ESTTA Tracking number: **ESTTA987333**

Filing date: **07/13/2019**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	92066392
Party	Plaintiff Covidien LP
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Submission	Motion for Summary Judgment **Yes**, the Filer previously made its initial disclosures pursuant to Trademark Rule 2.120(a); OR the motion for summary judgment is based on claim or issue preclusion, or lack of jurisdiction. The deadline for pretrial disclosures for the first testimony period as originally set or reset: **07/14/2019**
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Date	07/13/2019
Attachments	Covidien Renewed MSJ.pdf(350846 bytes) Buysse Decl Renewed MSJ.pdf(121909 bytes) Buysse Ex. A.pdf(44431 bytes) Buysse Ex. B.pdf(876607 bytes) Buysse Ex. C.pdf(4448348 bytes) Buysse Ex. D.pdf(514418 bytes) Buysse Ex. E.pdf(174012 bytes) Buysse Ex. F.pdf(3332487 bytes) Helland Decl Renewed MSJ.pdf(120685 bytes) Helland Exhibit A - CONFIDENTIAL.pdf(34329 bytes)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

COVIDIEN LP, Petitioner, v. ERBE ELEKTROMEDIZIN GMBH, Registrant.	Cancellation No. 92066392 Registration Nos. 4,236,231 and 4,686,396 Mark: SOFT COAG

PETITIONER'S RENEWED MOTION FOR SUMMARY JUDGMENT

Dated: July 13, 2019

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Petitioner Covidien LP ("Petitioner") moves for summary judgment on the ground that Registrant Erbe Elektromedizin GmBH's ("Erbe's") alleged mark Soft Coag is generic or merely descriptive without secondary meaning.[1]

INTRODUCTION

Surgeons have performed a medical procedure known as "soft coagulation" for decades. Surgeons use an electrosurgical generator to perform the procedure. Erbe uses "Soft Coag" as the name of the mode on its generator, which enables a surgeon to perform soft coagulation. More than a decade before Erbe, Petitioner's predecessor used "Soft Coag" as the name of the mode on its generator that enables a surgeon to perform soft coagulation. Today, Petitioner and more than a dozen other manufacturers use "Soft Coag" as the name of a generator mode that enables a surgeon to perform soft coagulation. The Board must cancel Erbe's registrations for SOFT COAG because the evidence is undisputed that Soft Coag is generic for the goods or, at a minimum, highly descriptive of the goods and lacks secondary meaning. The Board should also cancel Erbe's registrations for SOFT COAG because the evidence is undisputed that the term does not function as a mark.

STATEMENT OF UNDISPUTED MATERIAL FACTS ("SUMF")

I. PETITIONER AND ITS ELECTROSURGICAL GENERATORS SYSTEMS WITH A SOFT COAG MODE

1. Petitioner manufactures and sells electrosurgical generator systems used by surgeons to cut and coagulate tissue during surgery. Declaration of Steven Buysse ("Buysse Decl.") ¶¶ 3, 7-10.[2]

[1] Petitioner files this summary judgment motion pursuant to the Board's July 10, 2019 Order. 33 TTABVUE.

[2] Mr. Buysse was employed by Petitioner's predecessor Valleylab beginning in 1986, and has worked at the same factory since that date, even as it has changed ownership over years and is now owned by Medtronic. Buysse Decl. ¶ 2. He has dedicated his career to designing, testing and manufacturing

2. An electrosurgical generator system features various "modes" or pre-programmed settings, which allow the surgeon to achieve coagulation at different voltages, intensities, and surface distributions resulting in different effects on the tissue. *Id.* ¶ 7.

3. Petitioner's generators typically feature several coagulation modes called "Spray Coag," "Fulgurate Coag," "Dessicate Coag" and/or "Soft Coag." *Id.* ¶ 8. "Coag" is a common abbreviation for "coagulation." *Id.* ¶ 9; Ex. 58 (Rule 30(b)(6) deposition of Erbe via John Day) 48:17-19.

4. The "Soft Coag" mode on Petitioner's generators enables a surgeon to perform a common medical procedure or technique called "soft coagulation" or "soft coag," which is where a surgeon softly or gently coagulates tissue and minimizes tissue damage. Buysse Decl. ¶¶ 10-11. *See also* Ex. 58 (Erbe Dep.) 36:18-23. Soft coagulation is a type of "contact coagulation," meaning that the surgeon brings the electrode in contact with the tissue. Buysse Decl. ¶ 10. Hundreds of surgeons and researchers in the United States perform the soft coagulation technique every year using Petitioner's generators, Erbe's generators and the generators of third parties. *Id.* ¶ 11.

5. Petitioner's predecessor Valleylab and then Petitioner have used "Soft Coag" as the name of the generator mode that enables a surgeon to perform the soft coagulation procedure for more than 35 years. *Id.* ¶¶ 13-17.

6. In 1983, Valleylab launched the "Valleylab SSE4" generator system, which featured a

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electrosurgical generators, including researching and developing new generators. *Id.* ¶¶ 3-4. As part of his duties, he regularly communicates with users and purchasers of electrosurgical generators including surgeons and hospital personnel about generators and reads clinical and professional literature in the fields of electro-surgery and electrosurgical generators. *Id.* ¶ 5. Mr. Buysse is highly knowledgeable about how users and purchasers of electrosurgical generators understand and use "Soft Coag" and "Soft Coagulation." *Id.* Petitioner identified Mr. Buysse as a non-retained expert on these topics. *Id.* ¶ 6 and Buysse Ex. A.

mode named "Soft Coag" that enabled a surgeon to perform soft coagulation, Buysse Decl. ¶ 13 & Ex. B (SSE4 1983 manual excerpts) and Ex. C (SSE4 1984 manual) thereto. Later, Valleylab began to sell the "Valleylab Force 4B" generator system, which also offered a mode called "Soft Coag," which enabled a surgeon to perform soft coagulation. Buysse Decl. ¶ 14 and Ex. D (Force 4B manual).

7. Valleylab sold generators with a "Soft Coag" mode until 2005. Declaration of Kamrin Helland Ex. A (confidential sales records).

8. Valleylab's generator systems with a "Soft Coag" mode were among the best-selling generator systems in the United States in the 1980's and 1990's. Buysse Decl. ¶ 15. Valleylab sold thousands of these generators and earned tens of millions in revenues from the sales. *Id.* The generators were built to last for at least 20 years. *Id.* Many of Valleylab's Force 4B generators remain in use in the United States, and used Force 4B units are sold in the United States. *Id.*

9. In 2011, Petitioner began to plan its next generation of generator systems, eventually named the "Valleylab FT10." *Id.* ¶ 16. Like prior Valleylab models, the FT10 offers a "Soft Coag" mode, which enables a surgeon to perform soft coagulation. *Id.* & Ex. E thereto (excerpts from FT10 manual)). Petitioner released the FT10 in 2015. Buysse Decl. ¶ 16.

10. Petitioner and Petitioner's predecessor (Valleylab) sold a substantial number of units of electrosurgical generators with a "Soft Coag" mode from 1996 through 2017 as disclosed in Helland Exhibit A. Valleylab sold many more units of these generators from 1983 to 1995 (*see* Buysse Decl. ¶ 15), but detailed sales records from that time are no longer available. Helland Decl. ¶ 6.

II. ERBE AND ITS ELECTROSURGICAL GENERATOR SYSTEMS WITH A SOFT COAG MODE

11. Erbe, like Petitioner, manufactures and sells electrosurgical generator systems. *See*

Bukrinsky Decl. Ex. 1[3] (Erbe's Resp. to Interrog. No. 21).

12. In 1994, a decade after Petitioner's predecessor had launched a generator featuring a "Soft Coag" mode, Erbe began to sell an electrosurgical generator, which offered a mode called "Soft Coag." *Id.*

13. Erbe sells electrosurgical generator systems under the brands VIO and ICC. *Id.*; *see also* Ex. 2 (Erbe's sales records).

14. As Erbe admitted to the U.S. Patent and Trademark Office in prosecuting the "Soft Coag" registrations that are the subject of this proceeding, Erbe "does not specifically mention the Soft Coag mode when it advertises its electrosurgical generators in magazines and other publications." Ex. 14 at p. 20 & Ex. 15 at p. 19 (Erbe's Responses to Office Action in connection with its two registrations); Ex. 58 (Erbe Dep.) 151:3-8 (admitting that "Erbe does not specifically mention the SOFT COAG mode when it advertises its electrosurgical generators in magazines and other publications"). Erbe never uses the alleged mark "Soft Coag" on signs or banners at trade shows or the like. Ex. 58 (Erbe Dep.) 154:14-20 (admitting that "Soft Coag" never appears on signs or banners at trade shows). Indeed, Erbe's advertising flyers often fail to mention "Soft Coag" at all. *See e.g.* Ex. 8.

15. Erbe's use of "Soft Coag" is limited to brochures, training materials, instruction manuals and the display screen on its generator and its web site. *See, e.g.,* Exs. 3-13 (brochures, flyers and training materials); Exs. 14-15 (Erbe's Responses to Office Actions with copies of brochures and flyers); Ex. 16 (printout from Erbe USA website); Ex. 17-18, 20, 25 (instruction manuals and excerpts thereof); Ex. 19 (VIOD 300 generator screen).

16. In Erbe's brochures and training materials, Erbe's uses "Soft Coag" only in a list of

[3] Numbered exhibits 1-58 are to the Declaration of Katie Bukrinsky submitted herewith. Confidential exhibits are filed under seal.

modes offered by its VIO and ICC-branded generators as shown below (Ex. 5):

Only mention of "Soft Coag"

17. As a further example, in the Erbe brochure attached as Ex. 7, Erbe uses "Soft Coag" only on page 5 in a listing of "available modes." *Id.* at 4965-66.

18. The brochures and training materials that Erbe has produced are attached as Exhibits 3 through 13, and are also found in Erbe's Responses to Office Actions, which are attached as Exhibits 14 and 15. In all of those materials, Erbe uses "Soft Coag" only in a list of available modes on its generator. *Id.* Erbe does not advertise or sell generators as "Soft Coag" generators. *Id.*

19. In Erbe's instruction manuals for its generators, Erbe uses "Soft Coag" only in the table of contents and in a section of the manual describing the modes on the generator. *See, e.g.*, Ex. 17, 20 (ICC Manuals); Exs. 18, 25 (VIO manuals).

20. The screen on Erbe's electrosurgical generator displays "Soft Coag" only if a surgeon selects that "Mode." In contrast, the generator itself features the marks ERBE and VIO even when the screen is turned off (Ex. 19):

21. Erbe's website uses "Soft Coag" only in a list of modes on its VIO-branded generators. Ex. 16 (search results for "Soft Coag" on Erbe USA's website).

22. Erbe admits that the purpose of the "Soft Coag" mode on its electrosurgical generators is to enable a surgeon to perform soft coagulation. *See, e.g.*, Ex. 58 (Erbe Dep.) 103:23-104:4 (admitting that its manual (Ex. 17 at 2083) "refers to [what the SOFT COAG mode] does as 'soft coagulation'"); Ex. 20 at 2943-2944, 2959 (Erbe manual explains how to use the "Soft Coag" mode to perform "soft coagulation"); Ex. 21 (Erbe document refers to the "soft coagulation output" that results from use of "Soft Coag" mode).

23. Erbe informs actual and potential customers that the "Soft Coag" mode on its generator enables a surgeon to perform "soft coagulation." Ex. 58 (Erbe Dep.) 103:23-104:4; Ex. 17 at

2083 and Ex. 20 at 2943-44 and 2959 (Erbe's manuals). *See also* Ex. 22 (academic article edited by Erbe referring to the "snare tip soft coagulation (STSC) technique" which the surgeon conducted using Erbe's VIO generator in Soft Coag mode, and stating that "[s]oft coagulation through a snare tip is a readily available, effective, and safe hemostatic modality for intraprocedural bleeding.")[4].

24. Erbe uses "Soft Coag" and "Soft Coagulation" interchangeably to refer to the mode on its generator, which enables a surgeon to perform soft coagulation. *See, e.g.*, Ex. 23 (letter to customer referring to "soft coagulation mode" and "soft coag" mode); Ex. 24 (same); Ex. 25 at 776 (Erbe manual using "soft coag" and "soft coagulation" interchangeably); Ex. 58 (Erbe Dep.) 35:6-20 (referring to Erbe's "Soft Coag" mode as the "Erbe soft coagulation mode").

25. Erbe also uses "Soft Coag" and "Soft Coagulation" interchangeably to refer to a type of coagulation procedure that a surgeon is able to perform by using the "Soft Coag" or "Soft Coagulation" mode on its generator. Ex. 58 (Erbe Dep.) 103:23-104:4 (testifying about Ex. 17 at 2083); Ex. 26 at 6031-32 (demonstrating clinical applications of a "soft coagulation" procedure and abbreviating it as "Soft Coag" on the next page; Ex. 27 (Erbe's email to doctor describing the Soft Coagulation or Soft Coag "effect" while using the ENDO CUT setting of the generator which incorporates a "Soft Coag phase").

26. Erbe admits that the "Soft Coag" mode on electrosurgical generators sold by third parties enables a surgeon to perform soft coagulation. *See, e.g.*, Ex. 58 (Erbe Dep.) 77:6-9; *id.* 78:14-79:5 (testifying about Buysse Ex. F); Ex. 28 (Erbe's record of third parties that sell a generator with a "soft coag" or "soft coagulation" mode, including those that function in the same way as the "Soft Coag" mode on Erbe's generators); Ex. 29 at 702 (Olympus' soft coag mode "works

[4] "Snare tip" refers to using the tip of a snare electrode. A snare electrode is a widely available electrosurgical accessory not sold as "Soft Coag." *See* Ex. 58 (Erbe Dep.) 35:21-24.

nearly identically" to Erbe's soft coag mode).

III. ERBE'S REGISTRATIONS FOR SOFT COAG

27. Erbe owns Registration Nos. 4,236,231 and 4,686,396 for SOFT COAG. Both registrations issued based on Erbe's claim of acquired distinctiveness under Section 1052(f).

28. Registration No. 4,236,231 issued on November 6, 2012 for "medical instruments, namely, electrosurgical coagulation component of an electrosurgical generator system that operates at constant voltage" in Class 10.

29. Registration No. 4,686,396 issued on February 17, 2015 for:

"Computer software for use in electrosurgical generator systems to maintain constant voltage during fluid coagulation; high-frequency apparatus and measuring instruments, namely, electrosurgical generator systems comprised of computer software used to maintain constant voltage for in vivo use; software-programmable microprocessors" in Class 09;

"Electrosurgical generator systems comprising surgical instruments and apparatus and components thereof that operate at constant voltage; electrosurgical generator systems comprising high frequency surgical apparatus and instruments for medical purposes" in Class 010 and

"Development, programming and implementation of software for use in electrosurgical generator systems to maintain constant voltage; technical support services, namely, troubleshooting of computer software problems in electrosurgical generator systems" in Class 042.

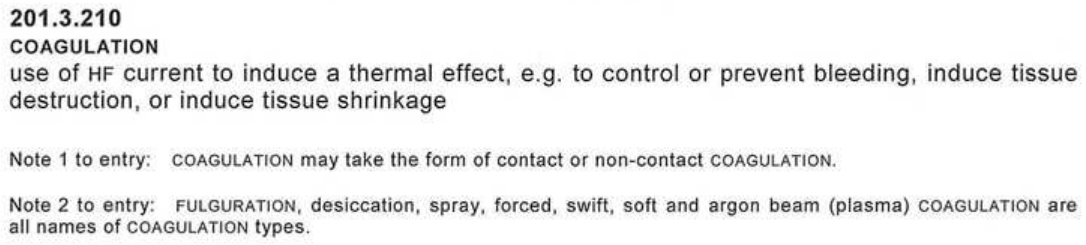
30. Erbe knows of no facts to support its claim that its alleged mark SOFT COAG has acquired distinctiveness. Ex. 58 (Erbe Dep.) 174:3-9.

31. Erbe is unaware of a survey or study that shows that its alleged mark SOFT COAG has acquired secondary meaning. Ex. 58 (Erbe Dep.) 104:5-105:4.

IV. INDUSTRY USE OF SOFT COAG TO REFER TO A GENERATOR MODE THAT ENABLES A SURGEON TO PERFORM SOFT COAGULATION

32. The International Electrotechnical Commission ("IEC"), the leading standards organization in the world for the electrosurgical industry, defines "Soft Coagulation" as a "type" of coagulation procedure. Buysse Decl. ¶¶ 18-19 & Ex. F at 2565; Ex. 58 (Erbe Dep.)78:14-18

(admitting IEC standards document identifies "soft coagulation" as the "name of a coagulation type."). The excerpt is below:



201.3.210
COAGULATION
use of HF current to induce a thermal effect, e.g. to control or prevent bleeding, induce tissue destruction, or induce tissue shrinkage

Note 1 to entry: COAGULATION may take the form of contact or non-contact COAGULATION.

Note 2 to entry: FULGURATION, desiccation, spray, forced, swift, soft and argon beam (plasma) COAGULATION are all names of COAGULATION types.

33. Both Erbe and Petitioner have representatives on the IEC. Ex. 58 (Erbe Dep.) 44:2-24; Buysse Decl. ¶ 18.

34. Over the last decade, as Erbe admits, more than a dozen different manufacturers have used and continue to use "Soft Coag" or "Soft Coagulation" as the name of a mode on an electrosurgical generator that enables a surgeon to perform soft coagulation, including Olympus, Karl Storz, ConMed, Genii, Aaron Bovie Medical, Ackermann, Aesculap, Alsa Apparecchi, Eschmann, EMED, Geister, HEBU, Integra, Kavandish, KLS Martin, Lamidey Noury Medical, Valleylab, Soring, and Tekno. Ex. 30 (Erbe's response to Req. for Admission No. 7, admitting that third parties have a Soft Coag mode); Ex. 1 (Erbe's Response to Interrog. No. 53, stating that Petitioner, Karl Storz, Valleylab, ConMed, Olympus, and Genii have used the term Soft Coag in connection with a generator mode); Ex. 28 at pp. 8-21 (Erbe's record of competitors who use Soft Coag or Soft Coagulation, or Bipolar Soft Coag in connection with a mode); Ex. 58 (Erbe Dep.) 154:25-163:1 (testifying about Ex. 28). *See also* Ex. 31 (Aesculap/B Braun brochure listing "soft coag" mode); Ex. 32 (EMED generator series with "soft coagulation" mode); Ex. 33 (Olympus 2008 510k); Ex. 34 (Olympus 2010 510k); Ex. 35 at 2171 (Olympus brochure with "softcoag" mode); Ex. 29 at 10702 (Olympus' softcoag mode "works nearly identically" to Erbe's soft coag mode); Ex. 36 (brochure for Bovie icon GI generator with a "soft coag" mode);

Ex. 37 (Genii 510k dated March 22, 2012 with a "soft coag" mode).

35. For decades, manufacturers have used "Soft Coagulation" in medical device patents to identify a coagulation procedure, including: Medtronic (Ex. 38 at 2331 (Patent No. 6,096,037, filed 1997 and issued 2000) and Ex. 39 at 2370 (Patent No. 7,470,272, filed 2004 and issued 2008)); BOWA-electronic GmbH (Ex. 40 at 2378 (Patent No. 7,666,182, filed 2005 and issued 2010, referring to soft coagulation as a "specific coagulation effect[]")); Karl Storz GmbH (Ex. 41 at 2395 (Patent No. 9,668,801, filed 2011 and issued in 2017, noting that soft coagulation is "characterized in that the amplitude of the RF voltage required for this purpose is less than 200 Volts")); and Genii, Inc. (Ex. 42 at 2291 (Patent No. 8,287,530, filed 2011 and issued 2012)).

36. Medical publications regularly publish articles about surgeons using the "soft coagulation" mode on a generator to perform a soft coagulation procedure. *See, e.g.*, Ex. 43 (article titled "A Randomized Trial of Monopolar Soft-Mode Coagulation . . ." which compares "the hemostatic efficacy of soft coagulation with heater probe thermocoagulation"); Ex. 44 at 1091 (noting that a process called "soft coagulation has been developed to solve" the problem of tissue carbonization and adhesion, and testing the efficacy of the process in spinal surgery); Ex. 45 at 603 (soft coagulation procedure using the "soft coagulation setting" on an Olympus generator); Ex. 46 (describing a tissue area being "marked with soft coagulation"); Ex. 47 (abstract describing "soft-coagulation" procedure); Ex. 48 (abstract titled "Efficacy of Hemostasis by Soft Coagulation…" and discussing availability of "endoscopic high-frequency soft coagulation"); Ex. 49 (abstract titled Laparoscopic Liver Resection Using a Monopolar Soft-Coagulation Device…"); Ex. 50 (noting that "[i]t is well-known the soft coagulation is useful and safety [sic] for stopping of hemorrhage and leakage in lung, liver and pancreas surgery."); Ex. 51 (article concluding that "endoscopic hemostasis by soft coagulation using hemostatic

forceps has been widely applied for hemostasis in UGIB with validity and safety[.]"); Ex. 52 at 1102 (stating that "[s]oft coagulation is the purest form of coagulation in that there is no spark generated to initiate a cut."); Ex. 53 at 586-587 (article "elucidat[ing] the feasibility of the new closure method using soft coagulation . . .." using a "VIO soft coagulation system"); Ex. 54 at 999 (article describing "soft coagulation procedure" conducted using "soft-mode coagulation"); Ex. 55 (article titled "Evaluation of hemostasis with soft coagulation using endoscopic hemostatic forceps").

37. Physicians and hospital personnel use and understand "Soft Coag" to be an abbreviation for "Soft Coagulation." Buysse Decl. ¶ 20. "Soft Coagulation" is abbreviated to "Soft Coag" on a generator screen due to space constraints. *Id.* ¶ 21.

38. Physicians and hospital personnel use "Soft Coag" and "Soft Coagulation" interchangeably to refer to a coagulation procedure performed by a surgeon using an electrosurgical generator, including those manufactured by Petitioner, Erbe and third parties. *Id.* ¶¶ 11, 22. Physicians and hospital personnel also use "Soft Coag" and "Soft Coagulation" interchangeably to refer to the mode on any number of commercially available electrosurgical generators (including Petitioner's generator) that enables a surgeon to perform a Soft Coag or Soft Coagulation procedure. *Id.* ¶ 22.

39. As early as 1998, the ECRI Institute, an independent non-profit institution that evaluates medical procedures and devices, stated that generator "modes intended for contact coagulation are typically labeled Dessicate, or Soft Coag." Ex. 57. "Contact coagulation" describes coagulation where the surgeon touches the tissue with the electrode. Buysse Decl. ¶ 10. "Dessicate Coagulation" and "Soft Coagulation" are different types of contact coagulation. *Id.*

40. Erbe admits that "soft coagulation" is a non-proprietary medical procedure. Ex. 58 (Erbe Dep.) 108:3-6.

41. Erbe admits that "Coag" is a "generally accepted" abbreviation for "coagulation." Ex. 58 (Erbe Dep.) 48:17-19.

42. *Merriam-Webster* medical dictionary defines "Coag" as an abbreviation of "coagulation." Ex. 57.

LEGAL STANDARD

Summary judgment should be granted if there is no genuine issue of material fact and Petitioner is entitled to judgment as a matter of law. *See, e.g., Celotex Corp. v. Catrett,* 477 U.S. 317, 322-23 (1986). Once Petitioner makes a *prima facie* case that there is no genuine dispute that Soft Coag was generic or lacked acquired descriptiveness for the goods at the time the registrations issued, Erbe can avoid summary judgment only by "present[ing] sufficient evidence to show an evidentiary conflict as to one or more material facts in issue." *Cashflow Techs., Inc. v. NetDecide*, 2002 WL 1485332, at *7 (TTAB July 10, 2002). The Board regularly grants summary judgment on claims of genericness and lack of acquired distinctiveness. *See, e.g.*, *Marquez Bros. Int'l, Inc. v. Zucrum Foods, L.L.C.*, 2009 TTAB LEXIS 695, *21 (TTAB Dec. 11, 2009) (genericness); *Cashflow Techs.,* 2002 WL 1485332 at *5 (lack of acquired distinctiveness); *Equibal Inc. v. Clientele, Inc.*, 2018 WL 1890932, *5 (TTAB Apr. 6, 2018) (same); *Historic Hotels Int'l., Inc. v. Nat'l Trust for Historic Preservation*, 91168312, 2008 WL 3333840, at *2 (TTAB July 31, 2008) (same).

ARGUMENT

I. PETITIONER HAS STANDING

Petitioner uses "Soft Coag" as the name of a generator mode and thus has standing to assert claims for genericness and lack of acquired distinctiveness. SUMF ¶¶ 1, 3, 9-10. *See Sheetz of Del., Inc. v. Doctor's Assocs. Inc.*, 108 U.S.P.Q.2d 1341, 1350 (TTAB 2013). *See generally Coach Services, Inc. v. Triumph Learning LLC*, 101 U.S.P.Q.2d 1713, 1727-28 (Fed. Cir. 2012) ("[O]nce an opposer meets the requirements for standing, it can rely on any of the statutory grounds for opposition set forth in 15 U.S.C. § 1052.").

II. SOFT COAG IS GENERIC

The Board uses the "primary significance" test to determine genericness. *H. Marvin Ginn Corp. v. Int'l Ass'n of Fire Chiefs, Inc.*, 782 F.2d 987, 989 (Fed. Cir. 1986). That test involves two questions, "First, what is the genus of goods or services at issue? Second, is the term sought to be registered … understood by the relevant public primarily to refer to that genus of goods or services?" *Id.* at 990. If a mark is generic for one good in a particular class of the registration, that class must be cancelled in its entirety. *Marquez Bros.*, 2009 TTAB LEXIS 695 at *6.

A. The Genus of Goods is Electrosurgical Generators

The "genus" of goods is defined by the goods in Erbe's registrations. *See, e.g., In re Reed Elsevier Prop. Inc.*, 77 U.S.P.Q.2d 1649, 1654 (TTAB 2005) ("We consider applicant's identification as largely defining the genus of services involved in this case"), *aff'd*, 82 U.S.P.Q.2d 1378 (Fed. Cir. 2007). Erbe's registrations for SOFT COAG cover electrosurgical generators. SUMF ¶¶ 28-29. The genus of goods here is electrosurgical generators. *See id.*

B. Soft Coag is Used and Understood to Mean a Generator Mode That Enables a Surgeon to Perform Soft Coagulation

"The critical issue in genericness cases is whether members of the relevant public primarily use or understand the term sought to be protected to refer to the genus of goods or services in question." *H. Marvin Ginn*, 782 F.2d at 989-90. A term is generic if it refers to a purpose or feature of the goods. *E.g., In re Cook Pacemaker Corp.*, 1999 TTAB LEXIS 450, *12 (TTAB Aug. 13, 1999) (LEAD EXTRACTION for kits used to extract lead was generic because a purpose of the goods was to remove lead); *In re Chronix Biomedical, Inc.*, 2018 TTAB LEXIS 248, *17 (TTAB July 10, 2018) (SECOND OPINION for diagnostic kits was generic because a purpose of the kits was to provide a second opinion as to necessity of medical procedures); *In re Central Sprinkler Co.,* 49 U.S.P.Q.2d 1194, 1199 (TTAB 1998) (ATTIC for sprinklers was generic because applicant's goods were intended to be used in the attic).

Evidence of use and understanding can come from "any competent source, including dictionaries, newspapers, magazines, trade journals and other publications." *Marquez*, 2009 TTAB LEXIS 695 at *9; *Coyne v. Dervaes Inst.*, 2017 TTAB LEXIS 121, *42 (TTAB Mar. 22, 2017) (granting summary judgment and cancelling registration for genericness).

As shown below, the evidence is undisputed that "soft coagulation" is a common type of medical procedure. The evidence is likewise undisputed that electrosurgical generators such as those sold by Erbe, Petitioner and more than a dozen other manufacturers offer a "Soft Coag" mode that enables a surgeon to perform the soft coagulation procedure. Finally, the evidence is undisputed that doctors, manufacturers, and Erbe itself use "Soft Coag" and "Soft Coagulation" interchangeably to refer to a generator mode that enables a surgeon to perform soft coagulation. SUMF ¶¶ 34-35, 37-38. *See In re LG Elecs., Inc.*, 2017 TTAB LEXIS 396, *11 (TTAB Oct. 20, 2017) (an abbreviation that is "substantially synonymous" with the unabbreviated generic term,

and "used interchangeably" with that term, is itself generic.); *Surgicenters of Am., Inc. v. Med. Dental Surgeries, Co.*, 601 F.2d 1011, 1018 (9th Cir. 1979) (mark SURGICENTER "obviously means surgical center" and is equally generic—summary judgment against registrant). Accordingly, Erbe's alleged mark Soft Coag is generic for a feature on an electrosurgical generator that enables a surgeon to perform the soft coagulation procedure.

1. Soft Coag is Generic According to the Leading Industry Organization

"Opinions of leaders in the industry are particularly helpful . . . in determining the genericness of a term." *Classic Foods Int'l Corp. v. Kettle Foods, Inc.*, 468 F. Supp. 2d 1181, 1192 (C.D. Cal. 2007) (citing 2 J. Thomas McCarthy, *McCarthy on Trademarks & Unfair Competition* § 12:13 (4th ed. 2013)). The IEC, the world's leading membership organization for the electrosurgical industry, defines "Soft Coagulation" as a "type" of coagulation procedure. SUMF ¶ 32. The evidence is undisputed that the "Soft Coag" mode on Erbe's electrosurgical generators, Petitioner and more than a dozen other manufacturers, enables a surgeon to perform the soft coagulation procedure. SUMF ¶¶ 4-6,9 22-23, 26, 34, 36, 38. This is substantial evidence that Soft Coag is generic for a feature on electrosurgical generators that enables a surgeon to perform soft coagulation. *See In re Noon Hour Food Prods.*, 2008 TTAB LEXIS 23, *5 (TTAB April 23, 2008) (genericness of BOND-OST for cheese shown by evidence that the USDA recognizes "bondost" as a type of cheese); *In re LG Elecs., Inc.*, 2017 TTAB LEXIS 396, *15 (TTAB October 20, 2017) (relying on technology industry publications to find QLED generic).

2. Erbe Uses Soft Coag Generically

"A party's own generic use of a term is strong evidence of genericness." *Coyne*, 2017 TTAB LEXIS 121 at *30 (summary judgment on genericness). Erbe uses the terms "Soft Coag" and "Soft Coagulation" interchangeably as the name of a generator mode that Erbe admits enables a surgeon to perform "Soft Coagulation." SUMF ¶¶ 22-26. Erbe also uses the term "Soft

Coag" to refer to the mode available on generators manufactured by Petitioner and third parties that enable a surgeon to perform soft coagulation. *Id.* ¶ 26.

3. Manufacturers Use Soft Coag Generically

Generic use "by competitors and other persons in the trade weighs strongly in favor of genericness." *Pilates, Inc. v. Current Concepts, Inc.*, 57 U.S.P.Q.2d 1174, 1183 (S.D.N.Y. 2000). *See also Classic Foods Int'l*, 468 F. Supp. 2d at 1190 (same).

Petitioner's predecessor Valleylab used "Soft Coag" as the name of a generator mode that enabled a surgeon to perform soft coagulation a decade before Erbe began to use Soft Coag, and Valleylab continued to use "Soft Coag" in this manner for a decade after Erbe adopted the term. SUMF ¶¶ 5-8. In that time, Valleylab sold thousands of generators with a Soft Coag mode and earned tens of millions in revenues from such sales. *Id.*

In 2008—four years before Erbe filed its first application for SOFT COAG—Olympus began to sell a generator with a "SoftCoag" mode, which enabled a surgeon to perform soft coagulation, and has done so continuously since then. SUMF ¶ 34 & Exs. 29, 33. As of 2015, over a dozen manufacturers use "Soft Coag" as the name of a generator mode that enables a surgeon to perform soft coagulation, including Aesculap, EMED, Ackermann, Bovie, Olympus, and HEBU. SUMF ¶ 34. This evidence proves that "Soft Coag" is generic for a feature of electrosurgical generators that enables a surgeon to perform soft coagulation. *See Schwan's IP, LLC v. Kraft Pizza Co.*, 460 F.3d 971, 975 (8th Cir. 2006) (affirming summary judgment to defendant—three competitors using "brick oven" for frozen pizza meant "brick oven" was generic, even though those uses began after plaintiff's use); *Osho Friends Int'l v. Osho Int'l Found.*, 2009 TTAB LEXIS 49, *36 (TTAB January 13, 2009) (use by competitors proved genericness); *Boston Duck Tours, LP v. Super Duck Tours, LLC,* 531 F.3d 1, 20 (1st Cir. 2008) (same).

4. Publications Use Soft Coag Generically

Generic use of a term in trade journals is strong evidence of genericness. *See, e.g., In re Cook Pacemaker Corp.*, 1999 TTAB LEXIS 450 at *12 (references in medical journals to techniques for "lead extraction" proved that LEAD EXTRACTION was generic for kits used to extract lead).

The undisputed evidence shows that researchers and doctors use "soft coagulation" in articles to refer to a medical procedure as well as a mode on any number of electrosurgical generators that enable a surgeon to perform the soft coagulation procedure. SUMF ¶ 36. Indeed, as early as 1998, the independent ECRI Institute recognized that "modes intended for contact coagulation are typically labeled Dessicate, or Soft Coag." SUMF ¶ 39.

Even the articles involving Erbe's generator discuss "soft coagulation" as a procedure that may be performed using any third-party generator with a "Soft Coag" mode. *See, e.g.*, Ex. 54 (article entitled "A Randomized Trial of Monopolar Soft-Mode Coagulation . . ." that discusses benefits of using a "soft coagulation" setting); Ex. 44 (article noting the availability of "soft coagulation systems" on generators "such as VIO"). For example, an article written with Erbe's cooperation observes "Soft coagulation through a snare tip is a readily available, effective, and safe hemostatic modality for intraprocedural bleeding." SUMF ¶ 23 & Ex. 22. "Snare tip" is a technique of using the tip of a snare electrode to carry out a procedure, regardless of generator used. *Id.* & Fn. 3. *See Osho Friends*, 2009 TTAB LEXIS at *27 (academic references were evidence of genericness where the references "identif[y] OSHO as a religious and meditative movement and not as a trademark.").

5. Soft Coag is Used Generically in Patents

For decades, manufacturers such as Medtronic, Karl Storz, BOWA-electronic GmbH and Genii, Inc. have obtained patents for medical devices used in connection with the performance of

the "soft coagulation" procedure. SUMF ¶ 35. This undisputed evidence shows that "Soft Coag" is generic for a feature on electrosurgical generators that enables a surgeon to perform soft coagulation. *See Roche Diagnostics GmbH v. Minipumps, LLC*, 2013 TTAB LEXIS 507 *12-13 (TTAB Sept. 9, 2013) (use of "micropump" in patents proved genericness as a matter of law).

* * *

The undisputed evidence shows that "Soft Coag" is generic for a feature found on an electrosurgical generator that enables a surgeon to perform soft coagulation. Manufacturers make electrosurgical generators with a mode called "Soft Coag" which enable a surgeon to perform soft coagulation. Scientific and trade publications use "Soft Coag" to refer to a mode on various electrosurgical generators that enables a surgeon to perform soft coagulation. The industry, including researchers, doctors, manufacturers, hospital personnel and Erbe itself use "Soft Coag" and "Soft Coagulation" interchangeably to refer to a generator mode that enables a surgeon to perform the soft coagulation procedure.

III. SOFT COAG IS MERELY DESCRIPTIVE WITHOUT SECONDARY MEANING

Erbe registered "Soft Coag" under Section 1052(f) and thus the mark is merely descriptive of the goods as a matter of law. SUMF ¶ 27. To prevail on summary judgment on mere descriptiveness, Petitioner can show either that Erbe's use of "Soft Coag" has not been "substantially exclusive," *see, e.g., Miller v. Miller*, 105 U.S.P.Q.2d 1615, 1625 (TTAB 2013) (refusing registration because applicant's use of merely descriptive mark was not "substantially exclusive") or that "Soft Coag" lacks secondary meaning, *see, e.g., Neopco Inc. v. Dana Corp.,* 12 U.S.P.Q.2d 1746, 1747 (TTAB 1998).

A. Erbe's Use of "Soft Coag" Was Never "Substantially Exclusive"

As the Federal Circuit has held,

> In respect of registration, there must be a trademark, *i.e.*, purchasers in the marketplace must be able to recognize that a term or device has or has acquired such distinctiveness that it may be relied on as indicating one source of quality control and thus one quality standard. When the record shows that purchasers are confronted with more than one (let alone numerous) independent users of a term or device, an application for registration under Section 2(f) cannot be successful[.]

Levi Strauss & Co. v. Genesco, Inc., 742 F.2d 1401, 1404-05 (Fed. Cir. 1984). In affirming summary judgment that the applied-for mark lacked acquired distinctiveness due to third party use, the Federal Circuit in *Levi Strauss* concluded that the undisputed evidence showed that applicant's use of the applied-for mark was "neither first nor exclusive." *Id.* at 1405.

Precisely the same is true here. The undisputed evidence is that Erbe's use of "Soft Coag" was "neither first nor exclusive." Beginning in 1983, Petitioner's predecessor Valleylab continuously sold electrosurgical generators in the United States featuring a "Soft Coag" mode, a full decade **before** Erbe began to use "Soft Coag" as the name of a mode on its generator. SUMF ¶¶ 6-8. The evidence is likewise undisputed that Valleylab continued to sell these generators featuring a "Soft Coag" mode for more than a decade **after** Erbe began using "Soft Coag." *Id.* Valleylab's electrosurgical generators with a "Soft Coag" mode were among the best-selling generators in the United States in the 1980's and 1990's and Valleylab sold thousands of units and earned tens of millions of dollars in revenues from those sales. *Id.* Although Valleylab stopped selling the generators in 2005, they were intended to last twenty years and many are still in use today. *Id.* ¶ 8. Furthermore, the evidence is undisputed that Petitioner launched an electrosurgical generator in 2015 that uses "Soft Coag" as the name of a mode that enables a surgeon to perform soft coagulation. SUMF ¶¶ 9-10. *See, e.g., Roselux Chem. Co. v. Parsons Ammonia Co.*, 299 F.2d 855, 863 (C.C.P.A. 1962) (the Board's finding that petitioner used the

mark two years before registrant proved registrant's use was not substantially exclusive and "alone should have been sufficient to support a finding of lack of 'distinctiveness.'").

Moreover, in 2008, Olympus began selling generators in the United States with a "Soft Coag" mode and those sales continue to date. SUMF ¶ 34 & Exs. 29, 33. As of 2015, more than a dozen different manufacturers sold electrosurgical generators with a mode called "Soft Coag" in the United States which enables surgeons to perform the soft coagulation procedure, including Olympus, Bovie, Karl Storz, ConMed, Ackermann, Aesculap, Alsa Apparecchi, EMED, HEBU, Integra, Kavandish, KLS Martin, Lamidey Noury, Valleylab, and Soring. SUMF ¶ 34. The Board can enter summary judgment for Petitioner and cancel Erbe's registrations for SOFT COAG based on these undisputed facts alone. *See, e.g., Levi Strauss,* 742 F.2d at 1404-05.

B. "Soft Coag" Lacks Acquired Distinctiveness

To determine if SOFT COAG has acquired secondary meaning, the Board examines the following factors: "length of use of the mark, advertising expenditures, sales, survey evidence, and affidavits asserting source-indicating recognition." *In re Franklin County Historical Soc'y*, 104 U.S.P.Q.2d (BNA) 1085, 1089 (TTAB September 5, 2012).

Because the evidence discussed *supra* in Section II proves not only that "Soft Coag" is generic, but also that "Soft Coag" is "highly descriptive," *see In re ActiveVideo Networks, Inc.*, 2014 TTAB LEXIS 283, *68 (TTAB July 9, 2014) (same evidence established mark was generic and highly descriptive), Petitioner has a lower burden to prove lack of acquired distinctiveness. *See Alcatraz Media v. Chesapeake Marine Tours Inc.*, 107 U.S.P.Q.2d (BNA) 1750, 1766 (TTAB July 2, 2013). Regardless of the weight of the burden, consideration of the undisputed evidence relating to the above factors proves that SOFT COAG lacks acquired distinctiveness as a matter of law.

1. Erbe's Alleged Advertising Is Not Evidence of Acquired Distinctiveness

"Where advertising always shows the mark accompanied by other trademarks, that advertising is insufficient to demonstrate acquired distinctiveness of the target mark." *In re Franklin County Historical Society*, 104 U.S.P.Q.2d at 1093.

The evidence is undisputed that Erbe does not use "Soft Coag" in magazines or written publication or on signs or banners at trade shows. SUMF ¶ 14. Instead, Erbe's use of "Soft Coag" in what Erbe called "advertising" in its Section 2(f) Declarations is confined to discrete references in brochures and user and instruction manuals. SUMF ¶¶ 15-18. Erbe admitted that up to 2015 it spent only $15,000 annually on literature that references the "Soft Coag" mode on its generator. Ex. 14 at 19.

The only time that Erbe uses "Soft Coag" in its so-called "advertising" is in a listing of modes on its generator, in the context of discussing the goods that are branded VIO, ICC and/or ERBE. SUMF ¶¶ 16-19. Erbe does not use "Soft Coag" by itself. *Id.* Such use says nothing about whether consumers associate "Soft Coag" exclusively with Erbe's goods. *See In re Franklin County Historical Society*, 104 U.S.P.Q.2d at 1093 (advertising failed to show secondary meaning in COSI because mark CENTER OF SCIENCE AND INDUSTRY appeared next to the mark COSI); *In re Mogen David Wine Corp.*, 372 F.2d 539, 54 C.C.P.A. 1086, 152 U.S.P.Q. 593, 595-96 (C.C.P.A. 1967) (where advertising depicting the applied-for bottle design featured the word mark MOGEN DAVID, the advertising did not show secondary meaning in the design); *N. Atl. Operating Co. v. DRL Enters.*, 2016 TTAB LEXIS 282, *102-103 (TTAB July 1, 2016) ("Because the decimal designations are always used with the JOB trademark, we cannot ascertain whether Defendant's sales success and advertising expenditures evidence that consumers recognize the decimal designations as source indicators.").

There is simply no evidence that Erbe's alleged advertising linked "Soft Coag" with Erbe. *See, e.g., Ayoub, Inc. v. ACS Ayoub Carpet Service*, 118 U.S.P.Q.2d 1392, 1403 (TTAB 2016) (advertising expenditures over 11 years did not demonstrate secondary meaning because no showing that the advertising was effective).

2. Erbe's Revenues Do Not Show Acquired Distinctiveness

Erbe's revenues from the sale of generators with a "Soft Coag" mode (which it claims in its Section 2(f) Declarations are $80 million dollars) are not evidence of acquired distinctiveness. As shown in the literature attached to those Declarations, as well as the materials produced by Erbe in this case, Erbe's generators are sold under the brands VIO and ICC and the house mark ERBE. SUMF ¶¶ 13, 16-19. Erbe never uses "Soft Coag" by itself. *Id. See In re Bongrain International (American) Corp.*, 13 U.S.P.Q.2d 1727, 1729 (Fed. Cir. 1990) (sales data was not evidence of secondary meaning because the applied-for mark always appeared alongside another mark); *N. Atl. Operating Co. v. DRL Enters.*, 2016 TTAB LEXIS 282, *103 (TTAB July 1, 2016) ("[W]here [] a party's advertising and sales data is based on materials and packaging in which the mark at issue is almost always displayed with another mark, such data does not prove that the mark at issue possesses the requisite degree of consumer recognition.").

3. No Consumer Studies

Erbe has not offered a study or survey that shows that "Soft Coag" has acquired distinctiveness. SUMF ¶ 31. In fact, Erbe admits that it is unaware of any evidence showing that "Soft Coag" has acquired secondary meaning. SUMF ¶ 30.

4. Length of Use Alone Does Not Prove Acquired Distinctiveness.

Erbe's use of "Soft Coag" for less than 20 years at the time the SOFT COAG registrations issued does not create a genuine issue of fact that the mark has acquired distinctiveness. *See Historic Hotels*, 2008 WL 3333840, at *2 (sustaining opposition on

summary judgment—19 years of use insufficient to show acquired distinctiveness of highly descriptive mark HISTORIC HOTELS for guidebooks); *E.T. Browne Drug Co. v. Cococare Prods., Inc.*, 538 F.3d 185, 199 (3d Cir. 2008) (20 years of use of COCOA BUTTER FORMULA insufficient to show acquired distinctiveness in mark for skin care products—entering summary judgment).

* * *

The undisputed evidence proves that "Soft Coag" lacks secondary meaning. Erbe's use of "Soft Coag" was not first and has never been substantially exclusive. That alone requires the entry of summary judgment in favor of Petitioner. Erbe's so-called advertising and "sales" information that it relied upon in registering "Soft Coag" is not evidence of acquired distinctiveness because Erbe's generators are not sold under the "Soft Coag" mark – Erbe's only use of "Soft Coag" is *de minimis* and buried in a handful of brochures and instruction manuals.

IV. ERBE DOES NOT USE SOFT COAG AS A TRADEMARK

"Matter that is merely informational is not registrable as a mark." *In re AOP LLC*, 107 U.S.P.Q.2d 1644, 1654 (TTAB Jul 12, 2013). The Board focuses "on likely consumer perceptions" of the alleged mark as used by registrant to determine if it is merely informational and thus unregistrable. *In re T.S. Designs, Inc.*, 2010 TTAB LEXIS 220, *4 (TTAB June 9, 2010).

Erbe displays "Soft Coag" only in a list of modes that are on its generator. *See* SUMF ¶¶ 16-19. *See In re AOP*, 107 U.S.P.Q.2d at 1644 ("Set in the midst of other clearly informational matter, and far from the mark naming the wine itself, this use of the term 'AOP' . . . convey[s] nothing more than information itself and would not likely be perceived as a mark."). Erbe does not use "Soft Coag" alone, but instead only with other, far more prominently used marks. *Id. See In re T.S. Designs,* 2010 TTAB LEXIS 220 at *6 (applicant's failure to promote the alleged mark

independently of other more prominent marks proves lack of trademark use). Nor is there any "evidence bearing on the purchasing public's reaction to [Erbe's] promotional efforts." SUMF ¶¶ 30-31. *In re Volvo Cars of N. Am., Inc.*, 1998 TTAB LEXIS 20, *20 (TTAB April 8, 1998) (phrase DRIVE SAFELY does not function as a mark). The evidence is undisputed that "Soft Coag" in the context of generators conveys to the consumer that the generator has a "Soft Coag" mode that enables a surgeon to perform soft coagulation. It simply does not function as a trademark.

CONCLUSION

For each of the three independent reasons above, the Board should cancel Erbe's registrations for SOFT COAG as a matter of law.

Dated: July 13, 2019

By: /Katie Bukrinsky/

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CERTIFICATE OF SERVICE

I hereby certify that on July 13, 2019, a true and correct copy of the foregoing document was served on Registrant via email to Registrant's counsel of record at address below:

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

COVIDIEN LP, Petitioner, v. ERBE ELEKTROMEDIZIN GMBH, Registrant.	Cancellation No. 92066392 Registration Nos. 4,236,231 and 4,686,396 Mark: SOFT COAG

DECLARATION OF STEVEN BUYSSE

I, Steven Buysse, do hereby declare under penalty of perjury as follows:

1. I am over twenty-one years of age and competent to make the following statements. I have personal knowledge of the facts set forth in this Declaration and, if called to testify as a witness, I can and will testify to these facts in a court of law or in an administrative agency, including the Trademark Trial and Appeal Board.

2. I was first employed by Covidien LP's predecessor Valleylab in 1986 and have stayed with the same factory for 33 years. Over the years the ownership changed and my current employer is Medtronic, Inc. In this declaration I refer to the company that employs me, including its predecessors Covidien and Valleylab, as "Medtronic."

3. My entire career at Medtronic has involved the testing, design and manufacture of electrosurgical generators. I began my career as an electronic technician 33 years ago. I tested and calibrated Valleylab-branded generators, including SSE4 and Force 4B generators with a Soft Coag mode. I then moved into a research and development role for generators, and was responsible for researching new products and complying with industry standards. Most recently, I was responsible for the development of the Valleylab FT10 generator.

4. I am knowledgeable about both Medtronic's and other manufacturers' generators and the modes available on those generators, including the Soft Coagulation mode which is regularly abbreviated as Soft Coag.

5. As part of my research and development duties I regularly interact with surgeons, nurses, technicians, researchers, and other purchasers and users of electrosurgical generators. I also regularly read clinical literature specific to the electrosurgical field. As a result, I am knowledgeable as to how customers and the industry in general understand and use the terms Soft Coag and Soft Coagulation.

6. I am a non-retained expert on manufacturers' use of the terms Soft Coag and Soft Coagulation in the electrosurgical industry, and on customers' understanding of these terms. My designation is attached as Exhibit A.

7. Electrosurgical generators are used to cut and coagulate tissue during surgery. An electrosurgical generator system features various "modes" or pre-programmed settings, which allow the surgeon to achieve coagulation at different voltages, intensities, and surface distributions resulting in different effects on the tissue.

8. Medtronic's generator systems typically feature coagulation modes called "Spray Coag," "Fulgurate Coag," "Dessicate Coag" and/or "Soft Coag."

9. "Coag" is a common abbreviation for "coagulation."

10. Dessicate and Soft Coag are two settings that allow a surgeon to perform contact coagulation. "Contact coagulation" describes coagulation where the surgeon touches the tissue with the electrode.

11. The Soft Coag mode of Medtronic's generators, like the Soft Coag modes of other manufacturers' generators, enable a surgeon to perform a common medical procedure or technique known as "soft coagulation," commonly abbreviated "Soft Coag," which is where a surgeon softly or gently coagulates tissue while minimizing tissue damage.

12. Hundreds of surgeons and researchers in the United States perform the Soft Coagulation technique every year using Medtronic's generators, Erbe's generators, and the generators of third parties.

13. Medtronic used the term Soft Coag to designate its Soft Coagulation mode since 1983, when it released its Valleylab SSE4 generator with a Soft Coag mode in the United States. Exhibits B and C are true and correct excerpts from manuals for the Valleylab SSE4 generator dated 1983 and 1984 showing a Soft Coag mode.

14. Medtronic then released the Force 4B generator, which also had a Soft Coag mode that enabled users to perform Soft Coagulation. Exhibit D is a true and correct copy of the Valleylab Force 4B manual, dated 1985.

15. The Valleylab SSE4 and Force 4B generators were among the best-selling generator systems in the United States in the 1980's and 1990's. Medtronic sold thousands of these generators and earned tens of millions of dollars from the sales. The generators were built to last for at least 20 years. Many Force 4B generators remain in use in the United States, and used units are still being sold in the United States.

16. Beginning in 2011 I was part of the team planning Medtronic's next generation of generators, which came to be named the Valleylab FT10. The Valleylab FT10 offers a Soft Coag mode which enables a surgeon to perform soft coagulation. Exhibit E is a true and correct copy of excerpts from the Valleylab FT10 User's Guide.

17. The FT10 was released in 2015.

18. Because my work for Medtronic involves ensuring compliance with industry standards, I am familiar with the standards set by the International Electrotechnical Commission ("IEC"). The IEC is the leading standards organization in the world for the electrosurgical industry. Medtronic, like most electrosurgical manufacturers, has a representative who serves on the IEC.

19. The IEC defines "Soft Coagulation" as a "type" of coagulation procedure that can be performed by a surgeon. A true and correct excerpt of the IEC standards is attached as Exhibit F to my declaration.

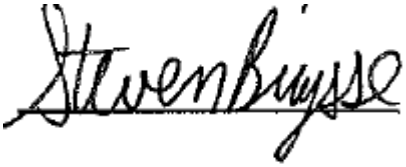
20. Doctors, surgeons, researchers, and other purchasers and users of electrosurgical generators understand Soft Coag to be an abbreviation of Soft Coagulation.

21. Space limitations on a generator screen require that Soft Coagulation be abbreviated as Soft Coag.

22. Doctors, surgeons, researchers, and other purchasers and users of electrosurgical generators use the terms Soft Coag and Soft Coagulation interchangeably to refer to the procedure of softly or gently coagulating tissue while minimizing tissue damage. They also use these terms interchangeably to refer to a mode on any manufacturer's generator, including Medtronic's FT10 generator, that allows the user to perform a Soft Coagulation procedure.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: July 12, 2019



STEVEN BUYSSE

Buysse Exhibit A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

COVIDIEN LP, Petitioner, v. ERBE ELEKTROMEDIZIN GMBH, Registrant.	Cancellation No. 92066392 Registration Nos. 4,236,231 and 4,686,396 Mark: SOFT COAG

PETITIONER COVIDIEN LP'S NON-RETAINED EXPERT DISCLOSURE PURSUANT TO RULE 26(a)(2)(C)

Pursuant to Fed. R. Civ. P. 26(a)(2)(C), Petitioner Covidien LP ("Petitioner") provides the following expert disclosure. Petitioner intends to rely upon the testimony of Mr. Steven Buysse, Principal R&D Engineer, employed by Petitioner.

The subject matter of Mr. Buysse's testimony will be the use of the terms "soft coag" and "soft coagulation" in the electrosurgical industry.

Mr. Buysse has worked in the electrosurgical field for approximately 30 years. He regularly interacts with doctors, scientists, and technicians who utilize electrosurgical equipment and accessories. His work requires him to be knowledgeable about third party manufacturers' electrosurgical equipment, including the modes available on such equipment. Mr. Buysse furthermore regularly reads scientific and medical literature specific to the electrosurgical field, and is well-versed in this field of research. Mr. Buysse will testify that "soft coag" describes a mode, feature, or function of electrosurgical devices, instruments, and related software. "Soft coag" is a common abbreviation for "soft coagulation" in the electrosurgical field. The terms

"soft coag" and "soft coagulation" are commonly used by medical professionals, scientists and manufacturers in the electrosurgical field.

Dated: May 9, 2018

By: /Katie Bukrinsky/

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Attorneys for Petitioner Covidien LP

CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2018, a true and correct copy of the foregoing PETITIONER COVIDIEN LP'S NON-RETAINED EXPERT DISCLOSURE PURSUANT TO RULE 26(a)(2)(C) was served on Registrant via email to Registrant's counsel of record at address below:

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Buysse Exhibit B


Valleylab
SSE4
SERVICE
MANUAL

SSE4

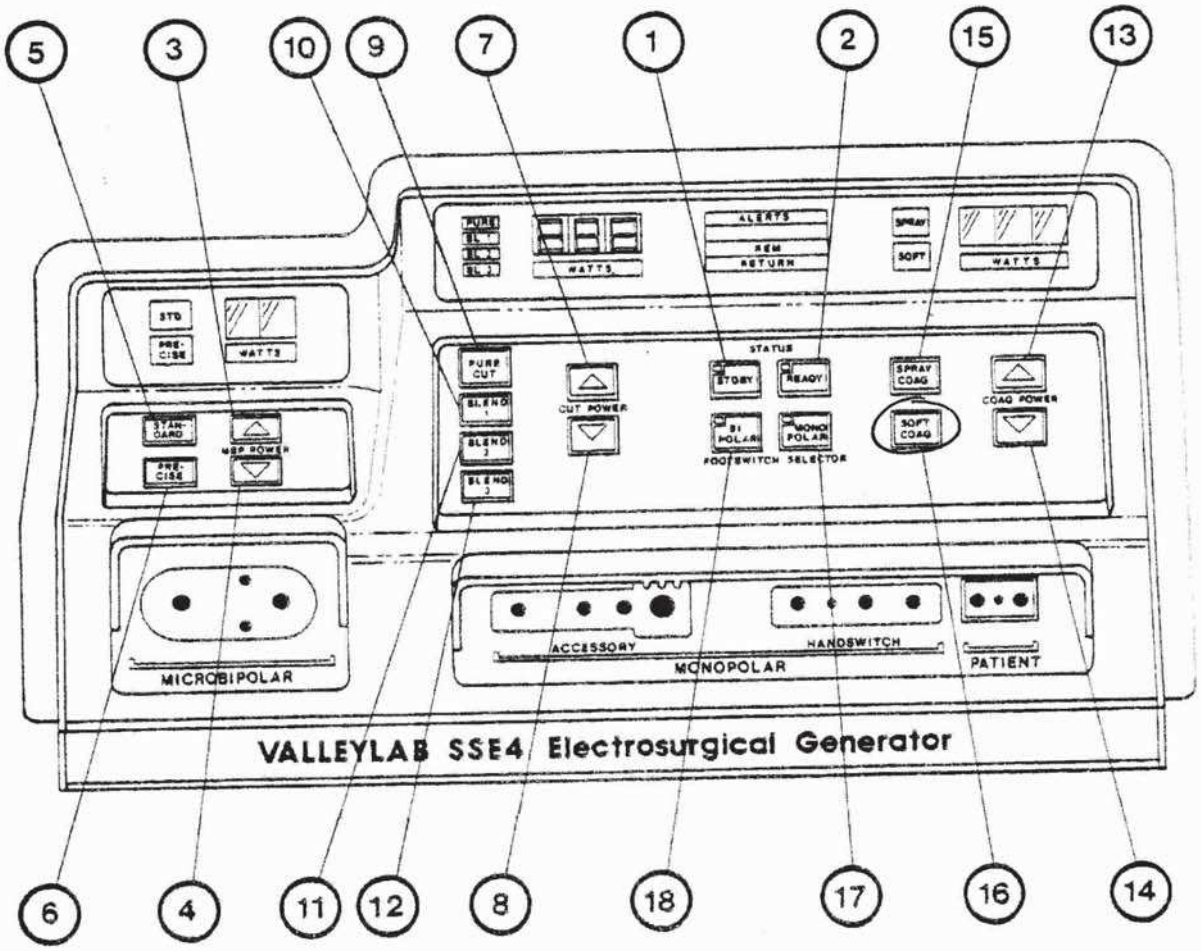
SERVICE MANUAL

110V

EFFECTIVE DATE: November 1, 1983

VALLEYLAB PART NUMBER A 945 100 042 A

PRINTED IN USA



3-6 *Bipolar Controls*
7-12 *Monopolar CUT controls*
1,2 *Standby, Ready Mode Selectors*
17,18 *Footswitch Keying Selectors*
13,16 *Monopolar COAG controls*

FIGURE 2

THE SSE4 CONTROL KEYBOARD ON THE FRONT PANEL

Electrosurgical
Generator

Service
Manual

Beacon
Laboratories 2150 W 6th Ave Unit P Broomfield, CO 80020
FAX 303-466-3042 800-955-2150

Valleylab

FORCE 4B

SERVICE MANUAL

Notice: This manual and the equipment it describes are for use only by qualified medical professionals.

EFFECTIVE DATE: JUNE, 1987

VALLEYLAB PART NUMBER A 945 100 083 A

PRINTED IN USA

VALLEYLAB, INC. 5920 LONGBOW DRIVE, P.O. BOX 9015 BOULDER, COLORADO 80301

(303) 530-2300 TWX 910-940-2514

SECTION 3

DESCRIPTION OF CONTROLS, INDICATORS, ALERTS AND RECEPTACLES

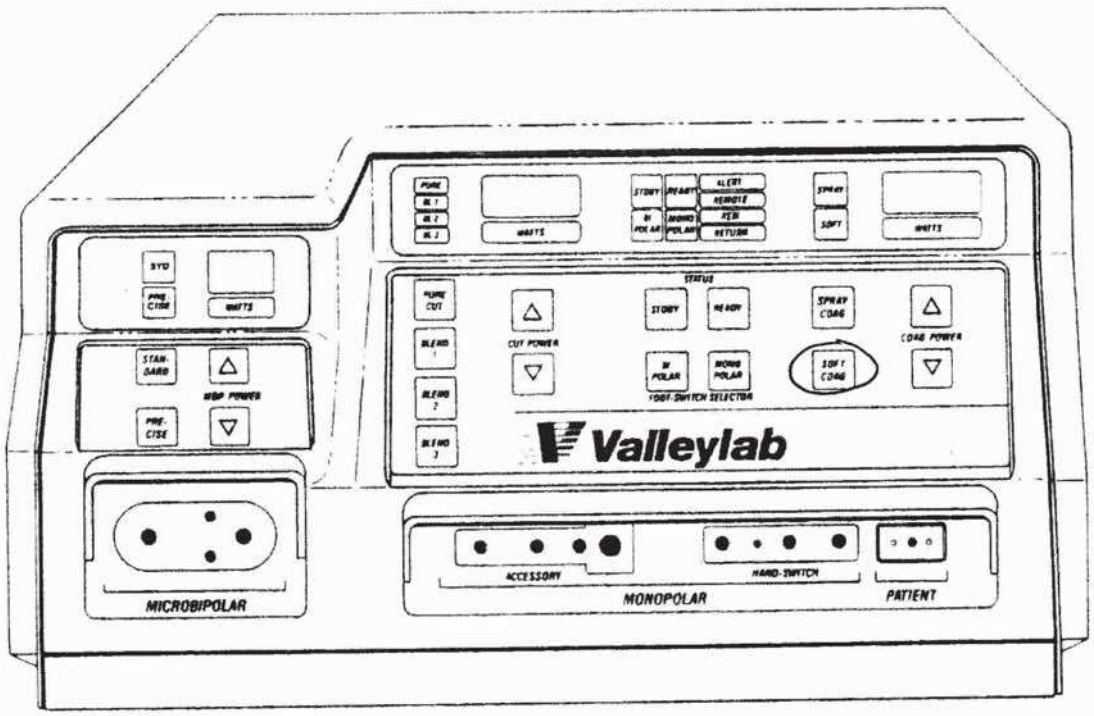


FIGURE 1

FORCE 4B FRONT PANEL

VL 888 Fig 4B 1987

CUT POWER

READY ▽

Remote Power Control Mode - The Remote Power Control feature does not have a dedicated button to access this mode. A two-step procedure is required. Refer to the Instruction Manual, Remote Power Changes.

SPRAY COAG

Spray - Selects coagulation current for general applications.

SOFT COAG

Soft - Selects coagulation mode for delicate applications.

COAG POWER

READY ▽

Low Voltage Coag - Low Voltage Coag does not have a dedicated button to access this mode. A two-step procedure is required. Refer to the Instruction Manual, Recommendations During Surgery.

STAN-DARD

Standard - Selects the standard Bipolar mode for desiccation.

PRE-CISE

Precise - Selects the precise mode for fine desiccation.

INDICATORS:

STDBY

Standby Indicator - Indicates generator is on, but cannot activate outputs.

READY

Ready Indicator - Indicates generator is ready for use.

PURE
BL 1
BL 2
BL 3

Mode Indicator Lamps - One of four CUT mode indicators is illuminated to show the selected Cut mode.

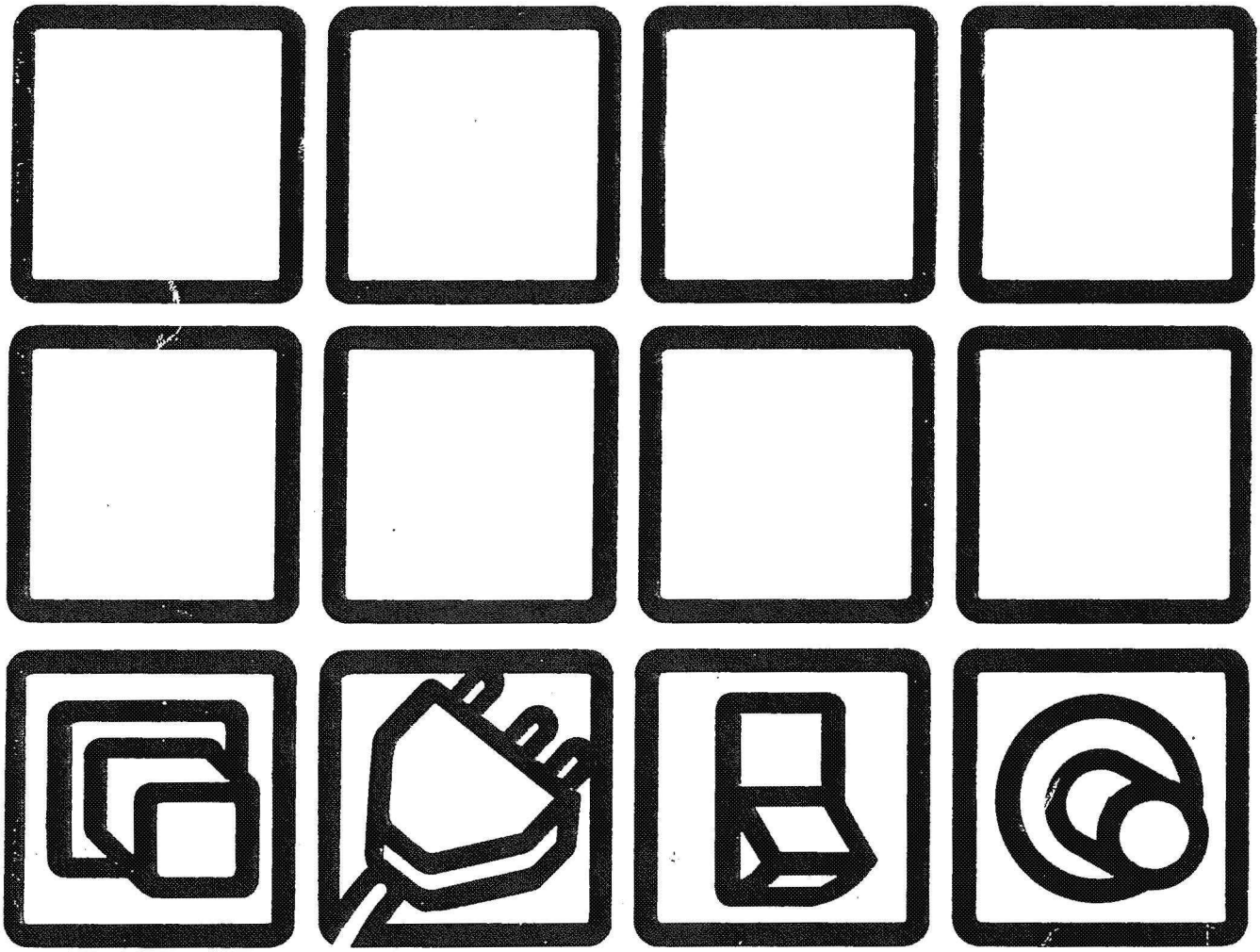
SPRAY
SOFT

One of the two COAG mode indicators is illuminated to show the selected Coag Mode. Note: Neither lamp is illuminated when the generator is in the Low Voltage Coag mode. See Instruction Manual.

STD
PRE-CISE

One of the two BIPOLAR mode indicators is illuminated to show the selected Bipolar mode. STANDARD is for "normal" and PRECISE is for delicate or microscopic procedures.

Buysse Exhibit C



Valleylab

SSE4

INSTRUCTION MANUAL

SSE4 INSTRUCTION MANUAL

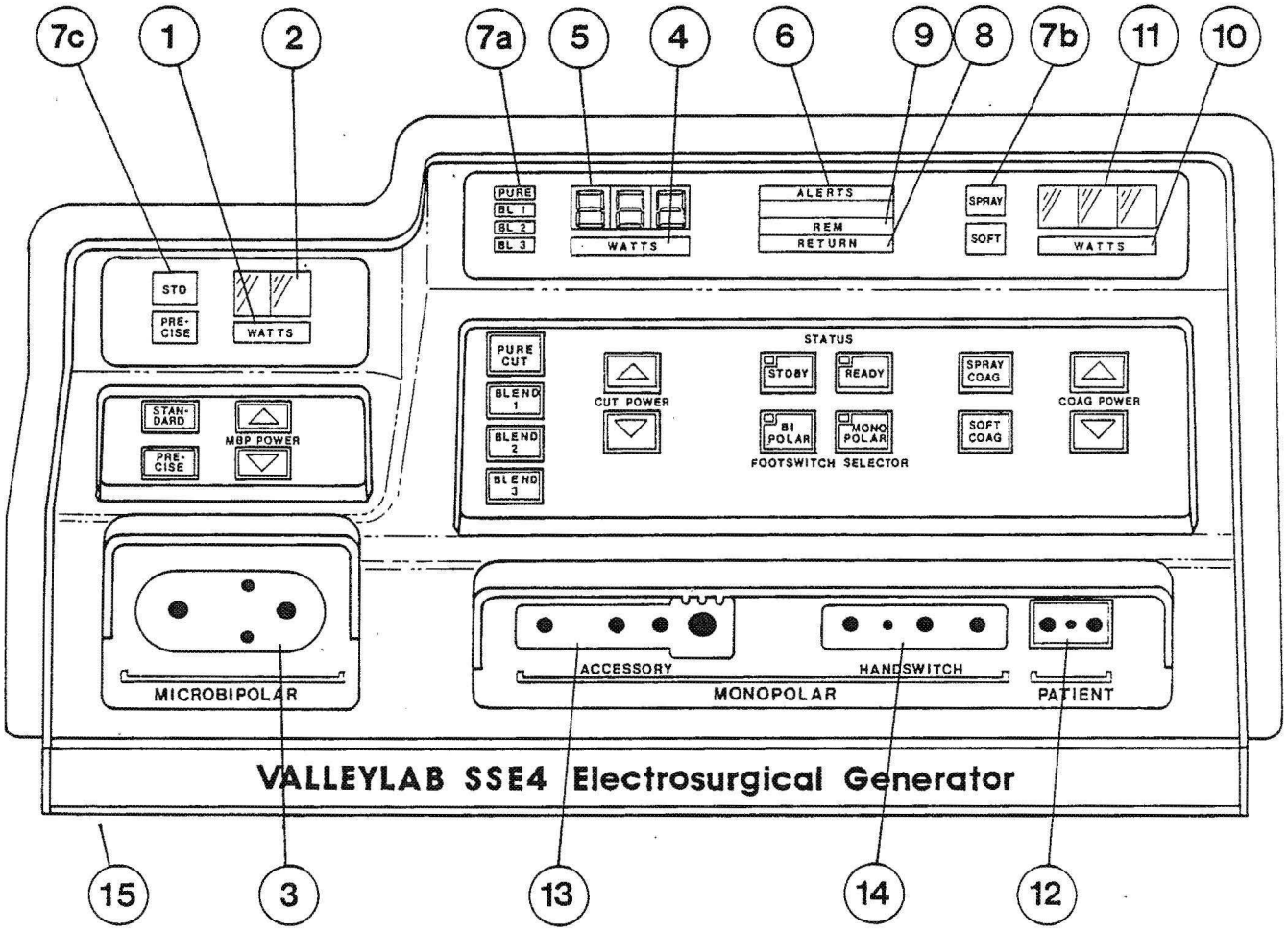
Effectivity Date: August 1, 1984

Valleylab P/N A 945 110 014 A

Printed in USA

SECTION 3

DESCRIPTION OF CONTROLS AND GENERATOR DESIGN



1,2 *Microbipolar Power*
4,5 *Monopolar Power - Cut*
6-9 *Alarm and Mode Indicators*
10,11 *Monopolar Power - Coag*
12 *REM connector*
13,14 *Monopolar Output Jacks*
3 *Bipolar Output Jacks*
15 *Audio Volume*

FIGURE 2

THE SSE4 INDICATORS AND OUTPUTS ON THE FRONT PANEL

FRONT PANEL INDICATORS AND OUTPUTS (SEE FIG. 2)

1. *BIPOLAR OUTPUT ACTIVE INDICATOR*

   The word 'WATTS' will be illuminated when useful output power is available at the Microbipolar Output Jack (3). Absence of illumination when the generator is keyed in the bipolar mode may indicate generator malfunction.

2. *BIPOLAR POWER READOUT*

   This digital LED display is visible when the generator is in the ready mode (2, Fig.3). The number displayed predicts the level of bipolar power, in watts, which will be delivered to a 100 ohm load when the generator is keyed in the bipolar mode.

3. *BIPOLAR ACTIVE RECEPTACLE*

   This receptacle will accept the three prong active bipolar accessories and will be keyed by the handswitch. It will also accept two prong active accessories and the bipolar generator is then keyed by the foot switch when the bipolar foot switch button, (18, Fig. 3), is pressed.

4. *MONOPOLAR CUT OUTPUT ACTIVE INDICATOR*

   The backlit word 'WATTS' will be visible when the generator is keyed in the cut mode and useful output power is available at either of the monopolar output jacks (13) and (14). Absence of illumination when the generator is keyed indicates a malfunction.

5. *MONOPOLAR CUT POWER READOUT*

   This digital LED display is visible when the generator is in the ready mode (2, Fig. 3). The number displayed predicts the level of monopolar cut power, in watts, which will be delivered to a 300 ohm load when the generator is keyed in the monopolar cut mode.

6. *ALERT INDICATOR*

   This LED lamp is on whenever the generator is disabled by an alarm condition. The audio alarm will sound twice when this lamp goes on.

7. *MODE INDICATOR LAMPS*

A. *One of four CUT mode indicators is illuminated to show the CUT power waveform. The mode may be changed by pressing one of the four mode selector push buttons (9,10,11,12; Fig. 3).*

Pure: 750 kHz sinusoid
Blend 1: 50% duty cycle 750 kHz sinusoid
Blend 2: 25% duty cycle 750 kHz sinusoid
Blend 3: 25% duty cycle 750 kHz sinusoid plus inductive discharge pulses.

B. *One of two COAG mode indicators is illuminated to show the COAG power waveform. Selection is done by pushing one of the mode selector push buttons (15,16; Fig. 3).*

SPRAY COAG: 31 kHz inductive discharge
SOFT COAG: 22 kHz inductive discharge

C. *One of two bipolar power mode indicators is illuminated to show the bipolar output power versus load impedance characteristics. Selection is by the push buttons (5,6; Fig. 3).*

STANDARD: Output power at 50 and 200 ohm loads is 1/2 of the power at a 100 ohm load.
PRECISE: Output power at a 200 ohm load is 1/4 of the 100 ohm output power.

8. *RETURN FAULT/GFI INDICATOR*

This LED illuminates if the SSE4 is keyed without a proper patient electrode connection, producing a situation where a significant proportion of the RF current returns to the generator by some path other than the patient connector (12). The SSE4 is disabled so long as the indicator is on. The audio alarm will sound three times when the alert is first detect- ed. The alarm can be cleared by releasing the hand or footswitch and then rekeying.

9. *REM FAULT INDICATOR (Return Electrode Monitor)*

This LED illuminates when the patient electrode contact monitor senses an alarm condition. For a single section (conventional) patient electrode the alarm condition is a resistance greater than 24 ohms between the pins of the patient electrode connector (12). For a Valleylab E7505/E7507 dual patient electrode the alarm condition is a resistance outside the range of 16 - 135 ohms or a 20% increase in resistance. The audio alarm will sound twice when the alarm is first detected. The alarm is cleared when the resistance is lowered and within the acceptance range.

10. *MONOPOLAR COAG OUTPUT ACTIVE INDICATOR*

The backlit word 'COAG' will be visible when the generator is keyed in the coagulation mode and useful output power is available at either of the monopolar output jacks (13) and (14). Absence of illumination when the generator is keyed may indicate a malfunction.

11. *MONOPOLAR COAGULATION POWER READOUT*

This digital LED display is visible when the generator is in the ready mode (2, Fig.3). The number displayed predicts the level of monopolar coagulation power, in watts, which will be delivered to a 300 ohm load when the generator is keyed in the monopolar coagulation mode.

12. *PATIENT RETURN ELECTRODE RECEPTACLE*

This 2 pin receptacle accepts the patient return electrode connector used in monopolar procedures. A pin on the patient electrode connector actuates a switch within the receptacle to indicate the use of the two section patient electrode used for contact area (REM) monitoring. (See Section 6, page 88.)

13. *MONOPOLAR ACTIVE RECEPTACLE - HAND OR FOOTSWITCH*

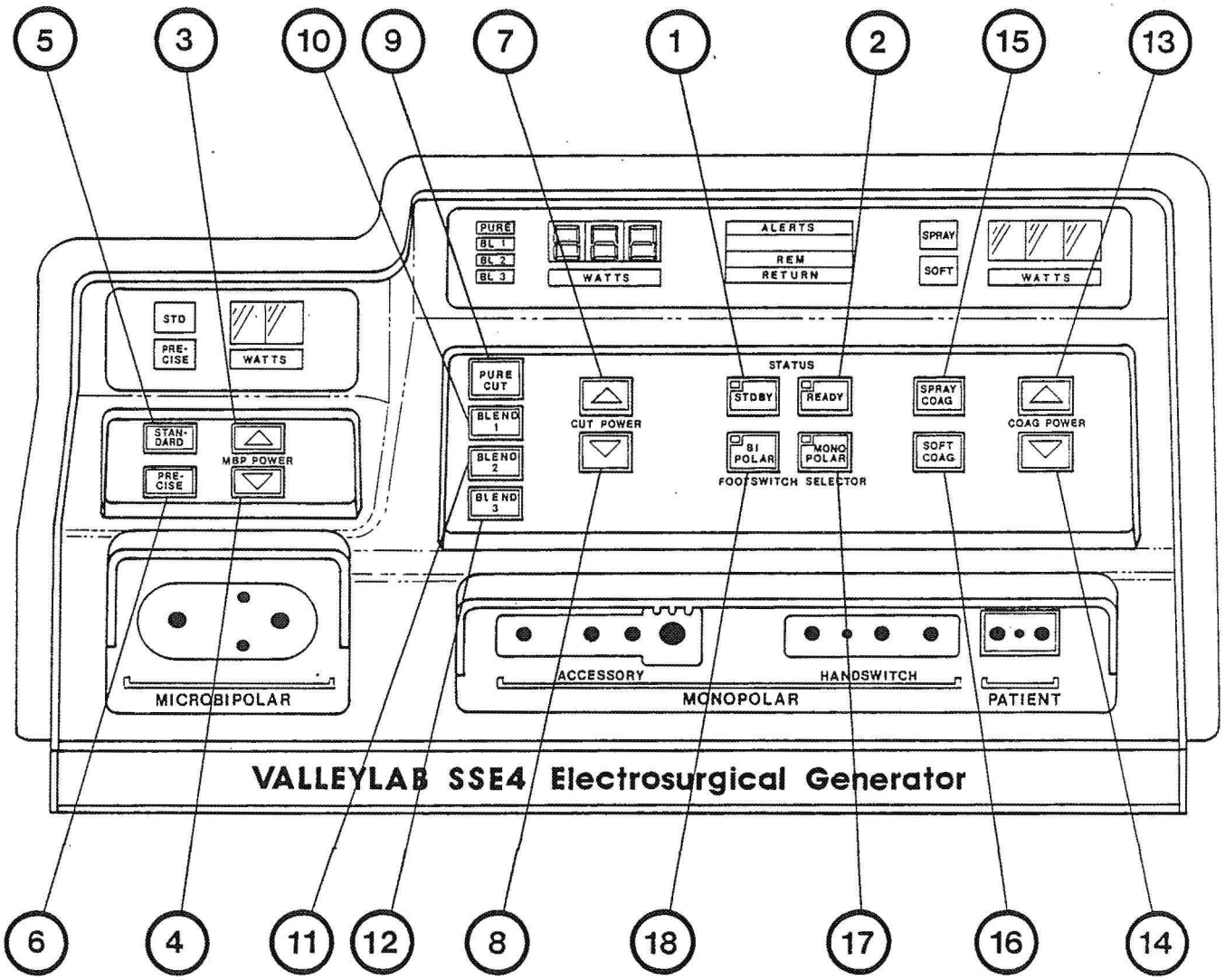
This receptacle will accept three prong handswitching active accessories (Valleylab E2502, E2508) or standard one prong active accessories (PL-55). This output can be activated by the footswitch when the monopolar footswitch button (17, Fig. 3) is pressed or by the handswitch accessory. Cut mode or coagulation mode power may be keyed at this receptacle.

14. *MONOPOLAR ACTIVE RECEPTACLE - HANDSWITCH*

This receptacle will accept the three prong handswitch active accessories (Valleylab E2502, E2508). This output is activated only by the handswitch and will have no power available if the generator is keyed by the footswitch. Cut mode or coagulation mode power may be keyed at this receptacle.

15. *AUDIO VOLUME CONTROL*

The volume of the cut and coag audio tones produced when the generator is keyed may be adjusted with this 4 position slide switch. Pull the switch forward to increase the volume, push it back to decrease the volume. The volume of the sound produced by alarm conditions is not adjustable.



3-6 *Bipolar Controls*
7-12 *Monopolar CUT controls*
1,2 *Standby, Ready Mode Selectors*
17,18 *Footswitch Keying Selectors*
13,16 *Monopolar COAG controls*

NOTE: On/Off switch is located on the back panel (See Figure 4).

FIGURE 3

THE SSE4 CONTROL KEYBOARD ON THE FRONT PANEL

FRONT PANEL KEYBOARD CONTROLS (SEE FIGURE 3)

1. *STANDBY MODE SELECTOR*

   In this mode the generator cannot be keyed and the audio alerts are suppressed. Prior power level settings are retained but the displays will be blank. The generator is in standby when power is first applied.

2. *READY MODE SELECTOR*

   Pressing this button places the generator in service with outputs and alarms fully active.

3. *BIPOLAR POWER INCREASE BUTTON*

   This button increases the bipolar power readout. A single push will raise the power by one watt. Holding the button down continuously will cause the display to increase continuously to 70 watts maximum.

4. *BIPOLAR POWER DECREASE BUTTON*

   Pressing this button decreases the bipolar power display by one watt per push, or continuously if the button is held down.

5. *STANDARD MODE SELECTOR*

   Pressing this button will select the Standard Microbipolar mode. See page 18 for the standard power versus impedance curve.

6. *PRECISE MODE SELECTOR*

   Pressing this button will select the Precise Microbipolar mode. See page 18 for the precise power versus impedance curve.

7. *MONOPOLAR CUT POWER INCREASE BUTTON*

   This button increases the monopolar cut power readout. A single push will increase the power by one watt, and holding the button down will increase the display to the mode maximum.

8. *MONOPOLAR CUT POWER DECREASE BUTTON*

   Pressing this button decreases the monopolar cut mode power display by one watt per push, or continuously if the button is held down.

9. *CUT MODE SELECTOR - PURE CUT*

Pressing this button will select a continuous sinewave cut waveform output.

10. *CUT MODE SELECTOR - BLEND 1*

Pressing this button will select a 50% duty cycle sinewave cut waveform output.

11. *CUT MODE SELECTOR - BLEND 2*

Pressing this button selects a cut mode waveform of 25% duty cycle sinewave for moderate hemostasis.

12. *CUT MODE SELECTOR - BLEND 3*

Pressing this button selects a cut mode output waveform of 25% sinewave plus inductive discharge. This is the cut waveform producing maximum hemostasis.

13. *MONOPOLAR COAGULATION POWER INCREASE BUTTON*

This button increases the monopolar coagulation power display. A single push will raise the power by one watt, and holding the button down will cause a continuous increase.

14. *MONOPOLAR COAGULATION POWER DECREASE BUTTON*

This button decreases the coagulation power display by one watt per push, or continuously when it is held down.

15. *COAG MODE SELECTOR - SPRAY COAG*

Pressing this button will select an inductive discharge with a 31 KHz repetition rate coagulation waveform.

16. *COAG MODE SELECTOR - SOFT COAG*

Pressing this button will select a coagulation waveform with inductive discharge at a lower repetition rate (22 KHz).

17. *FOOTSWITCH SELECTOR - MONOPOLAR*

Pressing this button places the monopolar output under footswitch keying control. (Footswitch Model E6008)

18. *FOOTSWITCH SELECTOR - BIPOLAR*

Pressing this button places the bipolar output under footswitch control. (Footswitch Model E6008)

SECTION 8

SSE4 TECHNICAL SPECIFICATIONS

OUTPUT WAVEFORM

CUT: 750 KHz sinusoid
BLEND 1 750 KHz bursts of sinusoid at 50% duty cycle recurring at 31 KHz.
BLEND 2 750 KHz bursts of sinusoid at 25% duty cycle recurring at 31 KHz.
BLEND 3 750 KHz bursts of sinusoid at 25% duty cycle plus inductive discharge damped sinusoid bursts, all bursts recurring at 31 KHz. Power is adjusted so that the sinusoidal bursts account for 75% of the power into a 300 ohm load and the damped sinusoid bursts account for the remainder.

SPRAY COAG: 750 KHz damped sinusoid bursts with a repetition frequency of 31 KHz.
SOFT COAG: 750 KHz damped sinusoid bursts with a repetition frequency of 22 KHz.
MICROBIPOLAR: 750 KHz sinusoid, unmodulated

OUTPUT CHARACTERISTICS

MODE	*MAXIMUM (OPEN CIRCUIT) P-P VOLTAGE*	*RATED LOAD (OHMS)*	*MAXIMUM POWER (AT RATED LOAD) WATTS*	*CREST FACTOR AT RATED LOAD + 20%*
CUT	*2500*	*300*	*300 ± 20*	*1.6 @ 100W*
BLEND 1	*2800*	*300*	*250 ± 20*	*2.6 @ 100W*
BLEND 2	*3000*	*300*	*200 ± 20*	*3.6 @ 100W*
BLEND 3	*3400*	*300*	*200 ± 20*	*4.4 @ 100W*
SPRAY COAG	*9000*	*300*	*120 ± 10*	*9.0 @ 50W*
SOFT COAG	*9000*	*300*	*60 ± 5*	*13.0 @ 30W*
MICROBIPOLAR	*400*	*100*	*70 ± 8*	*1.6 @ 40W*

Microbipolar has selectable output characteristics: power approximately proportional to $\frac{I}{R}$ *or* $\frac{I}{R^2}$ *(Standard and Precise).*

POWER READOUTS

Three L.E.D. displays (for coag, cut and microbipolar) indicate output power. Power readouts agree with actual power into rated load to within ± 15% or 5 watts whichever is greater.

LOW FREQUENCY LEAKAGE (50/60 HERTZ)

Source current, patient leads, all outputs tied together
Normal polarity, intact chassis ground, 2.0 uA
Normal polarity, ground open, 30uA
Reverse polarity, ground open, 30uA
Sink current, 140 volts applied, all inputs 150uA

Buysse Exhibit D

FORCE 4

SERVICE MANUAL

220V

EFFECTIVITY DATE: May 1, 1985

VALLEYLAB PART NUMBER A 945 100 055 A

PRINTED IN USA

5920 LONGBOW DRIVE, P.O. BOX 9015, BOULDER, COLORADO 80301

303 530-2300 TWX 910-940-2514

AF

26

Pure: *750 kHz sinusoid*
Blend 1: *50% duty cycle, 750 kHz sinusoid*
Blend 2: *25% duty cycle, 750 kHz sinusoid*
Blend 3: *25% duty cycle, 750 kHz sinusoid plus inductive discharge pulses.*

B. *One of two COAG mode indicators is illuminated to show the COAG power waveform. Select by pushing one of the mode selector push buttons (15,16; Fig. 3)*

SPRAY COAG: *31 kHz inductive discharge*
SOFT COAG: *22 kHz inductive discharge*

C. *One of two bipolar power mode indicators is illuminated to show the bipolar output power versus load impedance characteristics. Selection is by the push buttons (5,6; Fig. 2).*

STANDARD: *Output power at 50 and 200 ohm loads is 1/2 of the power at a 100 ohm load.*
PRECISE: *Output power at a 200 ohm load is 1/4 of the 100 ohm output power.*

8. *RETURN FAULT INDICATOR*

This LED illuminates if the FORCE 4 is keyed without a proper patient electrode connection, producing a situation where a significant proportion of the RF current returns to the generator by some path other than the patient connector (12). The FORCE 4 is disabled so long as the indicator is on. The audio alarm will sound twice when the alert is first detected. The alarm can be cleared by releasing the hand or footswitch and then rekeying the unit.

9. *REM FAULT INDICATOR (Return Electrode Monitor)*

This LED illuminates when the patient electrode contact monitor senses an alarm condition. For a single-section patient electrode the alarm condition is a resistance greater than 16 ohms between the pins of the patient electrode connector (12). For a dual-section patient electrode the alarm condition is a resistance outside the range of 5 - 135 ohms or a 30% increase in resistance. The audio alarm will sound twice when the alarm is first detected. The alarm is cleared when the resistance is lowered and is within the acceptance range.

10. *MONOPOLAR COAG OUTPUT ACTIVE INDICATOR*

The backlit word 'WATTS" will be visible when the generator is keyed in the coagulation mode and useful output power is available at either of the monopolar output jacks (13) and (14). Absence of illumination when the generator is keyed may indicate a malfunction.

10. *CUT MODE SELECTOR - BLEND 1*

Pressing this button will select a 50% duty cycle sinewave cut waveform output.

11. *CUT MODE SELECTOR - BLEND 2*

Pressing this button selects a cut mode waveform of 25% duty cycle sinewave for moderate hemostasis.

12. *CUT MODE SELECTOR - BLEND 3*

Pressing this button selects a cut mode output waveform of 25% sinewave plus inductive discharge. This is the cut waveform producing maximum hemostasis.

13. *MONOPOLAR COAGULATION POWER INCREASE BUTTON*

This button increases the monopolar coagulation power display. A single push will raise the power by one watt, and holding the button down will cause a continuous increase.

14. *MONOPOLAR COAGULATION POWER DECREASE BUTTON*

This button decreases the coagulation power display by one watt per push, or continuously when it is held down.

15. *COAG MODE SELECTOR - SPRAY COAG*

Pressing this button will select an inductive discharge with a 31 KHz repetition rate coagulation waveform.

16. *COAG MODE SELECTOR - SOFT COAG*

Pressing this button will select a coagulation waveform with inductive discharge at a lower repetition rate (22 KHz).

17. *FOOTSWITCH SELECTOR - MONOPOLAR*

Pressing this button places the monopolar output under footswitch keying control.

18. *FOOTSWITCH SELECTOR - BIPOLAR*

Pressing this button places the bipolar output under footswitch control.

SECTION 5

FORCE 4 TECHNICAL SPECIFICATIONS

OUTPUT WAVEFORM

CUT 750 kHz sinusoid

BLEND 1 750 kHz bursts of sinusoid at 50% duty cycle recurring at 31 kHz.

BLEND 2 750 kHz bursts of sinusoid at 25% duty cycle recurring at 31 kHz.

BLEND 3 750 kHz bursts of sinusoid at 25% duty cycle plus inductive discharge damped sinusoidal bursts, all bursts recurring at 31 kHz. Power is adjusted so that the sinusoid bursts account for 75% of the power into a 300 ohm load and the damped sinusoid bursts account for the remainder.

SPRAY COAG 750 kHz damped sinusoidal bursts with a repetition frequency of 31 kHz.

SOFT COAG 750 kHz damped sinusoidal bursts with a repetition frequency of 22 KHz.

MICROBIPOLAR 750 kHz sinusoid, unmodulated

OUTPUT CHARACTERISTICS

Mode	Maximum (open circuit) P-P Voltage	Rated Load (Ohms)	Maximum Power (at Rated Load) (Watts)	Crest Factor At Rated Load +10%
CUT	2500	300	300 ± 20	1.9 @ 100W
BLEND 1	2800	300	250 ± 20	2.6 @ 100W
BLEND 2	3000	300	200 ± 20	3.7 @ 100W
BLEND 3	3400	300	200 ± 20	4.4 @ 100W
SPRAY COAG	9000	300	120 ± 10	9.0 @ 50W
SOFT COAG	9000	300	60 ± 5	13.0 @ 30W
MICROBIPOLAR	400	100	70 ± 8	1.6 @ 40W

Microbipolar has selectable output characteristics: power approximately proportional to I/R or I/R^2 (Standard or Precise).

POWER READOUTS

Three L.E.D. displays (for coag, cut and microbipolar) indicate output power. Power readouts agree with actual power into rated load to within ± 10% or 5 watts, whichever is greater.

Buysse Exhibit E

COVIDIEN

User's Guide

Valleylab™ FT10

FT Series Energy Platform

Cov-SOFT00017

Modes & Settings

The VLFT10GEN provides the following modes and settings for a variety of surgical procedures:

Monopolar modes	Power-Setting Ranges	Peak Voltage
• CUT		
- PURE	Off, 1–300 W	1287 V
- BLEND	Off, 1–200 W	2178 V
• VALLEYLAB	5–85 W	2783 V
• COAG		
- SOFT	Off, 1–120 W	264 V
- FULGURATE	Off, 1–120 W	3449 V
- SPRAY	Off, 1–120 W	3933 V
Bipolar effects		
• LOW	Off, 1–15 W	133 V
• MEDIUM	16–40 W	214 V
• HIGH	45–95 W	462 V
LigaSure (tissue fusion)	No power settings	244 V
Bipolar Resection effect		
• CUT	1–6	742 V
• COAG	1–6	318 V

Monopolar Modes

The system produces six modes of monopolar power output.

Precaution

To provide expected functionality from a hand piece, proper insertion is required. Refer to the alignment dots below the receptacles for proper insertion orientation.

CUT Modes

PURE CUT provides a clean, precise cut in any tissue with little or no hemostasis.

BLEND CUT is a conventional blended waveform that provides slower cutting with simultaneous hemostasis.

VALLEYLAB Mode

VALLEYLAB mode is a unique combination of hemostasis and dissection that allows the user to slow down for more hemostasis and speed up for faster dissection. Thermal spread is equal to or less than CUT or BLEND modes.

COAG Modes

SOFT desiccates tissue at a relatively slower rate with deeper thermal penetration. It is typically performed with a ball electrode.

FULGURATE coagulates tissue by sparking from the active electrode, through air, to the patient tissue.

SPRAY delivers wider fulguration; penetration is shallower and the affected tissue area is larger than with the FULGURATE mode.

Compatible Monopolar Instruments & Devices

The following Covidien catalog numbers for monopolar surgical instruments, return electrodes, foot pedals, and adapters are fully compatible with the VLFT10GEN.

UFP-Receptacle Adapter (connect only to Monopolar 1)

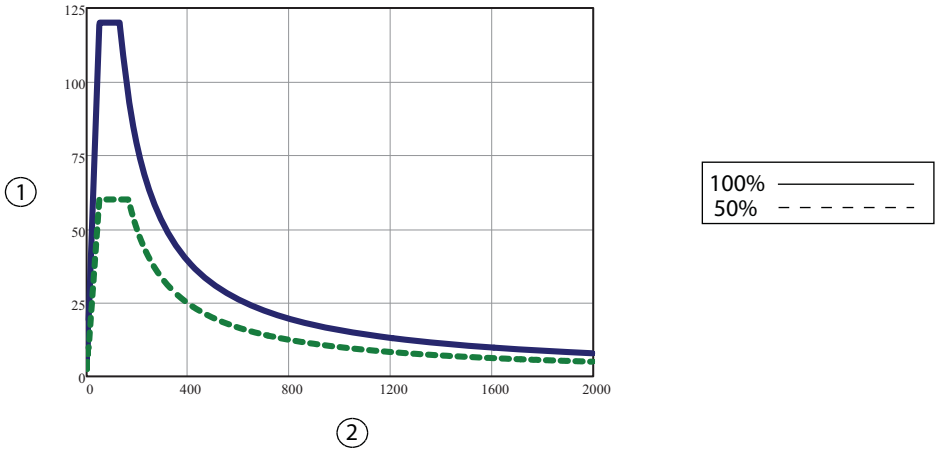
E05021 Monopolar Adapter
E050212 Monopolar Adapter

Instruments (connect only to Monopolar 2 receptacle)

FT3000DB Force TriVerse™ Electrosurgical Device
FT3000 Force TriVerse Electrosurgical Device

SOFT COAG

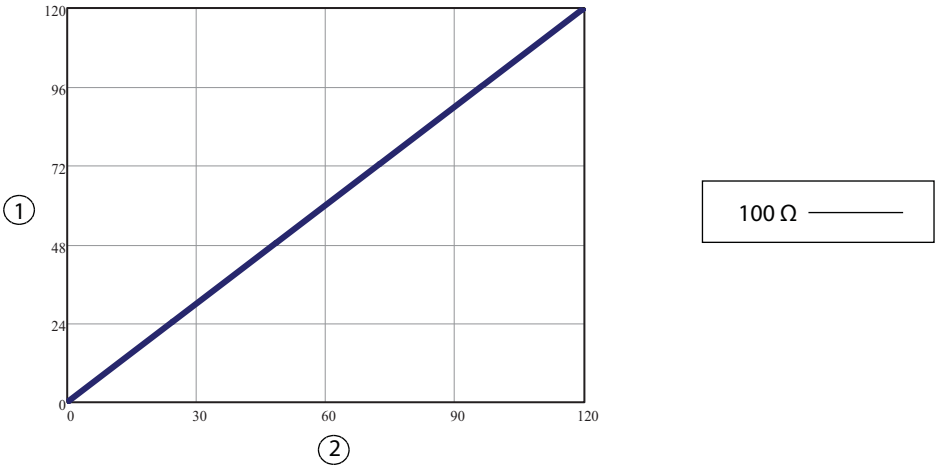
Output power versus impedance for SOFT COAG power



① Output power (watts)

② Load impedance (ohms)

Output power versus power setting for SOFT COAG power



① Output power (watts)

② Power setting

Rx ONLY

Consult instructions for use

ME20

0086

COVIDIEN

Part No. 1073652

Made in USA. Printed in USA.

Covidien llc, 15 Hampshire Street, Mansfield, MA 02048 USA.

EC REP Covidien Ireland Limited, IDA Business & Technology Park, Tullamore.

www.covidien.com

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1-800-255-8522 [T]

REV 01/2015

Buysse Exhibit F

IEC 60601-2-2

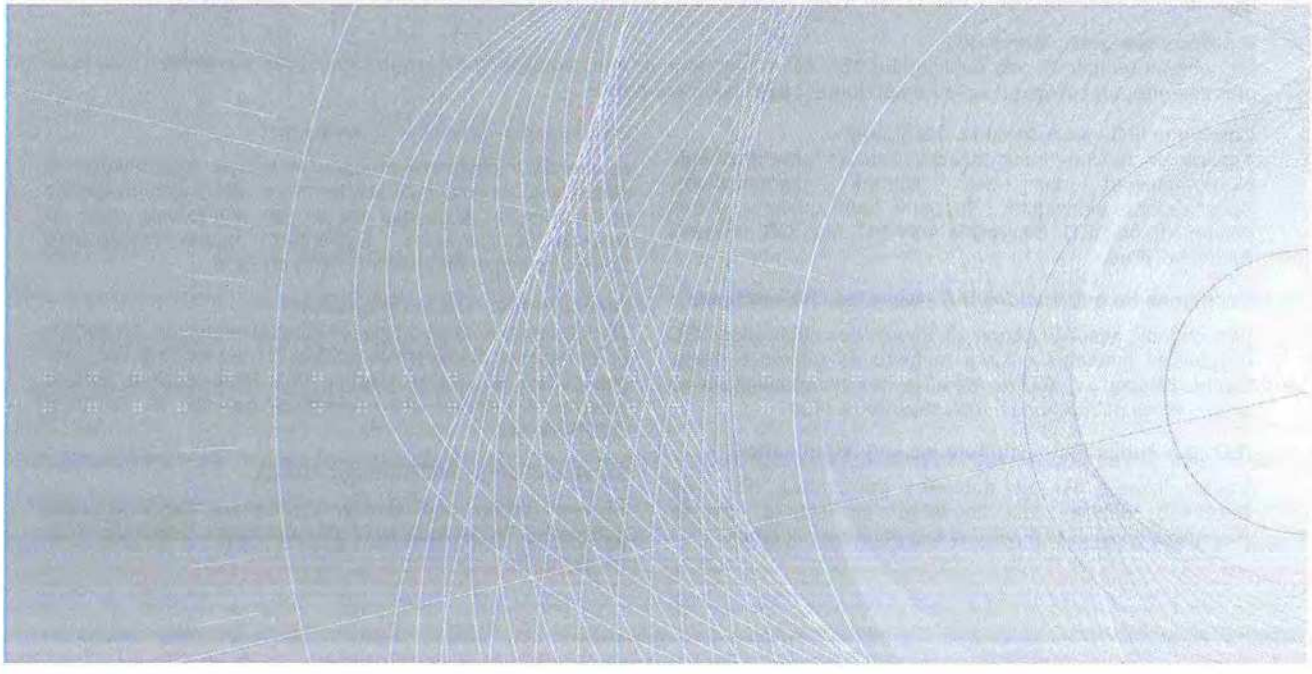
Edition 6.0 2017-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Appareils électromédicaux –
Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence



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Edition 6.0 2017-03

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ISBN 978-2-8322-4008-3

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-2 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This sixth edition cancels and replaces the fifth edition published in 2009. This edition constitutes a technical revision. This edition includes the following significant technical changes with respect to the previous edition:

- refinement and additions to the defined terms;
- additional separation of the requirements for HF surgical equipment and HF surgical accessories;
- a new requirement for adult neutral electrodes to be contact quality monitoring neutral electrodes;
- new requirements for devices that have or use a high current mode.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/1427/FDIS	62D/1442/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- requirements and definitions: roman type;
- *test specifications: italic type;*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of HIGH FREQUENCY SURGICAL EQUIPMENT.

This particular standard amends and supplements IEC 60601-1:2005 and Amendment 1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard (see 201.1.4).

The requirements are followed by specifications for the relevant tests.

A "Particular guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

Clauses or subclauses for which there are explanatory notes in Annex AA are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this document.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES as defined in 201.3.224 and 201.3.223.

HF SURGICAL EQUIPMENT having a RATED OUTPUT POWER not exceeding 50 W (for example for micro-COAGULATION, or for use in dentistry or ophthalmology) is exempt from certain of the requirements of this particular standard. These exemptions are indicated in the relevant requirements.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HF SURGICAL EQUIPMENT and HF SURGICAL ACCESSORIES as defined in 201.3.224 and 201.3.223.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2014 and IEC 60601-1-8:2006 apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3, IEC 60601-1-10 and IEC 60601-1-11 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

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[1] The general standard is IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"*Addition*" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 87.

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Addition:

CISPR 11:2015, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

IEC 61000-4-3:2006, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency electromagnetic field immunity test*

IEC 61000-4-6:2013, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

Replace NOTE 1 with the following:

NOTE 1 Where the terms "voltage" and "current" are used in this document, they mean the RMS values of an alternating, direct or composite voltage or current averaged over 1 s unless stated otherwise.

Addition:

201.3.201
ACTIVE ACCESSORY
HF SURGICAL ACCESSORY intended for manipulation by the OPERATOR to produce an effect by electrical conduction adjacent to the ACTIVE ELECTRODE at the intended site on the PATIENT, generally comprising an ACTIVE HANDLE, the cord of an ACTIVE ACCESSORY, ACTIVE CONNECTOR and ACTIVE ELECTRODE

201.3.202
ACTIVE CONNECTOR
part of an ACTIVE ACCESSORY intended for connection to an ACTIVE OUTPUT TERMINAL, which may include additional terminals for connection of a FINGERSWITCH to a SWITCH SENSOR

201.3.203
ACTIVE ELECTRODE
part of an ACTIVE ACCESSORY extending from the ACTIVE HANDLE to the surgical site and intended to pass HF current into body tissue

201.3.204
ACTIVE ELECTRODE INSULATION
electrical insulation material affixed to part of an ACTIVE ELECTRODE intended to prevent unintended injury to PATIENT tissue or the OPERATOR

201.3.205
ACTIVE HANDLE
part of an ACTIVE ACCESSORY intended to be held by the OPERATOR

201.3.206
ACTIVE OUTPUT TERMINAL
part of HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT intended for connection to an ACTIVE ACCESSORY and for delivery of HF current thereto

Note 1 to entry: An ACTIVE CONNECTOR is that which plugs into an ACTIVE OUTPUT TERMINAL.

Note 2 to entry: See Figure AA.1.

201.3.207
***ASSOCIATED EQUIPMENT**
MEDICAL ELECTRICAL EQUIPMENT other than HF SURGICAL EQUIPMENT that may be electrically connected to the PATIENT circuit

201.3.208
***BIPOLAR**
method of applying HF current to a PATIENT between two or more ACTIVE ELECTRODES without the need for a separately connected NEUTRAL ELECTRODE (or the need to use the PATIENT'S body capacitance to earth) in which an effect is intended in tissue near one or more ACTIVE ELECTRODES

Note 1 to entry: The BIPOLAR method includes devices energizing pairs of ACTIVE ELECTRODES as well as devices energizing groups of ACTIVE ELECTRODES where the HF current source and return may have different numbers of electrodes.

Note 2 to entry: See Figure AA.1 and Figure AA.3.

201.3.209
BIPOLAR ACCESSORY
ACTIVE ACCESSORY comprising two or more ACTIVE ELECTRODES on the same support, so constructed that, when energized, the HF current flows mainly amongst these electrodes

201.3.210
COAGULATION
use of HF current to induce a thermal effect, e.g. to control or prevent bleeding, induce tissue destruction, or induce tissue shrinkage

Note 1 to entry: COAGULATION may take the form of contact or non-contact COAGULATION.

Note 2 to entry: FULGURATION, desiccation, spray, forced, swift, soft and argon beam (plasma) COAGULATION are all names of COAGULATION types.

201.3.211
CONTACT QUALITY MONITOR
CQM
circuit in HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT intended for connection to a MONITORING NE providing an alarm in the event that NEUTRAL ELECTRODE (NE) contact with the PATIENT becomes insufficient

Note 1 to entry: CONTACT QUALITY MONITOR is functional only when used with a MONITORING NE.

201.3.212
CONTINUITY MONITOR
circuit in HF SURGICAL EQUIPMENT or ASSOCIATED EQUIPMENT intended for connection to an NE providing an alarm in the event of electrical discontinuity in the NE cable or its connections

201.3.213
***CREST FACTOR**
dimensionless value equal to the peak output voltage divided by the RMS voltage as measured at the output of HF SURGICAL EQUIPMENT in an open circuit condition

Note 1 to entry: Specific information on the correct way to make the measurements needed to calculate this value may be found in Annex AA.

201.3.214
***CUTTING**
division of body tissue caused by the passage of HIGH FREQUENCY current of high current density at the ACTIVE ELECTRODE (S)

201.3.215
***EARTH REFERENCED PATIENT CIRCUIT**
PATIENT circuit which includes components, such as capacitors, installed to provide a low-impedance path to earth for HF currents

201.3.216
FINGERSWITCH
device generally included with an ACTIVE ACCESSORY which, when manipulated by the OPERATOR, enables HF output to be produced and, when released disables HF output

Note 1 to entry: Requirements for similar switches intended to perform functions other than activation of HF output are under consideration.

201.3.217
***FULGURATION**
the use of HF current to produce an effect on a tissue surface by electrical sparks from an ACTIVE ELECTRODE that is not in physical contact with the tissue

201.3.218
***HEATING FACTOR**
a value equal to $I^2 \times t$ where I is the MONOPOLAR current in amperes and t is the duration of the current flow in s

Note 1 to entry: The HEATING FACTOR is expressed as A^2s (amperes squared seconds).

Note 2 to entry: See subclause 201.15.101.5 in Annex AA for additional information.

201.3.219
***HIGH CURRENT MODE**
MONOPOLAR output mode whose INTENDED USE (MAXIMUM OUTPUT CURRENT and maximum DUTY CYCLE) results in a HEATING FACTOR of greater than 30 A^2s in any 60 s period

201.3.220
***HIGH FREQUENCY**
HF
frequencies less than 5 MHz and generally greater than 200 kHz

201.3.221
HF ISOLATED PATIENT CIRCUIT
HF PATIENT CIRCUIT where there are no components installed to provide a low-impedance path to earth for HF currents

201.3.222
HF PATIENT CIRCUIT
any electrical circuit which contains one or more PATIENT CONNECTIONS including all conductive parts of the HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT circuits through which HF current is intended to flow between the ME EQUIPMENT and the PATIENT in NORMAL CONDITION or SINGLE FAULT CONDITION

201.3.223
HF SURGICAL ACCESSORY
ACCESSORY intended to conduct, supplement or monitor HF energy applied to the PATIENT from HF SURGICAL EQUIPMENT

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Additional subclause:

201.4.7.101 Specific SINGLE FAULT CONDITIONS

The following SINGLE FAULT CONDITIONS are the subject of specific requirements and tests in this document:

a) failure in the CONTINUITY MONITOR or CONTACT QUALITY MONITOR which might cause a unacceptable RISK (see 201.8.4.101);

b) a defect in the output switching circuit resulting in an excessive low-frequency PATIENT LEAKAGE CURRENT (see 201.8.10.4.101.1);

c) any defect which results in the unwanted energization of the PATIENT circuit (see 201.12.4.2.101);

d) any defect which results in a significant increase in output power relative to the output setting (see 201.12.4.4.101).

201.4.11 Power input

Replacement of first dash in compliance tests:

– The HF SURGICAL EQUIPMENT shall be operated in the output mode and using the load which creates the greatest steady state input current. Input current is measured and compared with markings and the contents of the technical description.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.4 * Other conditions

Addition:

aa) Particular care shall be taken to ensure accuracy and safety during measurement of HF output. See Annex AA for guidance.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.8.2 Other power sources

Amendment:

Subclause 7.2.8.2 of the general standard does not apply to ACTIVE OUTPUT TERMINALS or NE terminals.

201.7.2.10 APPLIED PARTS

Addition:

The relevant symbols required for marking DEFIBRILLATION-PROOF APPLIED PARTS shall be attached to the front panel, but are not required on the APPLIED PARTS.

Connections on the HF SURGICAL EQUIPMENT and ASSOCIATED EQUIPMENT for the connection of NE leads shall be marked with the symbols given in Figures 201.101 and 201.102 as follows:

Figure 201.101 – Symbol used with an EARTH REFERENCED PATIENT CIRCUIT

Figure 201.102 – Symbol used with a HF ISOLATED PATIENT CIRCUIT

Additional subclause:

201.7.2.10.101 * HF SURGICAL ACCESSORIES

HF SURGICAL ACCESSORIES (excluding HF ASSOCIATED EQUIPMENT) shall not be required to display the TYPE BF or TYPE CF mark on the ACCESSORY itself, the ACCOMPANYING DOCUMENTS, or on the packaging unless the RISK MANAGEMENT FILE identifies an unacceptable RISK associated with this exclusion.

201.7.4.2 * Control devices

Addition:

The output control shall have a scale and/or associated indicator showing the relative units of HIGH FREQUENCY output. The indication shall not be marked in watts unless the indicated power is delivered with an accuracy of ± 20 % over the total load resistance range specified in 201.7.9.3.1.

The numeral "0" shall not be used unless no HF power in excess of 10 mW is delivered from an ACTIVE ELECTRODE or BIPOLAR ACCESSORY in this position.

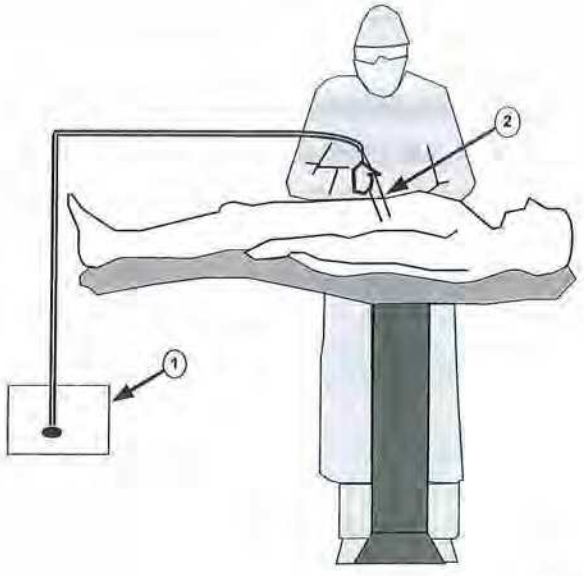
NOTE The compliance test is the application of subclause 201.12.1.102.

201.7.8.1 * Colours of indicator lights

Replace Table 2 in the general standard with the following Table 201.101:

Table 201.101 – Colours of indicator lights and their meaning for HF SURGICAL EQUIPMENT

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required, for example, a fault in the PATIENT circuit
Yellow	CUTTING mode
Blue	COAGULATION mode
Green	Ready for use
Any other colour	Meaning other than that of red, yellow, blue or green



Key

1 HF SURGICAL EQUIPMENT (generator)

2 BIPOLAR ACCESSORY

Figure AA.3 – Example of BIPOLAR method of HF surgery

Definition 201.3.213 – CREST FACTOR

The measurement of CREST FACTOR is mathematically simple but difficult to carry out in a reliable manner. The RMS voltage is particularly difficult to measure. The definition states that the measurements should be made in an open circuit condition. This means that the normal loads seen on the output of HF SURGICAL EQUIPMENT are not present. The load presented by the high voltage probe used to measure these voltages (10 MΩ to 100 MΩ typical) is considered to be essentially an open circuit. The following is a suggested method for these measurements that has shown a reasonable accuracy.

The measurements should be made from the output to the NE for MONOPOLAR outputs and across the two output poles for BIPOLAR outputs using a 1 000x or 100x high voltage probe connected to a high quality digital storage oscilloscope (DSO) with automatic measurement capabilities. First the exact period of the signal is then measured. For continuous sinusoidal waveforms (*cf* = 1,4) this is the reciprocal of the fundamental frequency of the waveform. For non-continuous waveforms, the time period of the bursts is measured. For example, a COAGULATION waveform may have a fundamental frequency of 400 kHz with a burst repetition rate of 20 kHz. It is the precise measurement of the 20 kHz burst repetition rate that is needed. Once this time period is measured, the time base of the DSO should be modified to make the entire screen hold between 5 and 10 exact periods. For example, if the burst repetition rate is exactly 20 kHz, the period will be 50 μs. By setting the time base of the DSO to 50 μs per division, you should get exactly 10 waveform bursts on the screen.

The waveform is then captured and stored. Measure and record the MAXIMUM OUTPUT VOLTAGE (the absolute value of the largest peak). The RMS voltage is then calculated. The most reliable method is to set the DSO to calculate the RMS. of the entire screen. Since the time base was adjusted to capture an exact multiple of waveforms, the calculation of RMS voltage should be accurate.

An alternate way of measuring the RMS voltage would be to connect the output of the high voltage probe into a thermal sensing true RMS voltmeter that is RATED for the CREST FACTOR of the waveform being measured.

The CREST FACTOR can now be calculated.

Definition 201.3.214 – CUTTING

It is generally believed that HF surgical CUTTING involves microscopic cellular ablation resulting from short electrical sparks being struck between the ACTIVE ELECTRODE and the tissue.

Definition 201.3.215 – EARTH REFERENCED PATIENT CIRCUIT

For purposes of this particular standard, the impedance of this path, at the lowest HF operating frequency, is 10 Ω or less. See Figure AA.5.

Definition 201.3.217 – FULGURATION

FULGURATION generally requires HF peak output voltages of at least 2 kV in order to ignite and sustain the long sparks. This mode is also known as spray or non-contact COAGULATION and may be enhanced by incorporation of a stream of inert gas such as argon.

Definition 201.3.218 – HEATING FACTOR

This value is a way to describe the thermal stress placed on a NE based on the energy delivered during a finite period of time.

NOTE See subclause 201.15.101.5 in this annex for additional information.

Definition 201.3.219 – HIGH CURRENT MODE

This mode describes situations where the NE thermal stress is greater than the value present in the validation test of subclause 201.15.101.5.

Definition 201.3.220 – HIGH FREQUENCY

Frequencies above 200 kHz should be used for MONOPOLAR applications in order to avoid the unwanted stimulation of nerves and muscles which would result from the use of low frequency current. Lower frequencies may be used for BIPOLAR techniques if the RISK ANALYSIS shows the possibility of neuromuscular stimulation has been mitigated to an acceptable level.

Normally, frequencies above 5 MHz are not used in order to minimize the problems associated with HIGH FREQUENCY LEAKAGE CURRENTS. It is generally recognized that 10 mA is the lower threshold of thermal effects on tissue.

Definition 201.3.225 – HF SURGICAL MODE

The term HF SURGICAL MODE should be clearly distinct from "mode of operation" as used in subclauses 6.6 and 7.2.11 of the general standard in reference to operational DUTY CYCLE.

Definition 201.3.226 – MAXIMUM OUTPUT CURRENT

This information is required by MANUFACTURERS in order to design a NE suitable for use with the HIGH CURRENT MODE. This value is used to calculate a maximum HEATING FACTOR to which the NE(S) will be exposed.

Definition 201.3.227 – MAXIMUM OUTPUT VOLTAGE

This parameter is intended for comparison by the OPERATOR to RATED ACCESSORY VOLTAGE to ensure safety.

1) In past editions of this document, this subclause included advice to place the NEUTRAL ELECTRODE as close to the operating field as possible. In general, minimising the distance between the operating field and the NEUTRAL ELECTRODE reduces the load resistance and, for a given power at the site of the ACTIVE ELECTRODE, the power output required from HF SURGICAL EQUIPMENT and also the HF voltage across the PATIENT. However, if the direct path between the ACTIVE ELECTRODE and the NEUTRAL ELECTRODE includes small cross sectional areas of tissue, the current density could cause undesired heating and tissue damage. Therefore the OPERATOR should rely on the instructions for use provided by the MANUFACTURER of the NEUTRAL ELECTRODE for specific placement instructions.
2) Small area contacts with objects having a low impedance to earth at HIGH FREQUENCIES may result in high current densities and hence unwanted burns.
3) There may be some HF voltage difference between these parts of the PATIENT's body which may cause an unwanted current to flow.
4) The current flowing to the leads of the monitoring equipment may cause burns at the site of the monitoring electrodes.
5) The capacitance between the electrode cable and the PATIENT may result in some local high current densities.
6) In certain cases, BIPOLAR technique can avoid unwanted tissue damage, especially where bony structures having a relatively high resistance or parts of the body having a relatively small cross section are involved
8) In this case, the application of the NEUTRAL ELECTRODE and its connections should be checked before selecting a higher output power.

Not all advice is necessary, if only a BIPOLAR output or a RATED OUTPUT POWER not exceeding 50 W without NEUTRAL ELECTRODE is available.

Subclause 201.7.9.2.2.101 c)

Past editions of IEC 60601-2-18 contained requirements prescribing that MANUFACTURERS of HF energized devices provide information regarding the maximum allowed peak HF voltage as well as modes of intended use. It is felt that this information on the one hand is insufficient, as the modes of intended use such as "spray COAGULATION" are not clearly technically defined and may vary considerably between different brands and models of HF SURGICAL EQUIPMENT. On the other hand, it was considered impracticable to give such rather complex information to the user of the equipment.

Therefore it was considered more practicable to provide the user only with a RATED ACCESSORY VOLTAGE and a MAXIMUM OUTPUT VOLTAGE for any output setting in order to enable the user to judge whether any HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT can be safely used with any certain output setting of the generator.

At HIGH FREQUENCY the stability of insulation is affected by dielectric heating so the relationship between the MAXIMUM OUTPUT VOLTAGE and the CREST FACTOR is important.

Further, it was considered that with all currently known brands and models of generators in modes and settings producing higher output voltages, the CREST FACTOR is always increased along with the voltage. Therefore a general relation between output voltage and CREST FACTOR was developed as shown in Figure AA.4.

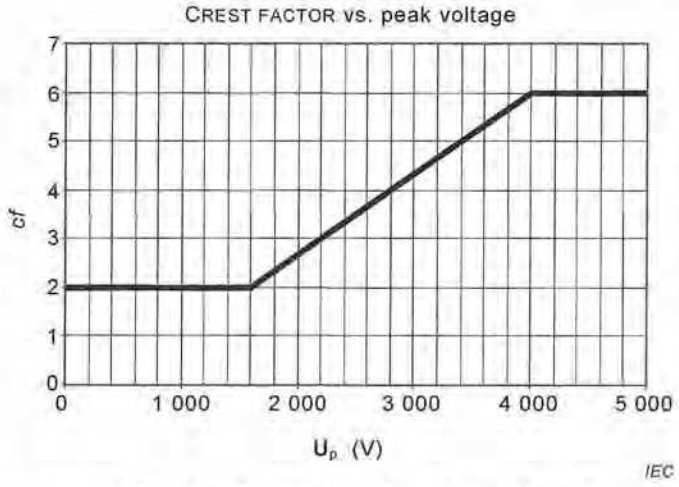


Figure AA.4 – CREST FACTOR vs. peak voltage

A safe situation exists whenever a RATED ACCESSORY VOLTAGE is matched to an output voltage of an HF SURGICAL EQUIPMENT having a CREST FACTOR which falls on or above the line in the diagram. The RATED ACCESSORY VOLTAGE shall not be less than the MAXIMUM OUTPUT VOLTAGE, since the HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT shall fulfil the requirements of 201.8.8.3.103 which takes into account the CREST FACTOR.

Provision is made for the case in which a generator at a certain setting has a MAXIMUM OUTPUT VOLTAGE with a corresponding CREST FACTOR which falls below the line. In this case, to ensure safety, the RATED ACCESSORY VOLTAGE shall be high enough to ensure that there is no insulation breakdown of the HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT when used with that particular HF SURGICAL EQUIPMENT in that particular HF SURGICAL MODE at that particular output setting. This precaution is necessary in order to take into account the dielectric heating produced by lower CREST FACTOR waveforms. The safe value of RATED ACCESSORY VOLTAGE shall be found by testing the HF SURGICAL ACCESSORY or ASSOCIATED EQUIPMENT with the HF SURGICAL EQUIPMENT.

Subclause 201.7.9.2.2.101 e)

The OPERATOR shall know which MONITORING NES are safe and functional with the CQM. Many OPERATORS mistakenly believe that with the advent of CQM, intraoperative surveillance of NE contact is no longer necessary.

Subclause 201.7.9.2.2.101 g)

Although the required measures in 201.8.4.102 are intended to reduce neuromuscular stimulation significantly, it cannot be completely eliminated especially when electrical arcs are produced. Therefore a warning is necessary to make the user aware that in sensitive structures neuromuscular stimulation can still occur leading to secondary RISKS like injury caused by muscle contractions. See also the rationale for 201.8.4.102.

Subclause 201.7.9.2.2.101 h)

For systems of HF surgical devices used under these conditions, there is an increased concern for NEUTRAL ELECTRODE burns.

Subclause 201.7.9.2.2.101 i)

It is understood that general purpose HF SURGICAL EQUIPMENT is utilized with a variety of ACTIVE ACCESSORIES not necessarily provided by the MANUFACTURER of the ME EQUIPMENT. For this reason, information regarding the maximum permissible length of ACCESSORIES to be used

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

COVIDIEN LP, Petitioner, v. ERBE ELEKTROMEDIZIN GMBH, Registrant.	Cancellation No. 92066392 Registration Nos. 4,236,231 and 4,686,396 Mark: SOFT COAG

DECLARATION OF KAMRIN HELLAND

I, Kamrin Helland, do hereby declare under penalty of perjury as follows:

1. I am over twenty-one years of age and competent to make the following statements. I have personal knowledge of the facts set forth in this Declaration and, if called to testify as a witness, I can and will testify to these facts in a court of law or in an administrative agency, including the Trademark Trial and Appeal Board.

2. I was an employee of Covidien LP before it was acquired by Medtronic Inc., and continue in the same role as an employee of Medtronic.

3. I am currently director of strategic marketing for Medtronic's surgical energy and safety business. Previously, I was the director of Medtronic's Minimally Invasive Therapies Group's energy portfolio. In that role I am responsible for the marketing and sales of electrosurgical generators including the Valleylab FT10. My department also maintains records of sales of our older generator models.

4. The Valleylab FT10 was released in November 2015.

5. The document attached as Exhibit A to my declaration is a true and correct excerpt of a business record showing units of certain Valleylab-branded electrosurgical

generators sold in the United States each year since 1996. The green highlighting indicates those generators that have a Soft Coag mode. The last two rows in the document show sales of the Valleylab FT10.

6. Records from earlier than 1996 are not readily available.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: July 12, 2019

KAMRIN HELLAND

CONFIDENTIAL
HELLAND
EXHIBIT A