a much higher quality pedal for irrigation. The gi4000 pedal is also totally submersible—a benefit to infection control concerns.

Notice the unique touch screen interface. The operator simply touches the method button (monopolar, bipolar or argon) and the screen reveals all information needed to perform a procedure with that method, including a picture of the most common accessory. The unit self-sets to the most common watt setting for that procedure, but gives obvious arrows for physician directed changes. A quick help menu lists tips such as “attach grounding pad,” etc. There is even a storage tray under the unit for the supplied quick start Procedure Guide or individual center’s notes which eliminates clutter.



Technology Advances

The **gi4000** will fit into any 20" X 20" X 7" space. The unit is fully self-contained *including the patented Genii miniaturized argon gas canister, regulators and delivery system*. The proprietary, compact, disposable argon gas canister slides into the unit just behind the water lavage bottle and holds 49 liters of highly compressed, 99.999% pure argon for several months of average use. (Typical procedures consume about .5 to 1 liter). The canister has an easy grip cap that makes changing the canister quick and easy. The price per procedure for argon gas is virtually identical to current large tanks.



The **gi4000** has the highest level of advanced instant tissue response technology. It is the first argon capable unit ever built from design to production with video endoscopic compatibility in mind to minimize video interference and minimize any potential for patient neuromuscular response. The argon beam is highly efficient and features the proprietary ArC Smart™ beam which is believed to be the best beam ever designed for flexible endoscopy. The beam is quick to ignite, has a robust arc length, but a markedly more gentle tissue effect than prior argon systems. (See the Genii August White Paper for details and data.)

All of the **gi4000** output choices have research based default power start points. Since the unit is designed ONLY for flexible endoscopy (GI and Bronchoscopy) procedures, all outputs and their associated 'power curves' (sometimes called auto 'dosing' of power depending on changing impedance) are perfectly tuned to work in conjunction with flexible endoscopic accessories in the upper and lower GI tract and lung procedures.

The user interface includes a proprietary 'Tap a Tool®' icon that automatically offers additional pre-set watt setting options common to certain 'tools' (accessories) such as snares or needle knives. All defaults reset automatically, and can be changed in rare cases of physician preference in the touch accessible Biomedical Engineering area. This area holds all default information as well as a log of all alerts and user errors.

The unit has four operating methods: Lavage; true GI specific Bipolar; Argon coagulation; and seven MODES of Monopolar outputs. The monopolar output modes offer gentle superficial TouchSoft® coagulation, Coagulation and Blend Coagulation modes for polypectomy, two Pulse Cut modes, (Pulse Blend Cut and Pulse Cut) especially favored for sphincterotomy and endoscopic mucosal resection, and Blend Cut, and Cut modes preferred for ESD or for non-pulse sphincterotomy. It is designed to be capable of performing all flexible endoscopic procedures from the simplest to the most complex. All settings chosen and power start points are visible to the user at all times.

The unit features a built-in variable speed lavage pump with a 650 ml/min max flow and adjustable head to accept multiple brands/sizes of disposable tubing. The lavage function provides the sterile water for lavage and bipolar probes using commercially available sterile water.

Safety Advances

The **gi4000** has an advanced Pad Safety System (PSS) that is fully compatible with all standard dual foil or sensing return electrode grounding pads. The system will alarm and cease delivery of power if an unsafe pad situation arises. The pad sensing indicator light is red if no pad is present, or if an unsafe impedance level is detected, and green if the impedance is measured in the acceptable range. Unique to the **gi4000** is the proprietary three color light system that affords a higher level of safety for those endoscopy units choosing to use a single or non-sensing pad. In this case the signal light is red if no pad is attached to the unit and yellow when the non-sensing pad is in use-- signaling that added caution is needed when these non-sensing pads are in use.

The **gi4000** has a unique STANDBY mode for added safety. The unit will provide lavage while in standby mode, but not energy. The mode is entered either by a touch key on the screen or by the physician using the black button on the foot pedal. Standby is instantly reversed by a touch anywhere on the touchscreen or by another tap on the foot pedal button.

The unit employs a series of safety warnings with audible tones, as well as general information displays.

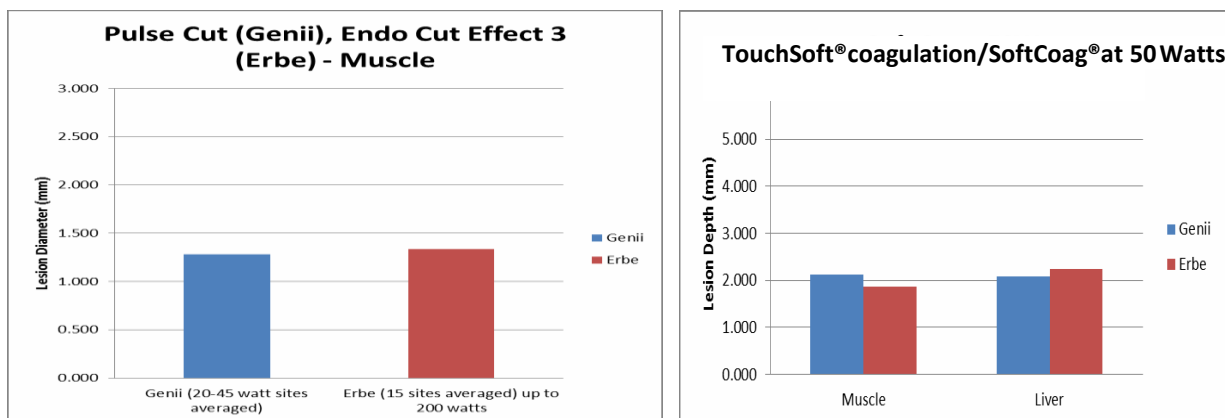


Pre-Clinical Data

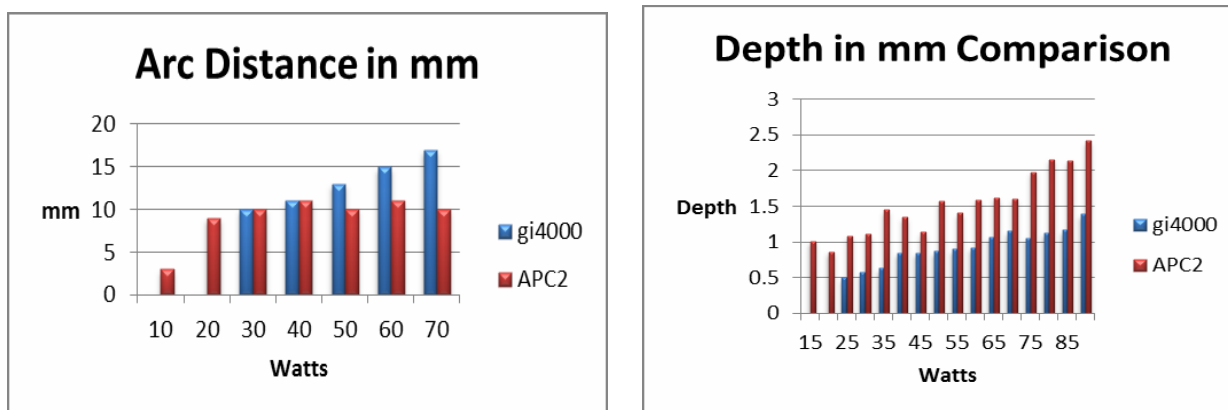
Several pre-clinical tissue studies and multiple animal studies were completed prior to FDA clearance. The studies successfully demonstrated safety and efficacy as well as a reduction in video interference. The following is data summarized from ex vivo histological tissue studies completed by an independent testing lab using two tissue types: muscle and liver. The intent was to compare the depth and breadth of tissue injury under identical conditions, using identical electrodes (accessories) between outputs from the **gi4000** and the ERBE ICC200EA/APC300, or the ERBE VIO300D/APC2 as noted.

The conclusions were that the data shows equivalence or improved performance in all corresponding outputs for the **gi4000**. (Complete studies on file).

Comparison of the **gi4000** in Pulse Cut mode to the Endo Cut, effect 3, mode of the ERBE ICC™ 200E (left) and the TouchSoft® coagulation and Soft Coag® outputs at 50 watts on the right.



Comparison of the **gi4000** Arc Smart™ argon beam with the ERBE VIO®300D/APC™2 in Forced mode. Tissue depth is measured at ONE second. Please see the Genii August White Paper, “Argon coagulation tissue effects using pre-clinical data comparing the Genii **gi4000** and the ERBE VIO300D/APC2 electrosurgery generators”. Note the longer arc beam of the **gi4000** and the significantly gentler tissue effect.



¹ ANON. Electrosurgical Units. Health Devices 1997;26:400-39

² AORN. Recommended practices for electrosurgery. Perioperative Standards and Recommended Practices. Denver, CO; AORN, Inc. 2010; 105-125

³ Morris Marcia L, Tucker Robert D, Baron Todd H, Wong Kee Song, Louis M. Electrosurgery in in Gastrointestinal Endoscopy: Principles to Practice. Am J Gastroenterol 2009; 104(6); 1563-74

⁴ Data on file at US Endoscopy.

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