IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

Neurovision Medical Products, Inc., *Plaintiff,* v. Medtronic Public Limited Company, et al., *Defendants.*	Case No. 2:16-cv-127-JRG-RSP

CLAIM CONSTRUCTION MEMORANDUM OPINION AND ORDER

Before the Court is the opening claim construction brief of Neurovision Medical Products, Inc. ("Plaintiff") (Dkt. No. 70, filed under seal on September 6, 2016),[1] the response of Medtronic Xomed, Inc., Medtronic, Inc., Medtronic PLC, HCA Holdings, Inc., and Healthtrust Purchasing Group, L.P. (collectively "Defendants") (Dkt. No. 76, filed on September 20, 2016), and the reply of Plaintiff (Dkt. No. 82, filed on September 27, 2016). The Court held a hearing on the issues of claim construction and claim definiteness on October 17, 2016. Having considered the arguments and evidence presented by the parties at the hearing and in their briefing, the Court issues this Order.

[1] Citations to the parties' filings are to the filing's number in the docket (Dkt. No.) and pin cites are to the page numbers assigned through ECF.

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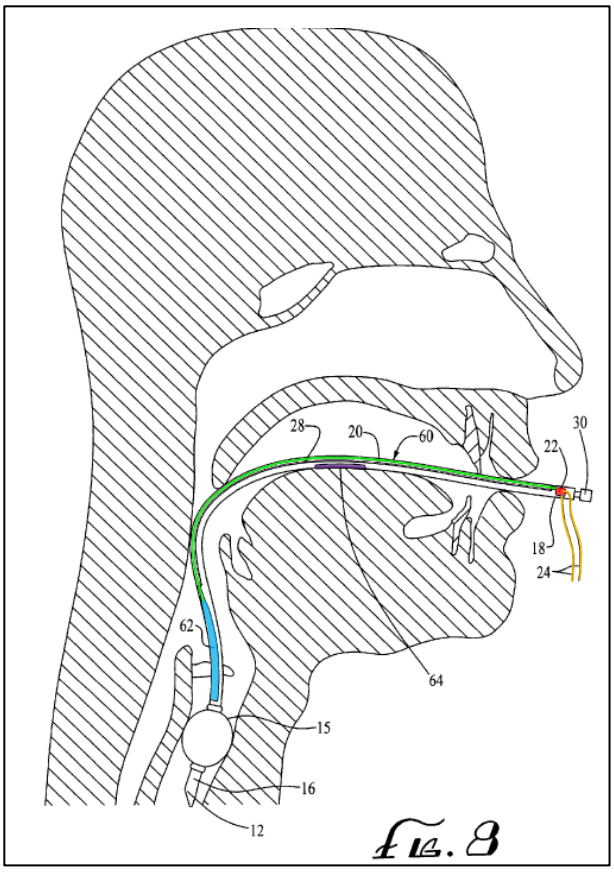
I. BACKGROUND

Plaintiff alleges infringement of two U.S. Patents: No. 8,467,844 (the "'844 Patent) and No. 8,634,894 (the "'894 Patent) (collectively, the "Asserted Patents"). The Asserted Patents are each entitled "Electrode for Prolonged Monitoring of Laryngeal Electromyography." The application leading to the '844 Patent was filed on September 21, 2010 and the patent issued on June 18, 2013. The application leading to the '894 Patent was filed on June 4, 2013 and the patent issued on January 21, 2014. The '894 Patent purports to have issued from a division of the '844 Patent's application. Each Asserted Patent claims priority to a provisional application filed on September 21, 2009.

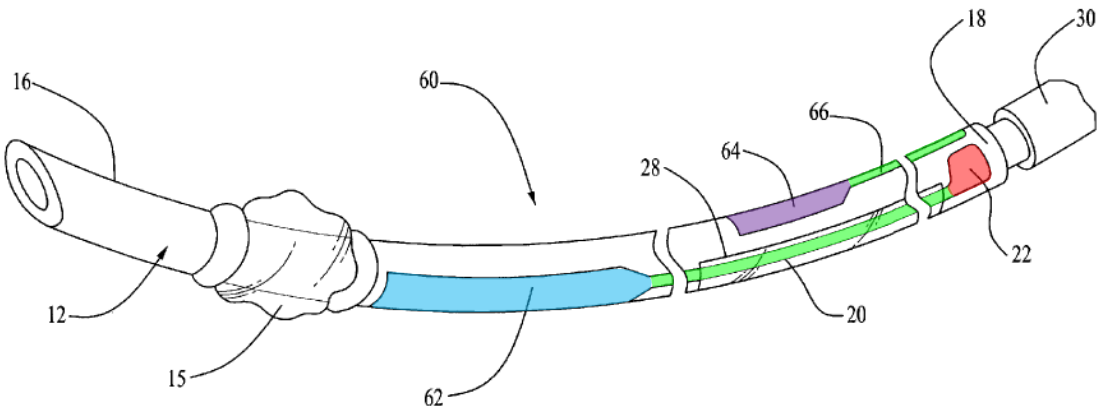
In general, the Asserted Patents are directed to technology for monitoring electrical signals during laryngeal electromyography. The technology can be generally understood with reference to Figures 7 and 8 of the Asserted Patents, reproduced below and annotated by the Court. The patent teaches that an endotracheal tube (12) may be used to support a patient's respiration. These tubes may include electrodes that are used to collect electrical signals from anatomical tissue (e.g., from the muscles of larynx). These signals are called electromyographic signals. The tube is placed through the patient's mouth and down into the trachea. Electrodes (62, in blue; 64, in purple) are positioned along the length of the tube to



pick up electromyographic signals from, for example, the vocal cords and tongue. The signals collected by the electrodes are conducted up the tube (to the proximal end, 18, at the patient's mouth) and from there are sent to monitoring equipment. The prior-art approaches purportedly have two main failings: (1) adding the electrodes and their electrical connections to the tracheal tubes results in raised portions on the tube that can cause injury to the patient during the procedure, and (2) the electrodes and their connections require the addition of material to the tube that is less flexible than the tube and, therefore, placing the electrode-laden tube in the patient may be more difficult than placing the tube alone.

The invention of the Asserted Patents addresses the purported failures of the prior-art devices by creating electrodes (62, in blue; 64, in purple), conductive traces (20, in green; 66, in green), and conductive pads (22, in red) directly on the surface of the tube by applying a conductive ink or paint to the surface. In this way, the detrimental effects of the wires, metallic plates, and adhesives of the prior-art devices are eliminated. That is, the invention reduces the threat of injury by minimizing raised surfaces and increases the ease of placement in the patient by minimizing the decrease in the tube's flexibility due to the electrodes and their connections.

FIG. 7



The abstracts of the Asserted Patents are identical and provide:

> Laryngeal surface electrodes are devices designed to hold a conductive surface against the vocal cords in order to pick up small electrical signals from the muscle known as electromyographic signals. Several embodiments of a laryngeal electromyography tube include a conductive electrode surface that is painted, screen printed or otherwise applied directly onto the body of an endotracheal tube, such that the final device has no raised surfaces which can injure the vocal cords. These endotracheal tube with integral laryngeal surface electrodes can be safely used placed for prolonged, continuous monitoring during surgery, after surgery and during intensive care treatment intubation without a need to remove and replace the tube at these various stages of treatment. In one embodiment, one electrode contacts the vocal cords and a second electrode contacts the tongue.

Claim 4 of the ’844 Patent, Claim 10 of the ’894 Patent and Claim 14 of the ’894 Patent, exemplary formation-method, device, and use-method system claims respectively, recite as follows:

’844 Patent

> **4.** A method of forming an electrode bearing endotracheal tube for laryngeal electromyography comprising:
> providing an endotracheal tube having a retaining balloon at a distal end thereof,

forming on an exterior surface of the endotracheal tube one or more electrode plates, at least one trace attached to each of the one or more electrode plates and a conductive pad attached to a proximal end of the traces, a first of said electrode plates located at the distal end of the endotracheal tube proximal of the retaining balloon, the conductive pad or pads located at a proximal end of the endotracheal tube,

the electrode plates, traces and electrode pads formed by applying a conductive ink in a liquid carrier to the exterior surface of the endotracheal tube,

evaporating the liquid carrier to provide an electrically conductive path from the electrode plates to the endotracheal tube proximal end, and

forming an insulating barrier over the traces, the barrier extending from a point of connection of the traces to the electrode plates to a point of connection of the traces to the electrode pads

wherein a second electrode plate is located proximal of said first electrode plate, the first electrode plate positioned to contact the vocal cords and the second electrode plate positioned to contact the tongue when properly positioned for performing laryngeal electromyography.

’894 Patent

10. A method of conducting monitoring of electrical signals during laryngeal electromyography for a period of time in excess of 8 hours without injury to the trachea comprising:

providing an endotracheal tube having a retention balloon at or adjacent a distal end thereof,

forming on the outer surface of said tube

a) one or more electrically conductive electrodes applied proximal of the balloon directly to the surface of the tube, without the inclusion of a carrier film between the tube surface and the electrodes,

b) electrically conductive traces connected to or integral with the electrodes, the traces applied directly to the tube surface and running along the length of the endotracheal tube to a proximal portion thereof,

c) connection points connected to or integral with the conductive traces applied directly to the tube surface at a proximal end of the traces, and

d) electrical leads attached to the connection points, said leads adapted for connection to monitoring equipment,

e) the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrodes to a point adjacent the proximal ends of the traces,

wherein said electrically conductive electrodes, traces and connection points comprise a conductive paint or printing ink,

placing the endotracheal tube in the trachea with at least one electrode in contact with the vocal cords, and

monitoring electrical signals with the at least one electrode, said monitored electrical signals not showing a detrimental reduction in the quality thereof during the period of monitoring.

14. A device for use in monitoring electrical signals during laryngeal electromyography comprising:

an endotracheal tube having a retention balloon at or adjacent a distal end thereof, said tube having on its outer surface at least first and second electrically conductive electrodes applied proximal of the balloon directly to the surface of the tube, without the inclusion of a carrier film between the tube surface and the electrodes, said first and second electrodes electrically isolated from each other, at least one of the first or second electrodes positioned to contact the vocal cords, a wall of the trachea or the tongue when the tube is positioned for electromyography in the trachea with the retention balloon distal of the vocal cords,

said tube having on its surface first and second electrically conductive traces, said first trace connected to or integral with the first electrode and said second trace integral with the second electrode, the traces applied directly to the tube surface, electrically isolated from each other, and running along the length of the endotracheal tube to a proximal portion thereof, and

electrical leads connected to the electrically conductive traces or to conductive pads connected to or integral with the conductive traces, said leads configured to connect to monitoring equipment,

the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrode to which it is attached to a point adjacent the electrical leads or the conductive pads.

II. LEGAL PRINCIPLES

A. Claim Construction

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). To determine the meaning of the claims, courts start by considering the intrinsic evidence. *Id.* at 1313; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). The intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1314; *C.R. Bard, Inc.*, 388 F.3d at 861. The general rule—subject to certain specific exceptions discussed *infra*—is that each claim term is construed according to its ordinary and accustomed meaning as understood by one of

ordinary skill in the art at the time of the invention in the context of the patent. *Phillips*, 415 F.3d at 1312–13; *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003); *Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1347 (Fed. Cir. 2014) ("There is a heavy presumption that claim terms carry their accustomed meaning in the relevant community at the relevant time.") (vacated on other grounds).

"The claim construction inquiry . . . begins and ends in all cases with the actual words of the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). "[I]n all aspects of claim construction, 'the name of the game is the claim.'" *Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1298 (Fed. Cir. 2014) (quoting *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998)). First, a term's context in the asserted claim can be instructive. *Phillips*, 415 F.3d at 1314. Other asserted or unasserted claims can also aid in determining the claim's meaning, because claim terms are typically used consistently throughout the patent. *Id.* Differences among the claim terms can also assist in understanding a term's meaning. *Id*. For example, when a dependent claim adds a limitation to an independent claim, it is presumed that the independent claim does not include the limitation. *Id*. at 1314–15.

"[C]laims 'must be read in view of the specification, of which they are a part.'" *Id*. (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc)). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id*. (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). But, "'[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.'" *Comark*

Commc'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)); *see also Phillips*, 415 F.3d at 1323. "[I]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004).

The prosecution history is another tool to supply the proper context for claim construction because, like the specification, the prosecution history provides evidence of how the U.S. Patent and Trademark Office ("PTO") and the inventor understood the patent. *Phillips*, 415 F.3d at 1317. However, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* at 1318; *see also Athletic Alternatives, Inc. v. Prince Mfg.*, 73 F.3d 1573, 1580 (Fed. Cir. 1996) (ambiguous prosecution history may be "unhelpful as an interpretive resource").

Although extrinsic evidence can also be useful, it is "'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc.*, 388 F.3d at 862). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id*. at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition are not helpful to a court. *Id*. Extrinsic evidence is "less

reliable than the patent and its prosecution history in determining how to read claim terms." *Id*. The Supreme Court recently explained the role of extrinsic evidence in claim construction:

> In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. *See, e.g., Seymour v. Osborne*, 11 Wall. 516, 546 (1871) (a patent may be "so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning"). In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the "evidentiary underpinnings" of claim construction that we discussed in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal.

Teva Pharm. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

B. Departing from the Ordinary Meaning of a Claim Term

There are "only two exceptions to [the] general rule" that claim terms are construed according to their plain and ordinary meaning: "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution."[2] *Golden Bridge Tech., Inc. v. Apple Inc.*, 758 F.3d 1362, 1365 (Fed. Cir. 2014) (quoting *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)); *see also GE Lighting Solutions, LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014) ("[T]he specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal."). The standards for finding lexicography or disavowal are "exacting." *GE Lighting Solutions*, 750 F.3d at 1309.

To act as his own lexicographer, the patentee must "clearly set forth a definition of the disputed claim term," and "clearly express an intent to define the term." *Id.* (quoting *Thorner*,

[2] Some cases have characterized other principles of claim construction as "exceptions" to the general rule, such as the statutory requirement that a means-plus-function term is construed to cover the corresponding structure disclosed in the specification. *See, e.g., CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1367 (Fed. Cir. 2002).

669 F.3d at 1365); *see also Renishaw*, 158 F.3d at 1249. The patentee's lexicography must appear "with reasonable clarity, deliberateness, and precision." *Renishaw*, 158 F.3d at 1249.

To disavow or disclaim the full scope of a claim term, the patentee's statements in the specification or prosecution history must amount to a "clear and unmistakable" surrender. *Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009); *see also Thorner*, 669 F.3d at 1366 ("The patentee may demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope."). "Where an applicant's statements are amenable to multiple reasonable interpretations, they cannot be deemed clear and unmistakable." *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1326 (Fed. Cir. 2013).

C. Functional Claiming and 35 U.S.C. § 112, ¶ 6 (pre-AIA) / § 112(f) (AIA)

A patent claim may be expressed using functional language. *See* 35 U.S.C. § 112, ¶ 6; *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1347–49 & n.3 (Fed. Cir. 2015) (en banc in relevant portion). Section 112, Paragraph 6, provides that a structure may be claimed as a "means . . . for performing a specified function" and that an act may be claimed as a "step for performing a specified function." *Masco Corp. v. United States*, 303 F.3d 1316, 1326 (Fed. Cir. 2002).

But § 112, ¶ 6 does not apply to all functional claim language. There is a rebuttable presumption that § 112, ¶ 6 applies when the claim language includes "means" or "step for" terms, and that it does not apply in the absence of those terms. *Masco Corp.*, 303 F.3d at 1326; *Williamson*, 792 F.3d at 1348. The presumption stands or falls according to whether one of ordinary skill in the art would understand the claim with the functional language, in the context of the entire specification, to denote sufficiently definite structure or acts for performing the

function. *See Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1372 (Fed. Cir. 2015) (§ 112, ¶ 6 does not apply when "the claim language, read in light of the specification, recites sufficiently definite structure" (quotation marks omitted) (citing *Williamson*, 792 F.3d at 1349; *Robert Bosch, LLC v. Snap-On Inc.*, 769 F.3d 1094, 1099 (Fed. Cir. 2014))); *Williamson*, 792 F.3d at 1349 (§ 112, ¶ 6 does not apply when "the words of the claim are understood by persons of ordinary skill in the art to have sufficiently definite meaning as the name for structure"); *Masco Corp.*, 303 F.3d at 1326 (§ 112, ¶ 6 does not apply when the claim includes an "act" corresponding to "how the function is performed"); *Personalized Media Communications, L.L.C. v. International Trade Commission*, 161 F.3d 696, 704 (Fed. Cir. 1998) (§ 112, ¶ 6 does not apply when the claim includes "sufficient structure, material, or acts within the claim itself to perform entirely the recited function . . . even if the claim uses the term 'means.'" (quotation marks and citation omitted)).

When it applies, § 112, ¶ 6 limits the scope of the functional term "to only the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof." *Williamson*, 792 F.3d at 1347. Construing a means-plus-function limitation involves multiple steps. "The first step . . . is a determination of the function of the means-plus-function limitation." *Medtronic, Inc. v. Advanced Cardiovascular Sys., Inc.*, 248 F.3d 1303, 1311 (Fed. Cir. 2001). "[T]he next step is to determine the corresponding structure disclosed in the specification and equivalents thereof." *Id.* A "structure disclosed in the specification is 'corresponding' structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." *Id.* The focus of the "corresponding structure" inquiry is not merely whether a structure is capable of performing the recited function, but rather whether the corresponding structure is "clearly linked or associated with the [recited]

function." *Id.* The corresponding structure "must include all structure that actually performs the recited function." *Default Proof Credit Card Sys. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1298 (Fed. Cir. 2005). However, § 112 does not permit "incorporation of structure from the written description beyond that necessary to perform the claimed function." *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999).

For § 112, ¶ 6 limitations implemented by a programmed general purpose computer or microprocessor, the corresponding structure described in the patent specification must include an algorithm for performing the function. *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1349 (Fed. Cir. 1999). The corresponding structure is not a general purpose computer but rather the special purpose computer programmed to perform the disclosed algorithm. *Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1333 (Fed. Cir. 2008).

D. Definiteness Under 35 U.S.C. § 112, ¶ 2 (pre-AIA) / § 112(b) (AIA)

Patent claims must particularly point out and distinctly claim the subject matter regarded as the invention. 35 U.S.C. § 112, ¶ 2. A claim, when viewed in light of the intrinsic evidence, must "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). If it does not, the claim fails § 112, ¶ 2 and is therefore invalid as indefinite. *Id.* at 2124. Whether a claim is indefinite is determined from the perspective of one of ordinary skill in the art as of the time the application for the patent was filed. *Id.* at 2130. As it is a challenge to the validity of a patent, the failure of any claim in suit to comply with § 112 must be shown by clear and convincing evidence. *Id.* at 2130 n.10. "[I]ndefiniteness is a question of law and in effect part of claim construction." *ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 517 (Fed. Cir. 2012).

When a term of degree is used in a claim, "the court must determine whether the patent provides some standard for measuring that degree." *Biosig Instruments, Inc. v. Nautilus, Inc.*,

783 F.3d 1374, 1378 (Fed. Cir. 2015) (quotation marks omitted). Likewise, when a subjective term is used in a claim, "the court must determine whether the patent's specification supplies some standard for measuring the scope of the [term]." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1351 (Fed. Cir. 2005); *accord Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014) (citing *Datamize*, 417 F.3d at 1351).

In the context of a claim governed by 35 U.S.C. § 112, ¶ 6, the claim is invalid as indefinite if the claim fails to disclose adequate corresponding structure to perform the claimed functions. *Williamson*, 792 F.3d at 1351–52. The disclosure is inadequate when one of ordinary skill in the art "would be unable to recognize the structure in the specification and associate it with the corresponding function in the claim." *Id*. at 1352.

III. CONSTRUCTION OF DISPUTED TERMS

A. "electrode," "electrode plate"

Disputed Term[3]	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"electrode" • '844 Patent Claims 1, 4 • '894 Patent Claims 1, 4, 10, 14	Plain and ordinary meaning.	"element designed to hold a conductive surface against a body part in order to pick up EMG signals from that body part"
"electrode plate" • '844 Patent Claims 1, 4	Plain and ordinary meaning.	"plate designed to hold a conductive surface against a body part in order to pick up EMG signals from that body part"

Because the parties' arguments and proposed constructions with respect to these terms are related, the Court addresses the terms together.

[3] For all term charts in this order, the claims in which the term is found are listed with the term but: (1) only the highest level claim in each dependency chain is listed, and (2) only asserted claims identified in the parties' Patent Rule 4-5(d) Claim Construction Charts (Dkt. No. 85; Dkt. No. 86) are listed.

The Parties' Positions

Plaintiff submits that "electrode" and "electrode plate" are each readily understood without construction—as something that conducts electricity. Dkt. No. 70 at 26. Plaintiff contends that Defendants' proposed construction is improper as it distinguishes between the "electrode" and a "conductive surface." *Id*. According to Plaintiff, the "electrodes" of the Asserted Patents were not redefined as something that "hold[s] a conductive surface against a body part." *Id*. Specifically, Plaintiff argues the statement in the common abstract that "[l]aryngeal surface electrodes are devices designed to hold a conductive surface against the vocal cords" is not definitional of "electrode" but rather refers to a "device." *Id*. at 26–27. And, Plaintiff contends, the abstract statement should be read in context of the rest of the patent, such as the summary statement,

> the endotracheal tube ***laryngeal surface electrode incorporates imprinted patterns which provide conductive electrode plates*** on the surface without adding any additional structure or materials to the standard endotracheal tube other than the conductive ink or materials applied to the surface to form ***the electrodes***.

Id. at 26–27 (quoting '844 Patent col.2 ll.33–38 (emphasis added by Plaintiff).

In addition to the claims themselves, Plaintiff cites the following intrinsic and extrinsic evidence to support its position: **Intrinsic evidence**: '844 Patent, at [57] Abstract, col.1 l.46, col.2 ll.33–38, col.4 l.20. **Extrinsic evidence**: Otto Decl.[4] ¶¶ 35–38 (Dkt. No. 70-1 at 10–11).

Defendants respond that the "electrode" and "electrode plate" of the Asserted Patents "refer to electrically conductive elements that pick up EMG signals from the area of the anatomy of interest." Dkt. No. 76 at 14. According to Defendants, that the electrodes are "sensing" electrodes (i.e., that they pick up EMG signals) is evinced by the description of the exemplary embodiments and by arguments made during prosecution. *Id*. Specifically, Defendants contend

[4] Expert Declaration of Dr. Randal A. Otto, Dkt. No. 70-1.

that the patentee distinguished a prior-art reference on the ground that the disclosed "electrode" was not a "sensing electrode." *Id*. And, Defendants contend, the only "electrodes" of the patents are electrodes that pick up (i.e., receive) EMG signals. *Id*. at 14–15.

In addition to the claims themselves, Defendants cite the following intrinsic and extrinsic evidence to support their position: **Intrinsic evidence**: '844 Patent, at [57] Abstract, col.1 ll.45–46, col.4 ll.14–21; '894 Patent File Wrapper, October 25, 2013 Amendment/Response (Defendants' Ex. I at 89–99, Dkt. No. 76-9 at 89–99). **Extrinsic evidence**: Otto Dep.[5] at 103:9–25 (Defendants' Ex. B, Dkt. No. 76-2 at 103).

Plaintiff replies that the statement in the abstract of the Asserted Patents that "[l]aryngeal surface electrodes are devices designed to hold a conductive surface against the vocal cords in order to pick up small electrical signals from the muscle known as electromyographic signals" does not define the invention, but rather refers generically to laryngeal surface electrode devices. Dkt. No. 82 at 9. Plaintiff further replies that the term at issue is "electrode" not "laryngeal surface electrode device." *Id*. And the electrode is the conductive surface, not a device for holding the conductive surface. *Id*. Plaintiff further replies that while the electrodes of one exemplary embodiment are described as "picking up" or "receiving" signals, it would be improper to read a feature of an exemplary embodiment into the claims. *Id*. at 10.

Plaintiff cites further **intrinsic evidence** to support its position: '844 Patent col.3 ll.34–39, col.4 ll.14–18.

Analysis

There are two issues raised by the dispute. First, whether "electrode" and "electrode plate" refer to something that holds a conductive surface against an anatomical feature. Second,

[5] Deposition of Randal A. Otto, M.D., September 12, 2016, Dkt. No. 76-2.

whether "electrode" and "electrode" plate are sensing electrodes configured to pick up electromyographic signals. With respect to the first, issue, the Court determines that the "electrode"/"electrode plate" of the Asserted Patents does not necessarily hold a conductive surface against a body part. With respect to the second issue, the Court determines that the "electrode"/"electrode plate" of the patents is an electrode to sense electromyographic signals—it is a sensing electrode.

The "electrode"/"electrode plate" of the patents does not necessarily hold a conductive surface against a body part. The patents distinguish between the "laryngeal surface electrode," which is a device, and the "electrode"/"electrode plate," which is a feature of the device. For example, the patents provide that

> the endotracheal tube laryngeal surface electrode incorporates imprinted patterns which provide conductive electrode plates on the surface without adding any additional structure or materials to the standard endotracheal tube other than the conductive ink or materials applied to the surface to form the electrodes.

'844 Patent col.2 ll.32–38. Similarly, the patents provide that

> [a]n additional object is to provide a PVC laryngeal surface electrode with the electrodes painted, printed or sprayed on the surface thereof, thereby providing the flexibility of the PVC material throughout the length of the device. The painted, printed or sprayed on electrodes does not create a zone of stiffness anywhere along the length of the endotracheal tube, and particularly near the vocal cords.

Id. at col.2 l.66 – col.3 l.5. That is, the "electrode"/"electrode plate" is a surface deposited on the endotracheal tube and together the electrode and tube comprise the laryngeal surface electrode device. *See also*, *id*. at col.3 ll.65–67 ("conductive electrode plates 14 are imprinted on the linear body of the tube 12"). Indeed, other than how the surface is affixed to the tube, this is how "electrode" is used to describe the prior art:

> it is common practice to monitor laryngeal electromyography using laryngeal electrodes (the electrical signal pickup surfaces used to collect the muscle signals)

> which are either adhesively secured to the surface of the endotracheal tube or are embedded into the tube surface during the manufacture of the endotracheal tube

Id. at col.1 ll.44–49. And this is how the patentee explained an "electrode" in prosecution. *See, e.g.*, '894 Patent File Wrapper, October 25, 2013 Amendment/Response at 7–8, Dkt. No. 70-8 at 8–9 (referring to "electrodes printed on the surface of the endotracheal tube").

In this context, the Court understands the statement in the patents' Abstracts that "[l]aryngeal surface electrodes are devices designed to hold a conductive surface against the vocal cords" refers to a device (the laryngeal surface electrode) that holds the electrode (the conductive surface) against the vocal cords. Indeed, the Abstracts further provide that

> [s]everal embodiments of a laryngeal electromyography tube include ***a conductive electrode surface*** that is painted, screen printed or otherwise applied directly onto the body of an endotracheal tube, such that the final device has no raised surfaces which can injure the vocal cords.

Id. at [57] Abstract (emphasis added). Simply, the Abstract statement is not a definition of "electrode" as Defendants contend.

That said, the "electrode"/"electrode plate" of the patents is a sensing electrode. When read in the context of the patents' disclosures and prosecution histories, this is apparent from the claims. For instance, Claim 1 of the '894 Patent is directed to a device for monitoring electrical signals. The electrodes are positioned to contact various body parts and are electrically connected to electrical leads that are adapted for connection to monitoring equipment. The patents explain that the "electrodes are located for optimal signal collection" and that they are "optimized for . . . collection of electrical signals from the muscles and nerves comprising the vocal cords." '844 Patent col.2 ll.8–12, col.2 ll.22–26. In fact, the patents refer to the prior-art electrodes that the invention purportedly improves upon as "the electrical signal pickup surfaces used to collect the muscle signals." *Id*. at col.1 ll.44–49. And the electrodes of the patents are also characterized in the prosecution history as sensing electrodes, as distinguished from electrodes that only

deliver current. *See* '894 Patent File Wrapper, October 25, 2013 Amendment/Response at 9–10, Dkt. No. 70-8 at 10–11 (distinguishing a prior-art reference by stating "[t]he current electrode 42 or electrode patch 44 [of the reference] are clearly not sensing electrodes and are in fact components for delivering current to the tracheal tissue"). That is, the electrodes are the sensing elements of the system for monitoring electrical signals, regardless of whether the electrodes may also deliver current.

The patents use "electrode" and "electrode plate" interchangeably. *See, e.g.*, '844 Patent col.2 ll.32–38 (referring to that which is deposited on the tube as "electrode plate" and "electrode"), col.2 l.66 – col.3 l.5 (referring to that which is deposited on the tube as "electrode"), col.4 ll.12–35 (describing various placements of the "electrode plate" on the tube and noting "that other electrode placements may be desired"). In the Asserted Patents, the "electrodes" and "electrode plates" are surfaces that are adapted to collect the electrical signals.

Finally, and as set forth in detail in the discussion of "trace" below, the electrode of the claims is formed of conductive ink or paint.

Accordingly, the Court construes "electrode" and "electrode plate" as follows:

- "electrode" / "electrode plate" means "surface that is adapted to collect electrical signals and that is formed of conductive ink or paint."

B. "positioned to contact . . . "

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"positioned to contact the vocal cords when placed within the trachea" • '844 Patent Claim 1	Plain and ordinary meaning.	Indefinite. **alternative**: • "positioned against the vocal cords in order to pick up EMG signals from the vocal cords when placed in a human patient's trachea"

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"positioned to contact the tongue" • '844 Patent Claim 1	Plain and ordinary meaning.	Indefinite. **alternative**: • "positioned against the tongue in order to pick up EMG signals from the tongue"
"positioned to contact the vocal cords" • '894 Patent Claims 1, 5, 12	Plain and ordinary meaning.	Indefinite. **alternative**: • "positioned against the vocal cords in order to pick up EMG signals from the vocal cords"
"positioned to contact tissue, nerves and muscle in the trachea or the tongue" • '894 Patent Claim 1	Plain and ordinary meaning.	Indefinite. **alternative**: • "positioned against the tissue, nerves and muscle in the trachea or the tongue in order to pick up EMG signals from these structures"
"positioned to contact the tongue or nerves and muscle in the rear of the trachea" • '894 Patent Claim 5	Plain and ordinary meaning.	Indefinite. **alternative**: • "positioned against the tongue or nerves and muscle in the rear of the trachea in order to pick up EMG signals from these structures"
"positioned so as to contact tissue, nerves and muscle in the rear of the trachea or the tongue" • '894 Patent Claim 12	Plain and ordinary meaning.	Indefinite. **alternative**: • "positioned against the tissue, nerves, muscle in the rear of the trachea or the tongue in order to pick up EMG signals from these structures"
"positioned to contact the vocal cords, a wall of the trachea or the tongue" • '894 Patent Claim 14	Plain and ordinary meaning.	Indefinite. **alternative**: • "positioned against the vocal cords, a wall of the trachea or the tongue in order to pick up EMG signals from these structures"

Because the parties' arguments and proposed constructions with respect to these terms are related, the Court addresses the terms together.

The Parties' Positions

Plaintiff submits that positioning electrodes to monitor signals during laryngeal electromyography was well known in in the art. Dkt. No. 70 at 15–16. This knowledge, according to Plaintiff, is recognized in the Asserted Patents as well as in the prosecution history. *Id*. at 16. Further, Plaintiff argues, the patents provide guidance as to the positioning. *Id*. at 16–17. For instance, the positon of a first electrode is described with reference to a retention balloon ("proximal of the balloon"), the position of a second electrode with reference to the balloon ("further proximal thereof"), and the position of the retention balloon is described with reference to the patient's anatomy ("distal of the vocal cords"). *Id*. (quoting '844 Patent Claim 1; '894 Patent Claim 14). Also, the position of the electrode is described with reference to the curve of the endotracheal tube to which the electrode is attached: "on the outer curved surface for receiving electrical signals generated from nerves and muscles in the rear of the trachea" and "on the concave (inner surface of the curve) for picking up signals generated from the vocal cord located on the front surface of the trachea." *Id*. at 17 (quoting '844 Patent col.4 ll.12–21). Plaintiff further submits that prior-art references of record in the prosecution history describe how to determine if the electrodes are in contact with the desired anatomy. *Id*. at 17–18.

In addition to the claims themselves, Plaintiff cites the following intrinsic and extrinsic evidence to support its position: **Intrinsic evidence**: '844 Patent figs.1–5, col.1 ll.17–21, col.1 ll.44–49, col.4 ll.12–21; '894 Patent File Wrapper October 25, 2013 Amendment/Response

(Plaintiff's Ex. 6, Dkt. No. 70-8); International Publication No. WO 2006/105121[6] (Plaintiff's Ex. 9, Dkt. No. 70-11); U.S. Patent No. 5,125,406[7] (Plaintiff's Ex. 10, Dkt. No. 70-12). **Extrinsic evidence**: Otto Decl. ¶¶ 18–22 (Dkt. No. 70-1 at 5–6); Medtronic, *NIM EMG Endotracheal Tube* (Plaintiff's Ex. 11, Dkt. No. 70-13).

Defendants respond that each of the "positioned to contact" terms are defined with reference to anatomy that is inherently variable and the terms therefore render the claims indefinite. Dkt. No. 76 at 16, 28–31. These anatomical references, according to Defendants, are so divergent in practice that there is no way to determine whether a particular configuration of electrodes are positioned according to the claims. *Id*. at 29–31.

Defendants further respond that "positioned to contact" a particular anatomical feature means that the "electrodes must be positioned against the recited structures in order to pick up EMG signals from them." *Id*. at 16. This, according to Defendants, is because the abstract states that the electrodes "hold a conductive surface against the vocal cords in order to pick up small electrical signals from the muscle known as electromyographic signals." *Id*. And, Defendants contend, the electrodes are depicted in the patents' figures as "against" the anatomical features that they are positioned to contact. *Id*. at 16–17. Defendants further contend that nothing in the patents' description or claims suggests that one electrode may "contact multiple anatomical structures." *Id*. at 17. Rather, Defendants argue, the claims recite separate electrodes as a condition of patentability. *Id*. at 17.

In addition to the claims themselves, Defendants cite the following intrinsic and extrinsic evidence to support their position: **Intrinsic evidence**: '844 Patent File Wrapper, October 15,

[6] International Publication No. WO 2006/105121 is cited on the face of the '844 and '894 Patents. '844 Patent, at [56] References Cited; '894 Patent, at [56] References Cited.

[7] U.S. Patent No. 5,125,406 is cited on the face of the '844 Patent. '844 Patent, at [56] References Cited.

2013 Office Action (Defendants' Ex. H at 61–66, Dkt. No. 76-8 at 61–66), January 14, 2013 Amendment (Defendants' Ex. H at 49–57, Dkt. No. 76-8 at 49–57), April 30, 2013 Notice of Allowance (Defendants' Ex. H at 9–12, Dkt. No. 76-8 at 9–12). **Extrinsic evidence**: Otto Decl. ¶ 22 (Defendants' Ex. D, Dkt. No. 76-4 at 6); Otto Dep. 67:18 – 68:10, 165:11–24, 191:22 – 193:6, 208:1–14 (Defendants' Ex. B, Dkt. No. 76-2 at 67–68, 165, 191–93, 208); Medtronic, *NIM EMG Endotracheal Tube* (Defendants' Ex. K, Dkt. No. 76-11).

Plaintiff replies that the statement in the abstract of the Asserted Patents that "[l]aryngeal surface electrodes are devices designed to hold a conductive surface against the vocal cords in order to pick up small electrical signals from the muscle known as electromyographic signals" is not definitional of the invention, but rather refers generically to laryngeal surface electrode devices. Dkt. No. 82 at 3–4. Plaintiff also argues that a claim is not indefinite simply because it defines structure according to anatomical references. *Id*. at 4 (citing *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1382–84 (Fed. Cir. 2015); *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1346 (Fed. Cir. 2007)). And, according to Plaintiff, one of ordinary skill in the art would be able to position the electrodes to contact the recited anatomical references. *Id*. at 5–6.

Analysis

There are two issues raised by the dispute. First, whether "positioned to contact [the anatomical feature]" should be rewritten as "positioned against [the anatomical feature] in order to pick up EMG signals from [the feature]." Second, whether defining electrode positioning with respect to anatomical features renders claims indefinite. With respect to the first issue, the Court declines to rewrite "positioned to contact" as "positioned against." With respect to the second issue, the Court determines that Defendants have failed to prove any claim is indefinite because of the "positioned to contact" term.

While the Court agrees with Defendants that the electrodes are positioned to collect electrical signals from a body part, the Court declines to rewrite the plain term "positioned to contact" as "positioned against" and rejects any limitation imposed by "positioned against" that is not also found in "positioned to contact." As set forth in the section on "electrode" above, the Court understands that the "electrodes" of the claims are to collect electrical signals from anatomical tissue, which is consistent with the patents' description. *See, e.g.*, '844 Patent col.1 l.45–46, col.2 ll.11–12 ("electrode[s] are located for optimal signal collection"). Indeed, Plaintiff argues that the positioning of the electrodes can be determined by measuring the electrical characteristics of the contact between electrode and tissue. Dkt. No. 70 at 17–18; *see also*, Otto Decl. ¶¶ 20–21, Dkt. No 70-1 at 5–6. But the patents do not redefine "positioned to contact" as "positioned against," as Defendants suggest. As stated above, the Court rejects Defendants' contention that the Abstract of the patents defines the electrode or its positioning. And while "positioned to contact" expresses a capability, Defendants proposed "positioned against" threatens to require that the electrode be in contact with the tissue (the tissue is not required by all the claims). That is, an electrode is positioned to collect electrical signals from the tissue in that it is "positioned to contact" the tissue when used. This is plainly expressed in the claims.

The Court also rejects Defendants' argument that would essentially read a negative limitation into the "positioned to contact" terms, one that prevents the electrode from contacting more than one anatomical feature. See Dkt. No. 76 at 17. While the Court agrees with Defendants that claims do not require that the electrodes be "positioned to contact" more than one anatomical feature, neither do the claims recite that the electrodes are "positioned to contact" one and only one anatomical feature. Defendants invoke the prosecution history to exclude electrodes that contact more than one anatomical feature, but fail to provide any reason why the

prosecution history mandates such a result. As such, neither a plain reading of the claims nor any statement in the prosecution history supports Defendants' argued negative limitation.

The "positioned to contact" terms do not render claims indefinite simply because they reference anatomical features. Defendants appear to argue that a claim to a medical device having a structure defined in part by reference to anatomy is per se indefinite. To the contrary, the Federal Circuit has found claims definite because the claims provide an anatomical reference point. *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1382–83 (Fed. Cir. 2015). *Biosig* considered claims to a heart-rate monitor that included electrodes "in spaced relationship" with each other. *Id*. at 1376. The Federal Circuit twice considered whether that limitation rendered the claims indefinite. *Id*. On first consideration and then again on remand from the Supreme Court, the Federal Circuit held that while the "spaced relationship" was not specifically set forth in the patents ("e.g., that the space between the . . . electrodes is one inch"), the limitation did not render any claim indefinite. *Id*. at 1382–83. Specifically, the Federal Circuit noted that because the electrodes were to collect electrical signals on a user's hand, the spaced relationship was not indefinite because it was implicitly defined, in part, by "the width of a user's hands." *Id*. Defining electrode spacing by "the width of a user's hands" is not meaningfully different than defining electrode positioning by the locations of a patient's vocal cords, tongue, and trachea. Like in *Biosig*, the claims here are not indefinite because they define electrode positioning by reference to anatomical features.

Accordingly, the Court holds that Defendants have failed to prove any claim is indefinite because of a "positioned to contact" term and determines that each of these terms has its plain and ordinary meaning, that meaning is readily understood from the claim language, and the terms need no further construction.

C. "[located] further proximal thereof," "[located] proximal [of said first electrode plate]," "[located at said same predetermined distance or] further proximal [thereof]"

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"[located] further proximal thereof" • '844 Patent Claim 1	Plain and ordinary meaning.	"separated from the first electrode plate along the length of the tube such that it is nearer to the proximal end of the tube"
"[located] proximal [of said first electrode plate]" • '844 Patent Claim 4		
"[located at said same predetermined distance or] further proximal [thereof]" • '894 Patent Claim 18		

Because the parties' arguments and proposed constructions with respect to these terms are related, the Court addresses the terms together.

The Parties' Positions

Plaintiff submits that these terms do not need to be construed because they are readily understandable by one of ordinary skill in the art. Dkt. No. 70 at 21. Plaintiff further submits that Defendants' proposed construction is improper because it obfuscates clear claim language instead of clarifying claim scope.[8] *Id.* at 21. And Plaintiff submits that Defendants' proposed construction is improperly narrow as it requires that the electrodes be longitudinally separated (i.e., excludes overlapping electrodes) when the Asserted Patents provide that the electrodes may be placed circumferentially. *Id*. at 22.

[8] Defendants originally proposed a construction "separated from the first electrode plate along the ***longitude*** of the tube such that it is nearer to the proximal end of the tube." Joint Claim Construction and Prehearing Statement at 24, Dkt. No. 68.

In addition to the claims themselves, Plaintiff cites the following intrinsic and extrinsic evidence to support its position: **Intrinsic evidence**: '844 Patent fig.2, col.4 ll.31–35; '894 Patent File Wrapper October 25, 2013 Amendment/Response (Plaintiff's Ex. 6, Dkt. No. 70-8). **Extrinsic evidence**: Otto Decl. ¶¶ 26–28 (Dkt. No. 70-1 at 7–8).

Defendants respond that the "proximal" end of the endotracheal tube in the Asserted Patents is the end sticking out of the patient's mouth and thus a feature of the tube that is "proximal of" another feature is farther along the length of the tube toward the end of the tube that sticks out of the patient's mouth. Dkt. No. 76 at 18–19. Defendants argue that "proximal" in this context does not allow overlap of electrodes, as one electrode cannot be positioned proximal to another electrode if there is overlap—the patents do not allow for "partially proximal" electrodes. *Id*. at 19. Specifically, Defendants argue that because "proximal" is used as a relative term, the claims are appropriately limited to the separate-and-distinct-electrode embodiments of the patents as they are the only embodiments. *Id*. at 19–20 (citing *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1321 (Fed. Cir. 2016)). Defendants further contend that the prosecution history and the technological need to separate electrodes to reduce noise and prevent mixing of signals mandate that each electrode is separately focused on a distinct anatomical feature. *Id*. at 21–22.

In addition to the claims themselves, Defendants cite the following intrinsic and extrinsic evidence to support their position: **Intrinsic evidence**: '844 Patent figs.7–8, col.4 ll.4–6; '844 Patent File Wrapper, October 15, 2013 Office Action (Defendants' Ex. H at 61–66, Dkt. No. 76-8 at 61–66), January 14, 2013 Amendment (Defendants' Ex. H at 49–57, Dkt. No. 76-8 at 49–57), April 30, 2013 Notice of Allowance (Defendants' Ex. H at 9–12, Dkt. No. 76-8 at 9–12);

U.S. Patent No. 5,125,406 (Defendants' Ex. E, Dkt. No. 76-5). **Extrinsic evidence**: Otto Dep. at 91:16–19, 227:24 – 228:4 (Defendants' Ex. B, Dkt. No. 76-2 at 91, 227–228).

Plaintiff replies that it would be improper to require that the electrodes do not partially overlap because the Asserted Patents provide that "[o]ne skilled in the art will recognize that other electrode placements may be desired." Dkt. No. 82 at 6. Plaintiff further replies that Claim 1 of the '844 Patent allows for this in that the positions of the two electrodes are recited with reference to the balloon—one is proximal of the balloon and the other is further proximal of the balloon. *Id*. Finally, Plaintiff contends that there is no discussion in the patents regarding the noise or mixed signals that Defendants argue mandates entirely longitudinally separated electrodes. *Id*. at 6–7.

Analysis

The issue in dispute is whether these "proximal" terms mandate that the electrodes are positioned on the tube such that electrodes are at entirely different distances along the length of the tube. There is no discernable reason in the evidence of record that would exclude from the scope of the claims electrodes that overlap (i.e., electrodes each having some portion that is found at the same distance along the length of the tube).

Nothing in the evidence of record excludes overlapping electrodes as a matter of technology or prosecution history. In fact, the Court understands Claim 18 of the '894 Patent to expressly allow what Defendants contend is excluded; namely, two electrodes at the same distance along the length of the tube. Claim 18 and Claim 14, from which Claim 18 depends, are quoted below with emphasis added by the Court. Claim 14 recites first and second electrodes on the surface of the tube "proximal of the balloon." Claim 18 further specifies that the "first electrode is located a predetermined distance proximal of the balloon" and that the "second

electrode . . . [is] located at said same predetermined distance or further proximal thereof." That is, Claim 18 explicitly states that the first and second electrodes may be at the same distance along the length of the tube. It is difficult for the Court to imagine that prosecution history statements or technological considerations described in the intrinsic record exclude an electrode configuration that is expressly recited in the claims.

The only evidence Defendants have presented in support of excluding overlapping electrodes is unpersuasive. That mere fact that the claims of the '844 Patent issued only after the second electrode plate was defined as "further proximal" of the balloon (Claim 1) or "proximal" of the first electrode (Claim 4) implies nothing about overlapping electrodes that is not already stated in the claim language. And Defendants' contention that there is no electrode overlap because "the Neurovision patents use electrical insulation to focus the electrode on a single area of interest" to prevent noise or mixed signals is belied by Claim 18 of the '894 Patent.

'894 Patent

14. A device for use in monitoring electrical signals during laryngeal electromyography comprising:

an endotracheal tube having a retention balloon at or adjacent a distal end thereof, said tube having on its outer surface at least ***first and second electrically conductive electrodes applied proximal of the balloon*** directly to the surface of the tube, without the inclusion of a carrier film between the tube surface and the electrodes, said first and second electrodes electrically isolated from each other, at least one of the first or second electrodes positioned to contact the vocal cords, a wall of the trachea or the tongue when the tube is positioned for electromyography in the trachea with the retention balloon distal of the vocal cords,

said tube having on its surface first and second electrically conductive traces, said first trace connected to or integral with the first electrode and said second trace integral with the second electrode, the traces applied directly to the tube surface, electrically isolated from each other, and running along the length of the endotracheal tube to a proximal portion thereof, and

electrical leads connected to the electrically conductive traces or to conductive pads connected to or integral with the conductive traces, said leads configured to connect to monitoring equipment,

the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrode to which it is attached to a point adjacent the electrical leads or the conductive pads.

18. The device of claim 14 wherein ***said first electrode is located a predetermined distance proximal of the balloon*** and positioned to contact the vocal cords, ***said second electrode*** electrically isolated from the first electrode and ***located at said same predetermined distance or further proximal thereof***.

Finally, while the Court understands that "proximal" in these terms as they appear in the claims means that the second electrode is nearer to the proximal end of the tube than is the first electrode, the Court does not understand that all portions of the second electrode must be nearer to the proximal end than all portions of the first electrode.

Accordingly, the Court rejects Defendants' proposed "separated" limitation (which the Court understands is meant to exclude overlapping electrodes) and construes the "proximal" terms as follows:

- "located further proximal thereof" means "located nearer to the proximal end of the tube than is the first electrode plate";
- "located proximal of said first electrode plate" means "located nearer to the proximal end of the tube than said first electrode plate"; and
- "located at said same predetermined distance or further proximal thereof" means "located at said same predetermined distance or nearer to the proximal end of the tube than the first electrode."

D. "trace"

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"trace" • '844 Patent Claims 1, 4 • '894 Patent Claims 1, 4, 10, 14	Plain and ordinary meaning, but not a wire.	"element running along the surface of the tube from the electrode to a conductive pad or connection point at the proximal end of the tube"

The Parties' Positions

Plaintiff submits that "wires" are excluded from the scope of "trace" in the Asserted Patents. Dkt. No. 70 at 9. According to Plaintiff, this is clear from the claims, which expressly require the trace to be "applied directly to the tube surface" by means of "conductive ink or

paint." *Id*. Plaintiff also argues that this is clear from the description of the invention, which distinguishes the invention from the prior art based in part on the invention's lack of wires and lack of "raised surfaces which can injure the vocal cords." *Id*. at 9–10 (citing, inter alia, '844 Patent, at [57] Abstract, col.6 ll.32–36, col.6 ll.48–49). Plaintiff further contends that "traces" were distinguished from "wires" during prosecution of the patents. *Id*. at 10–11. And, Plaintiff contends that "trace" does not include "wire" under the customary meaning of those terms. *Id*. at 11. This, according to Plaintiff, is evinced by the Court's finding in a case involving unrelated patents that "trace" does not include "insulated wire" based on a dictionary definition of "trace" as "a conductive path on a ***printed*** circuit board." *Id*. at 11 (citing *Anascape, Ltd. v. Microsoft Corp.*, Civil Action No. 9:06-cv-158, 2008 U.S. Dist. LEXIS 98821, at *17 (E.D. Tex. Feb. 2, 2008) (emphasis in original)). Plaintiff further submits that Defendants' proposed construction is: (1) improperly broad because it includes "wires," (2) improperly narrow because it suggests that the trace is necessarily separate from pad and electrode, and the claims allow that a trace may be "connected to ***or integral*** with" an electrode or pad, and (3) improperly excluding exemplary embodiments if Defendants' proposed "at the proximal end of the tube" means at the very end of the tube, because the exemplary embodiments have traces "extending . . . ***toward*** the proximal end." *Id*. at 11–12 (emphases by Plaintiff).

In addition to the claims themselves, Plaintiff cites the following intrinsic and extrinsic evidence to support its position: **Intrinsic evidence**: '844 Patent, at [57] Abstract, fig.2, col.1 ll.44–54, col.3 ll.7–10, col.4 l.4–7, col.4 ll.47–48, col.4 ll.60–66, col.5 ll.43–60, col.6 ll.4–6, col.6 ll.32–36, col.6 ll.48–49; '894 Patent File Wrapper October 25, 2013 Amendment/Response

(Plaintiff's Ex. 6, Dkt. No. 70-8); U.S. Patent Application No. 61/244,402[9] (Plaintiff's Ex .5, Dkt. No. 70-7). **Extrinsic evidence**: Otto Decl. ¶¶ 11–15 (Dkt. No. 70-1 at 2–4); Dictionary.com ("integral") (Plaintiff's Ex. 7, Dkt. No. 70-2)[10].

Defendants respond that the "trace" of the Asserted Patents is described "as the conductive element between the electrode plates and the conductive pad" in every exemplary embodiment and, therefore, "trace" should be so construed. Dkt. No. 76 at 25. Defendants further argue that "trace" of the patents does not exclude wires because there is no clear and unambiguous disclaimer of wires from the scope of "trace." *Id*. According to Defendants, the patents equate "trace" with "lead" and there is no dispute that "lead" includes wires. *Id*. (citing '844 Patent col.3 ll.8–10). Finally, Defendants argue that excluding wires from the scope of "trace" obfuscates claim scope as it is unclear what qualifies as a "wire." *Id*. at 26.

In addition to the claims themselves, Defendants cite the following **intrinsic evidence** to support their position: '844 Patent col.3 ll.8–10; '894 Patent figs.1–4, 6, 7, 8, col.4 ll.6–9; U.S. Patent No. 5,125,406 (Defendants' Ex. E, Dkt. No. 76-5).

Plaintiff replies to reiterate that the patents and prosecution history distinguish the claimed "trace" from the prior-art wires. Dkt. No. 82 at 2–3.

Plaintiff cites further **intrinsic evidence** to support its position: '844 Patent col.4 ll.6–9.

Analysis

The primary issue in dispute here is whether "trace" of the Asserted Patents encompasses wires. It does not.

[9] The '844 and '894 Patents each claim priority to U.S. Patent Application No. 61/244,402. '844 Patent, at [60] Related U.S. Application Data; '894 Patent, at [60] Related U.S. Application Data
[10] http://www.dictionary.com/browse/integral.

The "traces" of the Asserted Patents are formed using conductive ink or paint, not wires. The patents note that the prior-art laryngeal electromyography devices included features "such as metallic plates, adhesives, lead wires, and structural elements resulting in raised portions on the smooth physical profile of the endotracheal tube." '844 Patent col.1 ll.44–54. And because of this, the prior-art devices were not suitable "for monitoring purposes in excess of eight hours." *Id*. at col.1 ll.55–67. Another purported failing of the prior-art devices was that they incorporated structure or material that diminished the flexibility of the endotracheal tube. *Id*. at col.2 ll.1–8. The invention of the Asserted Patents purports to solve these failings in the prior art. *Id*. at col.2 ll.33–38, col.2 l.47 – col.3 l.14. And the solution is to use conductive ink or paint to form the electrodes and traces of the device. *Id*. at col.4 ll.47–50 ("A suitable conductive composition, referred to as an ink or paint, for forming the plates 14 and the traces 20 comprises a mixture of conductive materials."), col.6 ll.30–32 ("The endotracheal tube with imprinted electrode surfaces allows safe, long term intubation and clinical monitoring of human laryngeal electromyographic signals."), col.6 ll.57–60 ("Further, printing the electrode on the surface provides for optimization of the configuration of the electrode plates on the body of the endotracheal tube without introducing stiff attachments or physical additions."). That is, the traces are not made of wire. *See Inpro II Licensing, S.A.R.L. v. T-Mobile USA Inc.*, 450 F.3d 1350, 1353–57 (Fed. Cir. 2006) (limiting a claim to exclude certain technology when that technology was disparaged in the patent and prosecution history and when overcoming the failing of that technology was described as a purpose of the invention); *see also*, *Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1371–72 (Fed. Cir. 2012) (disparaged technology excluded from claims); *UltimatePointer, L.L.C. v. Nintendo Co.*, 816 F.3d 816, 822–24 (Fed. Cir. 2016) (same).

The Court's understanding based on the disclosure of the Asserted Patents is further supported by the prosecution history. For example, the patentee distinguished the claimed invention from a prior-art reference that uses "wires embedded in the wall of the tube" instead of "insulated conductors (traces) on the surface of the . . . tube." '894 Patent File Wrapper, October 25, 2013 Amendment/Response at 7–8, Dkt. No. 70-8 at 8–9. The patentee distinguished another prior-art reference that did not "show or suggest using a conductive ink or paint but instead refers to a solid metal laid down on the substrate." *Id*. at 10–11, Dkt. No. 70-8 at 11–12. According to the patentee, the claims of the '894 Patent "***all require one or more printed electrodes, leads and connection points formed directly on the surface of an endotracheal tube using a conductive ink or paint***." *Id*. (emphasis added); '844 Patent col.3 ll.8–9 ("the traces, also referred to as leads are likewise applied to the surface of the tube").

Defendants' proposed construction does not clarify claim scope. The claims of the Asserted Patents define how the claimed "traces" relate to the claimed electrodes and conductive pads/connection points, where the "traces" are located relative to the endotracheal tube, and where the conductive pads/connection points are located on the tube. For example, Claim 1 of the '844 Patent recites: (1) the traces are "applied directly to the tube surface," (2) the traces are "connected to or integral with the electrode plates," and (3) the conductive pads are "connected to or integral with the . . . traces." Claim 4 of the '844 Patent recites: (1) the traces are "formed by applying a conductive ink . . . to the exterior surface of the endotracheal tube," (2) the traces are "attached to . . . electrode plates," and (3) the conductive pads are "attached to a proximal end of the traces." Claim 1 of the '894 Patent recites: (1) the "tube having on its surface . . . traces," (2) the traces are "connected to or integral with an electrode," and (3) the connection points are "connected to or integral with each of the conductive traces." Claim 4 of

the ’894 Patent recites: (1) the traces are “formed by applying a conductive ink or paint to the exterior surface of the endotracheal tube,” (2) the traces are “attached to . . . the electrodes,” and (3) the connection points are “at a proximal end of the . . . traces.” Claim 10 of the ’894 Patent recites: (1) the traces are “applied directly to the tube surface,” (2) the traces are “connected to or integral with the electrodes,” and (3) the connection points are “connected to or integral with the conductive traces.” Finally, Claim 14 of the ’894 Patent recites that: (1) the “tube having on its surface . . . traces,” (2) the traces are “connected to or integral with the . . . electrode[s],” and (3) the conductive pads are “connected to or integral with the conductive traces.” Accordingly, the claims provide adequate scope for the term “trace.”

Defendants’ proposed construction is also inconsistent with the intrinsic record. For example, Claim 14 of the ’894 Patent recites “electrical leads connected to the electrically conductive traces or to conductive pads connected to or integral with the conductive traces.” The Court understands this to mean that the device of claim 14 optionally has “conductive pads” through which the traces connect to the electrical leads, or has traces that connect directly to the electrical leads. Defendants’ proposed construction of “trace” would require a “conductive pad or a connection point” when Claim 14 does not include such a requirement.

Accordingly, the Court holds that “trace” and “electrode” are specially defined in the Asserted Patents and construes “trace” as follows:

- “trace” means “element formed of conductive ink or paint.”

E. “applied […] directly to the surface of the tube,” “applied […] directly to the tube surface”

Disputed Term	Plaintiff’s Proposed Construction	Defendants’ Proposed Construction

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"applied […] directly to the surface of the tube" • '844 Patent Claim 1 • '894 Patent Claims 1, 10, 14	"applied […] directly [to the surface of the tube / to the tube surface] by, for example, painting, printing, spraying or metallizing, as opposed to being adhesively secured or embedded"	"applied […] directly [to the surface of the tube / to the tube surface]"
"applied […] directly to the tube surface" • '844 Patent Claim 1 • '894 Patent Claims 1, 10, 14		

Because the parties' arguments and proposed constructions with respect to these terms are related, the Court addresses the terms together.

The Parties' Positions

Plaintiff submits that "applied . . . directly to the surface of the tube" and "applied . . . directly to the tube surface" each exclude "adhesively securing or embedding electrodes, traces or pads to a tube." Dkt. No. 70 at 12. According to Plaintiff, the Asserted Patents distinguish the invention's approach to applying electrodes and traces directly to the surface from the prior art's approach of adhering electrodes/wires to, or embedding electrodes/wires in, the surface. *Id*. at 12–13 (citing, inter alia, '844 Patent col.1 ll.44–54, col.6 ll.32–36). And, Plaintiff contends, the prosecution history further makes this distinction clear. *Id*. at 14.

In addition to the claims themselves, Plaintiff cites the following intrinsic and extrinsic evidence to support its position: **Intrinsic evidence**: '844 Patent, at [57] Abstract, col.1 ll.44–54, col.2 ll.22–23, col.2 ll.33–46, col.2 l.67 – col.3 l.8, col.3 ll.65–68, col.4 l.15, col.4 ll.47–48, col.5 ll.34–35, col.5 ll.43–60, col.5 l.62, col.6 ll.4–6, col.6 ll.32–36, col.6 ll.57–60; '894 Patent File Wrapper October 25, 2013 Amendment/Response (Plaintiff's Ex. 6, Dkt. No. 70-8); U.S. Patent

Application No. 61/244,402 (Plaintiff's Ex. 5, Dkt. No. 70-7). **Extrinsic evidence**: Otto Decl. ¶¶ 16–17 (Dkt. No. 70-1 at 4–5).

Defendants respond that the meaning of these terms is apparent without construction. Dkt. No. 76 at 26. Defendants argue that Plaintiff's proposed construction is not a construction but rather a request for "ad hoc findings about what embodiments may or may not meet a claim term." *Id*. at 27.

Plaintiff replies that claimed inventions are described in the prosecution history as overcoming failings in the prior-art's "integrated wire ET tube" and the "stick-on electrode," which utilized adhesives and wires. Dkt. No. 82 at 3.

Analysis

The issue in dispute appears to be whether "applied . . . directly to" the surface includes embedding in the surface or bonding to the surface with an adhesive. It does not. The electrode or trace of the claims is applied to the surface of the tube without an intervening layer—which the Court understands is the plain and ordinary meaning of "applied . . . directly to" the surface.

The electrodes and traces are formed of conductive ink or paint that is applied to the surface of the endotracheal tube without any intervening material. As set forth in detail in the discussion of "trace" above, prior-art laryngeal electromyography devices purportedly failed because they included features "such as metallic plates, adhesives, lead wires, and structural elements resulting in raised portions on the smooth physical profile of the endotracheal tube" which made the devices unsuitable for prolonged monitoring. '844 Patent col.1 ll.44–67. The solution to this failing is to use conductive ink or paint to form the electrodes and traces of the device. *Id*. at col.4 ll.47–50 ("A suitable conductive composition, referred to as an ink or paint, for forming the plates 14 and the traces 20 comprises a mixture of conductive materials."), col.6

ll.30–32 ("The endotracheal tube with imprinted electrode surfaces allows safe, long term intubation and clinical monitoring of human laryngeal electromyographic signals."). This conductive ink or paint is deposited directly on the surface of the endotracheal tube, i.e., without any intervening material. *Id.* at col.5 l.37 – col.6 l.14 (describing various exemplary ways in which the ink or paint may be applied directly to the surface), col.6 ll.57–60 ("Further, printing the electrode on the surface provides for optimization of the configuration of the electrode plates on the body of the endotracheal tube without introducing stiff attachments or physical additions.").

Accordingly, the Court rejects Defendants' construction to the extent that construction is meant to encompass an intervening layer of adhesive (or any material) or embedding material in the surface. The Court determines that these terms have their plain and ordinary meaning without the need for further construction.

F. "electrical leads"

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"electrical leads" • '844 Patent Claim 1 • '894 Patent Claims 1, 10, 14	Plain and ordinary meaning.	"electrical wiring connecting the endotracheal tube to an external monitoring system"

The Parties' Positions

Plaintiff submits that the meaning of this term is clear without construction. Dkt. No. 70 at 27. Plaintiff contends that Defendants' proposed construction improperly limits "leads" to "wiring," yet a prior-art reference of record in the prosecution history evinces that "leads" may or may not be wires. *Id*. at 28.

In addition to the claims themselves, Plaintiff cites the following intrinsic and extrinsic evidence to support its position: **Intrinsic evidence**: '844 Patent figs.2, 6, 8, col.3 ll.10; U.S. Patent No. 4,461,304[11] (Plaintiff's Ex. 14, Dkt. No. 70-16). **Extrinsic evidence**: Otto Decl. ¶¶ 39–40 (Dkt. No. 70-1 at 11).

Defendants respond that they "are not aware of any material issue impacted by this claim term" and that because Plaintiff "has declined to give the Court a proposed construction, there is no need for the Court to even address the issue of whether 'electrical leads' includes something more than wires." Dkt. No. 76 at 27.

Plaintiff replies that the claims separately recite that the electrical leads "connect to monitoring equipment" so there is no need to read such a limitation into "electrical lead." Dkt. No. 82 at 10. And Plaintiff reiterates that there is no disclaimer of claim scope to justify limiting "electrical leads" to "electrical wiring." *Id*.

Analysis

The issue in dispute here is whether "electrical leads" is synonymous with "electrical wiring." While an "electrical lead" may be a wire, it is not limited to wires. The Court therefore declines to rewrite the claim language as Defendants propose.

"Electrical leads" are not necessarily wires. Defendants' argument to rewrite "leads" as "wiring" is unpersuasive. Defendants argue that "the asserted patents disclose only external wiring," and therefore "electrical leads" are "electrical wiring." It would be improper, however, to limit the claims to this single embodiment. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc) ("we have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that

[11] U.S. Patent No. 4,461,304 is cited on the face of the '844 and '894 Patents. '844 Patent, at [56] References Cited; '894 Patent, at [56] References Cited.

embodiment"); *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) ("It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation. We do not read limitations from the specification into claims; we do not redefine words. Only the patentee can do that."); *SRI Int'l v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc) ("The law does not require the impossible. Hence, it does not require that an applicant describe in his specification every conceivable and possible future embodiment of his invention."). Defendants have not provided evidence that the "leads" of the claims are limited to wires. Indeed, the traces of the Asserted Patents are described as a type of "lead." '844 Patent col.3 ll.8–9 ("the traces, also referred to as leads are likewise applied to the surface of the tube"). As set forth in detail in the discussion of "trace" above, the traces are not wires. It follows that not all "leads" are wires.

The Court also rejects Defendants' proposed phrase, "connecting the endotracheal tube to an external monitoring system." First, the claims recite that the electrical leads are capable of connecting to monitoring equipment because the leads are "adapted" or "configured" to make such a connection. The claims do not require that the leads are actually connected to a monitoring system, as Defendants' proposed construction requires. Second, it is unclear what Defendants mean by connecting the endotracheal tube to the monitoring system. As set forth in the claims, the leads are connected to the traces which are connected to the electrodes which are formed on the tube. Thus, the leads are meant to connect the electrodes, not the tube, to the monitoring system.

Accordingly, the Court determines that "electrical leads" has its plain and ordinary meaning without the need for further construction.

G. "trachea"

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"trachea" • '844 Patent Claim 1 • '894 Patent Claims 1, 5, 10, 14	Plain and ordinary meaning.	Indefinite due to the patent's usage of the term contrary to its customary meaning to a person of ordinary skill in the art. **alternative**: • the term should be given its customary meaning to a person of ordinary skill in the art.

The Parties' Positions

Plaintiff submits that "trachea" is used in the Asserted Patents according to its customary meaning—not redefined contrary to that meaning, as Defendants contend. Dkt. No. 70 at 23. Plaintiff contends that the patents' description of "the vocal cord located on the front surface of the trachea" is not a redefinition of "trachea" to include the "vocal cord." *Id*. (quoting '844 Patent col.4 ll.20–21). Rather, according to Plaintiff, when taken in context, this statement refers to the orientation of the curves/electrode of the endotracheal tube. *Id*. Plaintiff likewise contends that the prosecution-history statement "tracheal wall proximal of the vocal cords, such as closer to the tongue" does not redefine "trachea" to include the "vocal cord" or to be placed above the "vocal cord." *Id*. at 23–24. According to Plaintiff, when this statement is taken in context, it refers to a portion of the tracheal wall that is closer to the vocal cord as opposed to further from the vocal cord. *Id*.

Plaintiff further submits that other portions of the patents and prosecution history use the term "trachea" in a manner suggesting that the vocal cords are distinct from the trachea. *Id*. at 24–25. For instance, Claim 1 of the '894 Patent recites a first electrode "positioned to contact the

vocal cords" and a second electrode "positioned to contact tissues, nerves and muscle in the trachea." *Id*. at 24. Plaintiff contends that if "trachea" was redefined to include the vocal cords, then there is no distinction between the first and second electrodes. *Id*. Plaintiff also notes that a prior-art reference submitted during prosecution clearly delineates the "trachea" from the vocal cord. *Id*. at 25. Finally, Plaintiff submits that the Patent Trial and Appeal Board considered whether "trachea" was redefined in the Asserted Patents "contrary to human anatomy," and determined that it was not. *Id*. at 25 n.6 (quoting *Nuvasive Inc. v. Neurovision Medical Products, Inc.*, IPR2015-00502, Paper No. 15 at 10 (P.T.A.B. July 16, 2015), Dkt. No. 70-15 at 11).

In addition to the claims themselves, Plaintiff cites the following intrinsic and extrinsic evidence to support its position: **Intrinsic evidence**: '844 Patent figs.6, 8, col.3 ll.44–46, col.4 ll.20–21; '894 Patent File Wrapper October 25, 2013 Amendment/Response (Plaintiff's Ex. 6, Dkt. No. 70-8); *Nuvasive Inc. v. Neurovision Medical Products, Inc.*, IPR2015-00502, Paper No. 15 (P.T.A.B. July 16, 2015) (excerpts) (Plaintiff's Ex. 13, Dkt. No. 70-15). **Extrinsic evidence**: Otto Decl. ¶¶ 29–34 (Dkt. No. 70-1 at 8–10).

Defendants respond that "every single time the intrinsic evidence talks about the tracheal electrode, the patent refers to an anatomical structure different from the trachea or an impossible structure" and therefore "trachea" renders claims of the Asserted Patents indefinite. Dkt. No. 76 at 31–33. Defendants contend that, in customary usage in the art, the trachea is different from the larynx, and the vocal cords and epiglottis are in the larynx. *Id*. at 31 (citing Otto Dep. at 36:17 – 37:16, 39:11–40:5, 51:5 – 53:12, 54:9 – 55:17, 228:1–12. But, according to Defendants, the "trachea" of the Asserted Patents appears to include the vocal cords. *Id*. at 31–33. For example, Defendants contend that the "only description of an electrode contacting 'nerves and muscle in

the rear of the trachea' is an electrode contacting a vocal cord in the larynx, not the trachea." *Id*. at 33

In addition to the claims themselves, Defendants cite the following intrinsic and extrinsic evidence to support their position: **Intrinsic evidence**: '844 Patent figs.1–3, 6, col.4 ll.16–19. **Extrinsic evidence**: Otto Dep. 36:17 – 37:16, 39:11 – 40:5, 40:22 – 41:9, 51:5 – 53:12, 54:9–55:17, 56:10–19, 141:7–20, 147:21 – 148:13, 148:24 – 149:8, 228:1–12 (Defendants' Ex. B, Dkt. No. 76-2 at 36–37, 39–41, 51–56, 141, 147–49, 228); Hermes C. Grillo, *Surgery of the Trachea and Bronchi* (2004) (excerpts) (Defendants' Ex. N, Dkt. No. 76-14); M.L. Ajmani, *A Metrical Study of the Laryngeal Skeleton in Adult Nigerians*, Journal of Anatomy 171, 187–91 (1990) (Defendants' Ex. O, Dkt. No. 76-15).

Plaintiff replies that the "trachea" is not used "every single time" in the way suggested by Defendants. Dkt. No. 82 at 7. Specifically, Plaintiff contends that references in the '844 Patent show that "trachea" is used consistent with its customary meaning. *Id*. (citing '844 Patent col.3 ll.44–46, col.3 ll.50–52, col.6 ll.57–63, Claim 1). Plaintiff also contends that Figure 6 of the patents is described as depicting an electrode adjacent to the vocal cords, and not configured to contact the trachea. *Id*. at 7–8 (citing '844 Patent col.4 ll.19–23).

Plaintiff cites further **intrinsic evidence** to support its position: '844 Patent fig.6, col.3 ll.50–52, col.4 ll.16–23, col.6 ll.57–63.

Analysis

The issue with respect to "trachea" is whether it is used in the Asserted Patents contrary to its well-understood meaning in the art and therefore renders claims indefinite. The Court holds that "trachea" is used in the patents according to its customary meaning and that Defendants have failed to prove that any claim is rendered indefinite by the term "trachea."

"Trachea" was not redefined in the patents contrary to is plain and ordinary meaning in the art. There is no dispute that "trachea" has a plain and accepted meaning in the art. Departing from this plain meaning requires a showing of lexicography or disavowal. *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). And the standard for such is "exacting." *Id*. For lexicography, the "patentee must clearly set forth a definition of the disputed claim term and clearly express an intent to define the term." *Id*. (quotation marks omitted). Here, there is no clear expression of an intent to redefine "trachea." True, it appears that the patentee in some instances suggests that the vocal cords are part of the trachea. *See, e.g.*, '844 Patent col.4 ll.17–21 (referring to the "vocal cord located on the front surface of the trachea"). In other instances, the patentee suggests that the vocal cords are part of the larynx. '844 Patent col.1 ll.10–67 (referring to laryngeal monitoring by monitoring the "signals from the muscles of the vocal cords, or larynx" and noting the danger of the prior-art devices "that can also introduce structures in the vicinity of the larynx and can cause injury to the vocal cords"). In yet other instances, the patentee distinguishes between the vocal cords and trachea. *See, e.g.,*'894 Patent Claim 1 (referring to one electrode "to contact the vocal cords" and another "to contact the tissue, nerves, and muscle in the trachea"). And during prosecution, the patentee referred to technical anatomical descriptions of "trachea" that comport with the plain meaning of the term. *See, e.g.*, '894 Patent File Wrapper October 25, 2013 Amendment/Response at 9 ("The vocal cords are located below the epiglottis but above and adjacent the larynx."), Dkt. No. 70-8 at 10. In the context of the entirety of the intrinsic record, and given the plain meaning of "trachea," the Court holds that "trachea" is not clearly redefined in the patents to encompass anatomical features that are not part of the "trachea" as that term is customarily used in the art.[12]

[12] The Court notes that while it is not bound by the construction of "trachea" by the Patent Trial

The Court is not persuaded by Defendants' argument that the claims directed to an electrode positioned to contact parts of the trachea are indefinite. Defendants contend that there is no description in the patent of such electrode positioning. But whether there is an adequate description is a different question than whether the scope of the claims is reasonably certain. Given the plain meaning of "trachea," what it means for an electrode to contact a part of the trachea is reasonably certain. Similarly, given the plain meaning of "trachea," whether a given electrode "placed within the trachea" can contact the vocal cords is a question of infringement, not of definiteness.

Accordingly, the Court determines that "trachea" has its plain and ordinary meaning, does not render any claim indefinite, and requires no further construction.

H. Preambles of '844 Patent Claims 1, 4 and '894 Patent Claims 1, 4, 10, 14.

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"A device for use in monitoring electrical signals during laryngeal electromyography comprising" • '844 Patent Claim 1	Preamble is limiting.	Preamble is not limiting.
"A method of forming an electrode bearing endotracheal tube for laryngeal electromyography comprising" • '844 Patent Claim 4	Preamble is limiting.	Preamble is not limiting.
"A device for use in monitoring electrical signals during laryngeal electromyography comprising" • '894 Patent Claim 1	Preamble is limiting.	Preamble is not limiting.

and Appeal Board ("PTAB") in IPR2015-00502, it finds the PTAB's construction persuasive. *See Nuvasive Inc. v. Neurovision Medical Products, Inc.*, IPR2015-00502, Paper No. 15 at 8–10 (P.T.A.B. July 16, 2015) Dkt. No. 70-15 at 9–11.

Disputed Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"A method of forming an electrode bearing endotracheal tube for laryngeal electromyography comprising" • '894 Patent Claim 4	Preamble is limiting.	Preamble is not limiting.
"A method of conducting monitoring of electrical signals during laryngeal electromyography for a period of time in excess of 8 hours without injury to the trachea" • '894 Patent Claim 10	Preamble is not limiting. Plain and ordinary meaning.	This preamble requires active monitoring of electrical signals during laryngeal electromyography for over 8 hours without injuring the trachea of a human patient.
"A device for use in monitoring electrical signals during laryngeal electromyography comprising" • '894 Patent Claim 14	Preamble is limiting.	Preamble is not limiting.

Because the parties' arguments and proposed constructions with respect to these terms are related, the Court addresses the terms together.

The Parties' Positions

With respect to Claim 10 of the '894 Patent, Plaintiff submits that the preamble is not limiting because the claimed invention is set forth entirely in the body of the claim. Dkt. No. 70 at 28–29. Plaintiff contends that Defendants' proposed limiting construction is also improper as it injects "active monitoring" into the claim, the meaning of which is unclear, and because it requires monitoring for over eight hours, when such monitoring is "simply a benefit of the novel invention." *Id*. at 29. According to Plaintiff, a preamble that states a benefit of the claimed invention does not limit the claim. *Id*. at 29–30 (citing *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002)).

With respect to the other independent claims of the Asserted Patents, Plaintiff submits that the preambles are limiting because they are necessary to understand that the combined limitations are to "monitor[] electrical signals during laryngeal electromyography." *Id*. at 30 (quoting '844 Patent Claim 1 (quotation modification by Plaintiff)).

In addition to the claims themselves, Plaintiff cites the following **intrinsic evidence** to support its position: '844 Patent col.2 ll.51–55.

With respect to Claim 10 of the '894 Patent, Defendants respond that the preamble recites that the monitoring is "for a period of time in excess of 8 hours without injury to the trachea," this is not duplicative of any limitation in the claim body, and therefore the preamble is limiting. Dkt. No. 76 at 23. Defendants also contend that the preamble must be limiting because it provides antecedent basis for "during the period of monitoring" limitation recited in the body of the claim. *Id*. And, Defendants contend, Claim 11, which depends from Claim 10, recites "wherein the period of monitoring exceeds 24 hours" evincing a distinction between the claims based on the period of monitoring, namely, Claim 10 requires that the period exceed 8 hours and Claim 11 requires that the period exceed 24 hours. *Id*. at 23–24.

With respect to the other independent claims of the Asserted Patents, Defendants respond that the preambles simply recite intended uses and are therefore not limiting.

With respect to Claim 10 of the '894 Patent, Plaintiff replies that the claim's recited "monitoring electrical signals"—and not the preamble—forms the antecedent basis for "the period of monitoring." Dkt. No. 82 at 10–11. According to Plaintiff, the "monitoring electrical signals" language was added during prosecution for that purpose. *Id*. at 11.

With respect to the other independent claims of the Asserted Patents, Plaintiff replies that certain prior-art endotracheal tubes were distinguished from the claimed invention based on the

use of the tube—the prior-art tubes were used to measure cardiac output rather than for laryngeal electromyography. *Id*. at 11.

Plaintiff cites further **intrinsic evidence** to support its position: '894 Patent File Wrapper, October 31, 2013 Office Action (Plaintiff's Ex. 15, Dkt. No. 82-1), October 25, 2013 Amendment/Response (Plaintiff's Ex. 6, Dkt. No. 70-8), November 4, 2013 Amendment/Response (Plaintiff's Ex. 16, Dkt. No. 82-2).

Analysis

The primary issue in dispute is whether the preambles are limiting. The Court determines that the preambles of the independent claims are limiting because the preambles are necessary to understand the claims.

The preambles are necessary to understand the claims because the use stated in the preambles, "laryngeal electromyography," is required to give meaning to the claims. For example, Claim 1 of the '844 Patent defines the positioning of the electrodes with reference to "the vocal cords" and "the trachea" and "the tongue." The role that these terms play in defining claimed structure or steps is only apparent when read in the context of laryngeal electromyography. Indeed, there is no antecedent basis for these terms other than what is implicit in the use of the device. Further, the positioning of various structures is recited with reference to "proximal" and "distal." Again, these terms are understood with respect to the device as it is used for laryngeal electromyography. The proximal end of the device is the end sticking out of the patient's mouth during the procedure. The Court holds that the preambles implicitly introduce terms that form the antecedent basis for recitation of those terms in the body of the claims and provide meaningful context necessary to understand the limitations recited in the body of the

claims. Therefore, the preambles are limiting. *See Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015).

With respect to Claim 10 of the '894 Patent, while the Court agrees with Defendants that the preamble is limiting, the Court rejects Defendants' proposed "active" monitoring limitation. Defendants have not provided an explanation of what "active monitoring" is, how it differs from "monitoring," or why the Court should rewrite "monitoring" as "active monitoring." Defendants argument seems to be that "monitoring" requires "actually monitoring" and therefore "monitoring" means "active monitoring." The Court is not persuaded. If the distinction is between actually monitoring and not monitoring, "monitoring" alone is sufficient and the term "active" does not help convey the concept. Injecting "active" into the claims also presents an issue of whether "passive monitoring" is possible and, if so, whether it should be excluded from the scope of the claim.

Accordingly, the Court determines that each of the preambles is necessary to understand the claims and therefore each preamble is limiting. The Court further determines that each of the preambles has its plain and ordinary meaning without the need for further construction.

IV. CONCLUSION

The Court adopts the constructions above for the disputed and agreed terms of the Asserted Patents. Furthermore, the parties should ensure that all testimony that relates to the terms addressed in this Order is constrained by the Court's reasoning. However, in the presence of the jury the parties should not expressly or implicitly refer to each other's claim construction positions and should not expressly refer to any portion of this Order that is not an actual construction adopted by the Court. The references to the claim construction process should be limited to informing the jury of the constructions adopted by the Court.

SIGNED this 27th day of October, 2016.

ROY S. PAYNE
UNITED STATES MAGISTRATE JUDGE