Filed on behalf of: Medtronic Xomed, Inc.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Medtronic Xomed, Inc.
   Petitioner
v.
Neurovision Medical Products, Inc.
   Patent Owner

Case
U.S. Patent 8,467,844

PETITION FOR INTER PARTES REVIEW
Table of Contents

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8 ............................................... 1
   A. Real Party-in-Interest Under 37 C.F.R. § 42.8(b)(1) .............................. 1
   B. Related Matters Under 37 C.F.R. § 42.8(b)(2) ....................................... 1
   C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3) .................. 1
   D. Service Information Under 37 C.F.R. § 42.8(b)(4) .............................. 2

II. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103 ....................................... 2

III. REQUIREMENTS UNDER 37 C.F.R. § 42.104 ............................................. 2
   A. Grounds for Standing Under 37 C.F.R. § 42.104(a) .............................. 2
   B. Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested ............. 2
   C. Claim Construction under 37 C.F.R. § 42.104(b)(3) ............................. 3

IV. SUMMARY OF THE ’844 PATENT .................................................................. 4
   A. The Background of the Technology ...................................................... 4
   B. The Claimed Subject Matter ............................................................... 15
   C. Prosecution History and Lack of Support for Priority Claim .................. 16

V. ARGUMENTS .................................................................................................. 17
   A. Statement of the Law ....................................................................... 17
      1. Obviousness .................................................................................. 17
      2. Negative Limitations ..................................................................... 18
   B. Grounds of Unpatentability ............................................................... 18
1. Ground 1: Claims 1-7 are Obvious in View of Kartush, Topsakal, Cook, and Hon ...........................................18

2. Ground 2: Claims 1-7 are Obvious in View of Goldstone, Teves, Cook, and Hon ............................................39

3. Alternative Grounds: Interchanging Kartush and Goldstone ........................................................................59

VI. Conclusion .................................................................................................................................................60
EXHIBITS

1001 — U.S. Patent No. 8,467,844, issued June 18, 2013 (the “‘844 patent”)


1003 — U.S. Patent No. 5,024,228, issued June 18, 1991 (“Goldstone”)

1004 — U.S. Patent No. 4,890,623, issued June 2, 1990 (“Cook”)

1005 — “Direct writing technology – Advances and developments,” Hon, et al.,

1006 — “Continuous ink-jet printing electronic components using novel
   conductive inks,” Mei et al., Fifteenth Solid Freeform Fabrication (SFF)
   Symposium held at The University of Texas in Austin on August 2-4, 2004 (“Mei”)

1007 — “Intraoperative monitoring of lower cranial nerves in skull base surgery:
   technical report and review of 123 monitored cases,” Topsakal et al.,


1009 — Declaration of Dr. Ralph P. Tufano (“Tufano Declaration”)


1011 — U.S. Provisional App. 61/244,402
1012 — Declaration of Guy Lowery (“Dec. Lowery”)
1014 — “Intraoperative Facial Nerve Monitoring,” Kartush et al., Chap. 5,
Neuromonitoring in Otology and Head and Neck Surgery, Raven Press,
1015 — Infringement Contentions, Exhibit A, Neurovision Medical Products, Inc.
v. Medtronic PLC, 2:16-CV-00127 (“Infringement Contentions”)
1016 — U.S. Patent No. 4,351,330, issued September 28, 1982 (“Scarberry”)
1017 — “Intraoperative monitoring during surgery for hypoglossal schwannoma,”
Ishikawa et al., Journal of Clinical Neuroscience, Vol. 17, pp. 1053-1056
(2009) (“Ishikawa”)
1018 — “Quantitative Estimation of the Recurrent Laryngeal Nerve Irritation by
Employing Spontaneous Intraoperative Electromyographic Monitoring
During Anterior Cervical Discectomy and Fusion,” Dimopoulos et al., J.
Spinal Disorder Tech, Vol. 22, No. 1, pp. 1-7 (February 2009)
(“Dimopoulos”)
1019 — “Intra-operative electromyographic monitoring of the lower cranial motor
nerve (LCN IX-XII) in skull base surgery,” Schlake et al., Clinical
1020 — Gray’s Anatomy, Churchill Livingstone, pp. 1225-1236, 1243-1256,
1721-1732 (1995)


1022 — Clinical Neurophysiology 3rd Ed., Oxford Univ. Press, Chap. 25, 43 and 44 (“Clinical Neurophysiology”)


Medtronic Xomed, Inc. petitions for *Inter Partes* Review (“IPR”) under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42 of claims 1-7 of U.S. Patent No. 8,467,844 (“’844 patent”) (Ex 1001). For the reasons set forth below, there is a reasonable likelihood of finding at least one of those claims unpatentable.

**I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8**

**A. Real Party-in-Interest Under 37 C.F.R. § 42.8(b)(1)**

Medtronic Xomed, Inc. (“Petitioner”), Medtronic, Inc., and Medtronic PLC are the real parties-in-interest.

**B. Related Matters Under 37 C.F.R. § 42.8(b)(2)**

Petitioner is a named defendant in a patent infringement litigation involving the ’844 patent (currently case No. 2:16-CV-00127 in the Eastern District of Texas). Petitioner has filed two IPRs against the child of the ’844 patent (IPR2016-01405 and IPR2016-01406).

**C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)**

<table>
<thead>
<tr>
<th>LEAD COUNSEL</th>
<th>BACK-UP COUNSEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Justin J. Oliver, Reg. No. 44,986</td>
<td>Jason Dorsky, Reg. No. 64,710</td>
</tr>
<tr>
<td>Fitzpatrick, Cella, Harper &amp; Scinto</td>
<td>Fitzpatrick, Cella, Harper &amp; Scinto</td>
</tr>
<tr>
<td>975 F Street, NW Fourth Floor</td>
<td>975 F Street, NW Fourth Floor</td>
</tr>
<tr>
<td>Washington, D.C. 20004</td>
<td>Washington, D.C. 20004</td>
</tr>
<tr>
<td>(202) 530-1010 (o)/(202) 530-1055 (f)</td>
<td>(202) 530-1010 (o)/(202) 530-1055 (f)</td>
</tr>
</tbody>
</table>
D. **Service Information Under 37 C.F.R. § 42.8(b)(4)**

Petitioner consents to service by email at Medtronic894IPR@fchs.com.

II. **PAYMENT OF FEES UNDER 37 C.F.R. § 42.103**

The USPTO may charge Deposit Account No. 50-3939 for any fees associated with the present petition (referencing docket number 03190.008900).

III. **REQUIREMENTS UNDER 37 C.F.R. § 42.104**

A. **Grounds for Standing Under 37 C.F.R. § 42.104(a)**

Petitioner certifies that the ’844 patent is eligible for IPR and that Petitioner is not barred or estopped from requesting IPR. This Petition is filed within one year of service of the above-identified infringement complaint against Petitioner.

B. **Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested**

Petitioner requests (i) review of claims 1-7 of the ’844 patent on the grounds set forth below and (ii) that each of those claims be found unpatentable.

<table>
<thead>
<tr>
<th>Ground</th>
<th>Claim(s)</th>
<th>Basis for Unpatentability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1-7</td>
<td>Obvious (§103) in view of Kartush, Topsakal, Cook, and Hon</td>
</tr>
<tr>
<td>2</td>
<td>1-7</td>
<td>Obvious (§103) in view of Goldstone, Teves, Cook, and Hon</td>
</tr>
</tbody>
</table>
C. Claim Construction under 37 C.F.R. § 42.104(b)(3)

The USPTO applies the broadest reasonable interpretation (“BRI”) of the claims, which may be different than that applied by a district court. Nothing asserted herein should be understood as waiving alternative claim constructions in any related litigation. Petitioner may rely on claim constructions that correspond to infringement contentions by Patent Owner for purpose of simplifying this proceeding, which should not be understood as an admission as to their applicability under district court construction standards.

“Positioned to contact” (claims 1 and 4) – Patent Owner has argued that the recitation of electrodes “positioned to contact” anatomical structures (e.g., tongue) is met where the position of the electrodes along the tube is such that the electrodes can contact the recited structures when positioned in the patient for use. Patent Owner has asserted the claims against an endotracheal tube with offset, but overlapping, electrodes intended to contact the vocal cords alone, under a theory that the electrodes could allow for simultaneous contact with the vocal cords and tongue in some patients. Ex. 1015, pp. 11-16; p. 15 (discussing tongue distance).

Petitioner reserves the right to challenge Patent Owner’s construction in the district court proceeding and does not concede that its accused device contacts particular anatomical structures. Nevertheless, in this proceeding alone, Petitioner proposes that electrodes “positioned to contact” anatomical structure(s) be
construed to require positioning along the tube that provides for such contact when the tube is placed in a human patient.

“Electrode plate” (claims 1 and 4) – Petitioner understands this term to mean a conductive material formed on a surface by, for instance, printing or painting. Ex. 1001, 2:32-38; 4:47-51.

IV. SUMMARY OF THE ’844 PATENT

A. The Background of the Technology

The ’844 patent is directed to endotracheal tubes “commonly used during anesthesia and intensive care in order to support respiration of a human patient who may be unable to breathe without the use of mechanical breathing support devices.” Ex. 1001, 1:10-13. The patent describes the incorporation of electrodes on such an endotracheal tube. As acknowledged in the ’844 patent, electrodes on endotracheal tubes “are currently used in various surgical procedures to provide monitoring of the electromyographic signals from the muscles of the vocal cords, or larynx.” Ex. 1001, 1:17-21.

Endotracheal Tubes

Endotracheal tubes have long been used during surgeries, intensive care situations, and medical emergencies to ventilate a patient’s lungs. Ex. 1003, 1:32-40; 4:29-35. These tubes are inserted through a patient’s mouth into the trachea in a process called intubation. Ex. 1009, ¶22-27; Ex. 1012, ¶9. Endotracheal tubes
typically include a cuff/balloon that is inflated once the tube is positioned in the trachea. Ex. 1002, ¶[0026]. An example of Goldstone’s endotracheal tube 10 with an inflated cuff 13 (left) is shown below next to the tube from the ’844 patent (right).

Ex. 1003, Fig. 6 (electrodes 43)     Ex. 1001, Fig 6 (electrodes 14)

In addition to securing the tube in place, the cuff prevents air (and gaseous anesthesia) from escaping the lungs from around sides of the tube, thus allowing medical personnel to control proper air flow into and out of the lungs. Ex. 1003,
1:32-40; Ex. 1002, ¶[0026]; Ex. 1009, ¶26. To achieve this end, the proximal end of the tube (outside of the patient’s mouth) connects to a respirator that mechanically replicates breathing patterns for the patient. Ex. 1003, 5:1-13.

The prior art describes the inclusion of electrodes on endotracheal tubes long before the ’844 patent. See Ex. 1009, ¶¶29-42. The electrodes were provided at various positions along the tube to contact different anatomical structures, in order to monitor electrical events associated with various health conditions or physiological events. Ex. 1009, ¶¶39-49; Ex. 1012, ¶9. For instance, electrodes were positioned to contact the patient’s trachea in order to monitor bioelectric impedance, which indicates cardiac output. Ex. 1002, ¶¶[0003]-[0004]; Ex. 1012, ¶9.

In addition, prior art endotracheal tubes included electrodes for contacting the tongue or trachea in order to monitor a patient’s internal temperature. Ex. 1013, 3:4-68. Other tube designs utilized tongue-contacting electrodes for purposes of providing internal defibrillation. Ex. 1016, Abstract; 3:46-52; 4:43-46.

Even more commonly, electrodes had been provided on endotracheal tubes (and elsewhere) to contact muscles in connection with locating nerves at a surgical site—the same use described in the ’844 patent. These electrodes monitored electromyographic activity in the muscles as an indicator of the location of, and potential injury to, motor nerves that controlled those muscles. Ex. 1009, ¶¶23, 28-
32. For monitoring the recurrent laryngeal nerve (RLN), the electrodes monitored laryngeal muscles (including the vocal cords), which are located in the larynx (between the tongue and trachea). Ex. 1009, ¶24, 32-33; Ex. 1020, p. 1637 ("Larynx"); Ex. 1018, p. 1, col. 2-p. 2, col. 1.

Ex. 1020, Fig. 11.23

Damage to the RLN during surgery on the head or neck may result in loss of control over the vocal cords—causing speech loss. Ex. 1003, 1:5-31. To prevent such damage, it is important to avoid significant manipulation of the RLN. However, identification and avoidance of nerves during surgery had been difficult, given their sizes and resemblance to other tissue structures. Ex. 1021, ¶[0002]-
[0007]. For that reason, well before the filing date, it had become common to use endotracheal tubes containing electrodes for detecting nerves through electromyography (EMG).

**EMG Nerve Detection**

Nerve detection methods based on EMG activity have been used in a wide array of operations that risk nerve damage, including surgeries on the head, spine, and neck. Ex. 1014, pp. 99-100; Ex. 1009, ¶¶33-40. For head and neck surgery, it has been known to use intraoperative EMG monitoring in connection “with almost any cranial muscle.” Ex. 1022, p. 741, col. 1, ln. 11-17; p. 746, col. 1-2.

No matter the surgical location, to alert the surgeon to the location of at-risk nerves, (i) stimulating electrodes were typically provided on surgical instruments/probes and (ii) EMG sensing electrodes were provided at the muscles innervated by the nerves. Ex. 1022, p. 766, col.1-2 (EMG Recording); Ex. 1021, ¶¶[0002]-[0008]. For instance, if the stimulating instrument moves into proximity of the RLN, the electrical stimulus causes that nerve to depolarize. Ex. 1003, 3:59-4:35. The RLN is a branch of the vagus nerve (cranial nerve 10). RLN depolarization results in signals being sent along the nerve to the vocal cords, causing a detectable muscle contraction (EMG response). Alternatively, the mere physical manipulation of the nerve may result in an EMG response. Ex. 1003, 4:4-15; see Ex. 1018, p. 4, col. 2. In either case, an electrode at the muscle detects
electrical activity indicative of nerve action. Such monitoring provides an alert that helps avoid nerve injury, thus preserving the function of the associated muscles. Ex. 1007, p. 51, col. 2, ln. 28-35; Ex. 1023, p. 377, ll. 10-23.

For surgery implicating the hypoglossal nerve (cranial nerve 12), depolarization causes EMG activity in the muscles of the tongue. Ex. 1007, p. 47, col. 1, ln. 27-35; p. 50, col. 1, ln. 20-44; Ex. 1009, ¶¶34, 39. In some operations at the base of the skull, it is preferable to monitor EMG responses from both the tongue and the vocal cords simultaneously, so as to protect against damage to either cranial nerve (10 or 12). Ex. 1022, p. 746, col. 1, ln. 15 – col. 2, ln. 6.

Ex. 1007, Fig. 2

Monitoring risks to multiple nerves simultaneously is particularly important in procedures that remove cranial tumors, as various cranial nerves may be closely
positioned near such tumors. Ex. 1017, p. 1053, Sec. 2.1; Fig. 2; p. 1054, col. 2, ln. 18-23; Ex. 1007, p. 47, 6-25, 46-51; Ex. 1019, 72, col. 1, ln. 1 – p. 73, col. 1, ln. 19; Ex. 1025, p. 69. In addition, damage to the hypoglossal nerve (CN12) can result in a more debilitating injury if there is concurrent injury to the vagus nerve/RLN (CN10). Even without a CN10 injury, bilateral loss of CN12 can be “devastating.” Ex. 1024, 300:6-22.

Early methods for monitoring EMG activity involved inserting needle electrodes into muscles innervated by the at-risk nerves. Ex. 1014, 101:8-13; Ex. 1022, p. 746, col. 1, ln. 1-8; p. 747, col. 2, ln. 14-23; Ex. 1007, p. 49, col. 2, ln. 28 – p. 50, col. 1, ln. 10. When monitoring laryngeal muscles, initially needle electrodes were down the patient’s throat and into the vocal cords. Ex. 1019, p. 75, col. 2, ln. 1-13; Fig. 2. More recently, and prior to the ’844 patent, a simpler method was adopted for monitoring laryngeal EMG in which the EMG monitoring electrodes were provided on an endotracheal tube that is inserted through the larynx and into the trachea. Both Goldstone and Kartush describe endotracheal tubes with integrated electrodes that monitor EMG activity in the vocal cords to avoid damage to the RLN during surgery.

**Tongue Electrodes**

As with other muscle groups, tongue EMG was conventionally detected using needle electrodes. However, in addition to contacting the vocal cords,
endotracheal tubes rest directly on the patient’s tongue. Ex. 1003, Fig. 6; Ex. 1021, Fig. 4.

This contact is due to the general design and operation of endotracheal tubes.

Ex. 1003, Figs. 2 and 6; 1:64-2:4; 3:61-64; Ex. 1016, Abstract; 4:43-46; Ex. 1025, p. 86. Because of such tongue contact, it has been known to integrate electrodes/sensors on proximal sections of endotracheal tubes so as to contact the tongue, including for purposes of internal defibrillation and temperature sensing.

Ex. 1013, 3:61-68; Ex. 1016, 4:43-64.
Ex. 1013, Fig. 3 (showing sensor 42 positioned against the tongue)

Ex. 1013, Fig. 6

The inclusion of tongue-contacting electrodes on endotracheal tubes was known to “reduce the number of separate instruments that must be used during a medical procedure.” Ex. 1013, 1:23-31.
For these and other reasons discussed in more detail below, prior to the ’844 patent, it was known in the field to integrate electrodes on endotracheal tubes in order to contact both the tongue and vocal cords.

**Formation of Electrodes on Endotracheal Tubes**

Goldstone, Cook and other prior art references describe methods for printing or painting electrodes directly on the surface of endotracheal tubes. Ex. 1002, ¶¶[0005]; ¶¶[0038]-[0048]. In early iterations, the electrodes were printed on flat substrates and then applied to the tube surface (either face up or face down). Ex. 1004, 2:51-67; 6:1-16. However, well before the ’844 patent, direct printing techniques were used to deposit the electrodes directly onto the curved surfaces of the tubes. In particular, inks and paints containing conductive materials (e.g., metals) were printed directly on tube surfaces to form circuitry. Ex. 1005, p. 611, col. 2, sec. 5.2. Doing so achieved thin electrodes that conformed to the tube’s shape and avoided altering the size of the tube. Ex. 1002, ¶¶[0005].

In particular, the prior art describes applying the conductive material along portions of the length of an endotracheal tube, with the electrode being defined by an uninsulated, exposed portion of the conductive material. Ex. 1009, ¶28, 43; Ex. 1012, ¶17. This standard insulation design limits the electrode area to only a section positioned to contact the anatomy of interest when in use, while allowing electrical signals to be conducted along the insulated trace, without interference
from electrical activity in other anatomy. These insulated traces/wires then connected to leads/wires that plugged into monitoring equipment. Goldstone shows this general design, with electrodes (43) provided proximal of balloon (13). Traces (42) connect the electrodes to external lead (16).

Ex. 1003, Fig. 1

The relative placement of electrodes on the tube was determined based the anatomical structures to be monitored (e.g., tongue, laryngeal muscles, trachea, etc.). Ex. 1009, ¶¶30-40.
B. The Claimed Subject Matter

The ’844 patent includes two independent claims (1 and 4). Claim 1 recites a device for use in monitoring electrical signals during laryngeal electromyography. The device generally includes the following elements:

- an endotracheal tube having a retention balloon at … a distal end thereof
- said tube having on its outer surface one or more electrically conductive electrode plates 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 electrode plates
- electrically conductive traces connected to … the electrode plates
- conductive pads connected to … the conductive traces
- electrical leads connected to the pads
- the conductive traces covered by an insulating material along their length
- a first of said electrode plates is … positioned to contact the vocal cords
- a second electrode plate is located further proximal thereof and positioned to contact the tongue

Claim 4 recites a “method of forming an electrode bearing endotracheal tube.” That claim generally recites a method of forming an endotracheal tube similar to that recited in claim 1. In the method, the conductive materials are
formed by applying a conductive ink in a liquid carrier to the surface of the tube and evaporating the liquid carrier.

C. Prosecution History and Lack of Support for Priority Claim

The ’844 patent issued from U.S. Appl. 12/887,427 (filed September 21, 2010), which claims priority to U.S. Appl. No. 61/244,402 (filed September 21, 2009). However, the priority application does not support the claims of the ‘844 patent. Specifically, the provisional application does not support, at least, the recitation in the independent claims of electrode plates positioned to the tongue. Ex. 1011, pp. 7-10; Ex. 1001, claim 1 (“a second electrode plate … positioned to contact the tongue when the first electrode plate is positioned to contact the vocal cords” (emphasis added)), claim 4 (“second electrode plate positioned to contact the tongue when properly positioned” (emphasis added)). Instead, the provisional application only describes electrodes positioned to contact the vocal cords, which are below the tongue. Ex. 1011, p. 9, ll. 11-13; p. 10 (“Sketch”); Ex. 1020, p. 1637 (“Larynx”); p. 1721, col. 1; Fig. 12.63. The provisional application never mentions the tongue, let alone an electrode positioned to contact that structure. Ex. 1009, ¶16; see Ex.1011. Given the recitation in each independent claim of such an electrode, the ’844 patent is not entitled to the benefit of the filing date of the provisional application, and thus, the effective filing date for determining prior art is September 21, 2010.
During prosecution, the Examiner found the original independent claims to be obvious in view of a combination of Goldstone (Ex. 1003), Lowery (Ex. 1002) and either Cook (Ex. 1004) or U.S. Patent No. 4,461,304. Ex. 1026, p. 3. The Examiner also noted that it was known to form conductive materials directly on the surfaces of an endotracheal tube. *Id.*

In response, Patent Owner amended the independent claims to incorporate subject matter from dependent claims indicated as being allowable. Specifically, the amended claims added that a first electrode plate is positioned to contact the vocal cords and that a second electrode plate is positioned further proximal of the first electrode plate to contact the tongue. *See* Ex. 1027.

The prosecution history does not indicate consideration of references such as Topsakal or Teves, which establish that it was known to use tongue electrodes. Hon and Kartush also were not considered during prosecution.

V. **ARGUMENTS**

A. **Statement of the Law**

1. **Obviousness**

The proposed grounds of unpatentability rely on obviousness under 35 U.S.C. § 103. A claim is obvious when “the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C.
§ 103(a); see KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

2. **Negative Limitations**

   Silence in a reference concerning a negative limitation may fully meet the limitation. (Ex parte Cheng, Appeal 2007-0959, p. 6 (BPAI 2007) (non-precedential) (stating that silence in a reference as to whether specific data was transferred anticipated a negative limitation that the data was not transferred); see also Ex parte Chang, Appeal 2009-013592, pp. 7-8 (BPAI 2012).)

B. **Grounds of Unpatentability**

   1. **Ground 1: Claims 1-7 are Obvious in View of Kartush, Topsakal, Cook, and Hon**

      Given that the ’844 patent is not entitled to the filing date of the provisional application, Topsakal, Cook, and Hon are prior art under 35 U.S.C. §102(b) (pre-AIA). Kartush is prior art under, at least, 35 U.S.C. §102(a) (pre-AIA) because it published before September 21, 2010. Kartush, Hon, and Topsakal were not considered during prosecution.

      As discussed above, allowance of the claims was based on recitation of an electrode for contacting the tongue proximal of an electrode for contacting the vocal cords. Kartush describes electrodes (e.g., 14 and 114) positioned on an endotracheal tube to contact the vocal cords and shows that the tube contacts the tongue at a position proximal vocal cord electrodes. Ex. 1021, ¶¶[0052-57]; [0067]; Figs. 4 and 5. While Kartush does not explicitly describe an electrode
positioned to contact the tongue, it states that additional electrodes may be
provided to contact other muscles, whether for monitoring injury to other nerves or
to help filter noise. Ex. 1021, ¶¶[0052], [0056-57], [0066-67], [0086-87]. To do
so, Kartush connects the various electrodes to different “channels” of a monitoring
device so that the surgeon can decide which electrodes to monitor during a given
procedure. Ex. 1021, ¶¶[0022], [0087].

Topsakal explains that use of EMG electrodes for contacting both the tongue
and vocal cords was preferred in skull base operations. For this and other reasons
discussed below, it would have been obvious to one of ordinary skill in the art
(“POSA”) to combine tongue-contacting electrodes known in the field with
Kartush’s endotracheal tube, particularly given Kartush’s invitation to provide
multiple electrodes to monitor multiple muscles. A POSA would have appreciated
that incorporating such electrodes on one tube would have provided a simpler and
more user friendly design. Ex. 1009, ¶61.

Topsakal explains that intraoperative nerve monitoring reduces the risk of
debilitating injury to cranial nerves 9-12 when performing certain operations,
2, ln. 6-51; p. 51, col. 2, ln. 28-38. These nerves include the vagus nerve (10th) and
the hypoglossal nerve (12th). The vagus nerve includes extracranial segments such
as the RLN. Ex. 1007, p. 46, col. 1, ln. 1-9.
Topsakal also explains that EMG monitoring electrodes used on, for instance, the vocal cords can take the form of stand-alone needle electrodes or surface electrodes integrated on an endotracheal tube. Ex. 1007, p. 47, col. 1, ln. 13-31; p. 50, col. 1, ln. 2-10. In fact, Topsakal notes that tubes with integrated electrodes for contacting the vocal cords were commercially available at the time and that integrated electrodes were less invasive and resulted in “less false positives.” Ex. 1007, p. 47, col. 1, ln. 13-31; p. 50, col. 1, ln. 2-10; Ex. 1009 ¶61. Kartush also states the same goal—less false positives. Ex. 1021, ¶[0008].

Topsakal also describes monitoring EMG activity from the tongue in connection with hypoglossal nerve injury. Ex. 1007, p. 47, col. 1, ln. 31-35; p. 50, col. 1, ln. 20-44. The tongue electrodes were needle electrodes, inasmuch as the commercially available endotracheal tubes for EMG monitoring did not include tongue electrodes. Ex. 1009, ¶¶51, 60-61; Ex. 1007, p. 46, col. 1, ln. 1-9; p.47, col. 1, ln. 13-35 (Xomed-NIM2); p. 50, col. 1, ln. 20-44; Fig. 2. Despite the status of the commercially available options at the time, Topsakal described the importance of simultaneously monitoring a variety of muscles to protect against injury to multiple cranial nerves during surgery. Ex. 1007, p. 50, col. 1, ln. 20-44. In fact, Topsakal explains that injury to the hypoglossal nerve (12\textsuperscript{th}), innervating the tongue, becomes more debilitating when there occurs a concurrent injury to the vagus nerve (10\textsuperscript{th}), innervating the vocal cords through the RLN. Ex. 1007, p. 47,
col. 1, ln. 31-35; p. 50, col. 1, ln. 20-44. Thus, Topsakal documented the need to monitor both sets of muscles during surgery.

Because it was important to monitor EMG activity from both the tongue and vocal cords, a POSA would have appreciated that integrating electrodes for both structures on a single tube would have simplified the procedure by avoiding the need for separate needle electrodes. In fact, Kartush notes that the integration of EMG electrodes onto the tube had become a “common procedure.” Ex. 1021, ¶¶[0005]. Kartush provides further motivation to combine in that it discusses providing an array of electrodes to contact multiple muscles, and allow the user to select which electrodes to monitor at any one time. Ex. 1021, ¶¶[0022] (“allowing complete user selection of whichever electrode combination provides the most useful montage”), [0025] (“target muscle(s”), [0067] (“additional recording sensors can be placed on the tube in locations to engage convenient ‘non-relevant,’ that is, non-target, muscles”), [0086] (using “multichannel recording devices” for “additional sensors”), [0088] (“monitor selected channels”). Thus, it would have been a logical step to integrate tongue-contacting electrodes for monitoring an additional anatomical structure contacted by the tube.

As Topsakal explains, the decision on which anatomical structure(s) to monitor was a simple factor of, e.g., the position of a lesion to be removed. Ex. 1007, p. 46, col. 2, ln. 20-21. Even for operations that only implicated one nerve,
having multiple sets of electrodes on a single tube would have allowed the surgeon to select the monitoring to be used for that particular procedure, and to filter artifact (noise). Ex. 1021, ¶¶[0022], [0067].

Thus, a POSA would have had reasons to position electrodes for monitoring tongue EMG responses with Kartush’s tube. And there would have been no technical barrier to doing so inasmuch as the art (including Kartush, Cook, and Hon) had provided a roadmap for integrating multiple electrodes on such devices.

**Electrode Configuration**

Kartush’s endotracheal tube includes EMG electrodes positioned to contact the vocal cords (or other target muscles), when the distal end of the tube is positioned in the patient’s trachea. Ex. 1021, ¶¶[0052], [0055], [0061]. The electrodes are positioned along the axial length of the tube so as to ensure contact with the target muscles. Ex. 1021, ¶¶[0052], [0067]; Figs. 4 and 12. The preferred positioning in Kartush helps prevent damage to the vagus or RLN, which can result in speech loss and breathing disruption for the patient. Ex. 1021, ¶¶[0004]. As discussed, to prevent damage to the hypoglossal nerve, surgeons use EMG monitoring of the tongue, which is positioned proximal of the vocal cords, above the epiglottis.
Ex. 1020, Fig. 11.24

Kartush’s electrodes 14 are provided at a distal end of the tube to ensure contact with the vocal cords 119 when cuff/balloon 118 is positioned in the patient’s trachea. Ex. 1021, ¶¶[0052], [0078]; Fig. 4, 6, and 12. Kartush’s preferred electrode arrangement is the same design as that described and claimed in the ’844 patent, as shown below.
As shown, when Kartush’s electrodes 14 contact the vocal cords, the patient’s tongue contacts a more proximal position of the tube. Consequently, a POSA would have appreciated that electrodes for monitoring EMG responses from the tongue, as described in Topsakal, would have been integrated with Kartush’s tube in the same way as the electrodes for the vocal cords, just at a more proximal position. Ex. 1009, ¶63.

Electrode Plates, Traces, and Connection Pads Applied to the Tube Surface

Kartush describes that conductive elements (“plates”) may be applied “directly to the exterior surface” of the tube using various techniques. Ex. 1021,
¶¶[0075], [0068]. Kartush also explains that electrodes are connected via a “wire” to output element 40 (e.g., an EMG monitoring device). Ex. 1021, ¶¶[0076], [0101]. Such a wire extends along the tube before departing the tube at a proximal position, outside of the patient’s mouth, to connect to element 40. Ex. 1021, Figs. 4-6, 12, 18.

While Kartush does not describe in detail the nature of the circuitry extending along the tube or the transition to external leads that connect to monitoring equipment, such options would have been obvious to a POSA in light of the prior art.

A POSA would have appreciated that, when conductive elements are applied directly to the surface of the tube, there would have been a conductive connection from the electrode to the monitoring equipment. Cook describes such electrical connections, including electrodes, traces, and pads. Ex. 1004, Fig. 3; 4:25-32 (“The printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34.” (emphasis added); Ex. 1009, ¶¶64-66. Cook also describes insulating traces/wires so as to avoid signal errors from other anatomical structures along the path. Ex. 1004, 1:41-45 (“each discrete wire in such sensing devices normally has separate insulation”); Ex. 1012, ¶¶64-65.
Cook describes sensing electrodes used on medical devices—including “tube-shaped” elements—during surgery and other medical procedures. Ex. 1004, 1:6-23 (“Such potentials are normally sensed by placing an electrode in contact with or adjacent to the area being monitored and connecting the electrode through a wire to a terminal”); 2:64-67. A POSA would have appreciated that, when forming electrodes and traces on Kartush’s endotracheal tube, it would have been obvious to use Cook’s techniques for circuit formation on medical tubes. Ex. 1004, 6:17-65 (stating that printed circuit technology (i) helps maintain the size thickness of the device, (ii) “permits the size, shape and orientation of each electrode to be individually controlled” and (iii) allows for designs “many times less expensive than existing devices”). In essence, the incorporation of Cook’s disclosure of printing electrodes on medical tubes with Kartush’s tube merely combines prior art elements to yield predictable results by using a “known technique to improve a similar device.” Examination Guidelines, 72 Fed. Reg. 57526 (Oct. 10, 2007); Ex. 1009, ¶¶64-68.

While Cook describes an example in which the electrodes are deposited on a flat substrate (30) and then wrapped around a tube—such that the substrate is positioned between the circuitry and the tube surface—Cook also discusses an embodiment in which the circuitry side of the substrate faces the tube surface, including “pads.” Ex. 1004, 2:51-66; 6:1-41; 4:13-24. In that latter embodiment,
the substrate serves as the insulation. Thus, Cook describes applying the circuitry directly to the tube without a carrier layer between the electrode and tube surface.

Moreover, since the publication of Cook in 1990, and prior to the ’844 patent, the technology had evolved to the point at which a POSA would have understood that the electrodes and related circuitry would preferably have been printed directly on the tube. Ex. 1012, ¶¶61, 85-87; Ex. 1009, ¶¶64-69. Hon teaches numerous techniques for directly applying electrodes (using metal paints/inks) on rounded substrates, without first forming the same on a carrier substrate and explicitly describes use of the same for medical devices. Ex. 1005, p. 601, col. 1, sec. 1 - p. 602, col. 2, sec. 2; p. 617, col. 2, sec. 10; Ex. 1009 ¶¶69-70. In fact, Hon describes printing such circuitry on expandable medical balloons, such as those used on endotracheal tubes. Ex. 1005, p. 611, sec. 5.2; Ex. 1021, ¶¶[0091-93]. Kartush even calls for electrodes to be formed on an expandable portion of the tube so that the electrodes are “adapted to withstand some flexure.” Ex. 1021, ¶¶[0091-93]; Fig. 12. A POSA would also have had other reasons to use Hon’s techniques to apply traces and electrodes directly to the surface of an endotracheal tube, as called for in Kartush and Cook, including (i) “cost reduction,” (ii) “process chain simplification through the reduction of process steps,” (iii) “greater design freedom due to its geometrical versatility,” and (iv) a lower “environmental footprint” by eliminating excess materials (e.g., Cook’s
substrate). Ex. 1005, p. 617, col. 2, sec. 10. Moreover, Hon simply provides
known techniques for manufacturing devices similar to Kartush, Topsakal, and
Cook, with no technical barriers to the combination. 72 Fed. Reg. at 57529.

**Dependent Claims**

With respect to claim 3, a POSA would have appreciated that the thinner the
electrode on the tube, the less material needed, the less the electrode affected the
diameter of the tube and the easier to form expandable electrodes. Ex. 1009, ¶¶74-
75; Ex. 1012, ¶82. Consequently, a POSA would have had reason to employ the
thin layers in Hon to provide electrodes. Ex. 1005, p. 611, col. 2, sec. 5.2. In fact,
Hon describes using the very technology described for forming electrodes having
heights of a few microns for expandable medical devices. Ex. 1005, p. 611, col. 2,
sec. 5.2. While the ’844 patent does not define claim 3’s “substantially flush”
language, the patent states that the electrodes and traces have a thickness of “about
0.001 inches (25 microns) … so that the diameter of the endotracheal tube is
substantially unchanged and there are no extraneous intervening materials, such as
is present when a stick-on electrode is used, which can lift up or present sharp
edges.” Ex. 1001, 5:57-61; Ex. 1012, ¶¶32, 82. This example thickness is within
Hon’s range. Ex. 1005, p. 611, col. 2, sec. 5.2.

Provided below is a claim chart that sets forth the manner in which the
combination of Kartush, Topsakal, Cook, and Hon applies to each claim of the
The claim chart is for illustrative purposes and it should be understood that the explanations concerning an element in one claim apply equally to similar elements in other claims, even if not fully repeated elsewhere in the chart.

<table>
<thead>
<tr>
<th>Claim</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1. A device for use in monitoring electrical signals during laryngeal electromyography comprising: | Kartush describes an endotracheal tube for monitoring laryngeal EMG signals. Ex. 1021, ¶¶[0002-08].

Topsakal describes surgical procedures in which the Xomed-NIM2 endotracheal tube with integrated electrodes is used for laryngeal electromyography. Ex. 1007, p. 47, col. 1, ln. 13-19.


Ex. 1009 ¶¶56, 60-61, 65; Ex. 1012, ¶¶37, 40, 18-21, 23. |
| an endotracheal tube having a retention balloon at or adjacent a distal end thereof, | Kartush describes that endotracheal tube 12 has a balloon/cuff 118 at a distal end. Ex. 1021, ¶¶[0054], [0078]; Fig. 4.

Ex. 1009, ¶¶57; Ex. 1012, ¶¶41, 18. |
| said tube having on its outer surface one or more electrically conductive electrode plates applied proximal of the balloon directly to the surface of the tube, without the inclusion of a carrier film between the tube | Kartush’s tube (12) has multiple sensors/electrodes (e.g., 14, 114, 314, 514, 518) applied proximal of balloon/cuff 118 “directly to the exterior surface of cannula 12.” Ex. 1021, ¶¶[0075], [0068] (“plates”); Fig. 4.

Topsakal also describes the use of an endotracheal tube with electrodes. Ex. 1007, p. 47, col. 1, ln. 13-19.

Cook describes methods for providing printed conducting electrodes and other circuitry on medical tubes used in surgery, including where the circuitry is directly contacting |
<table>
<thead>
<tr>
<th>sentence</th>
<th>reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>surface and the electrode plates,</td>
<td>Ex. 1004, Fig. 3; 4:25-32 (“The printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34 [connection points].”); 2:51-3:17; 6:34-41 (“wiring [can] be placed on the underside” of the substrate).</td>
</tr>
<tr>
<td>Hon describes that metal paints/inks for forming electrodes and wires may be printed directly on a rounded surface using “direct writing” techniques. Ex. 1005, p. 601, col. 1-col. 2, sec. 1 (describing depositing conductive materials onto “flat, curvilinear, round, flexible, irregular or inflatable” surfaces); p. 613, col. 2, sec. 7.2 (“Possible routes to metallic deposits include the direct deposition of liquid metals, printing of metallic particles ….”); p. 614, col. 2, sec. 7.4; p. 611, col. 2, sec. 5.2; p. 615, col. 1, sec. 8 (discussing printing electronics on surfaces that may be “round, flexible, [and] inflatable”). Hon states that the techniques are suitable for “medical devices.” Ex. 1005, p. 617, col. 2, sec. 10; p. 611, col. 2, sec. 5.2 (“medical balloons”).</td>
<td></td>
</tr>
<tr>
<td>Ex. 1009, ¶¶48, 52, 57-58, 60, 64, 69-70; Ex. 1012, ¶¶44, 46, 17-23.</td>
<td></td>
</tr>
<tr>
<td>said tube having on its surface electrically conductive traces connected to or integral with the electrode plates, the traces applied directly to the tube surface and running along the length of the endotracheal tube to a proximal end thereof,</td>
<td>Kartush explains that electrodes (e.g., sensors 14) are connected by wires (i.e., traces) to monitoring equipment. Ex. 1021, ¶¶[0076], [0101-02]. The wires can be seen connected to the sensors in Figs. 6, 12 and 15 (including wires 517 and 518). Kartush shows the departure of the wire from the tube at a proximal end thereof in Fig. 4 (line connecting to output element 40). Ex. 1021, ¶¶[0076]; Fig. 4.</td>
</tr>
<tr>
<td>Cook describes a printed sensing circuit that includes traces connected to electrodes. Ex. 1004, Fig. 3; 4:25-32 (“The printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34.”); 1:41-55; 4:67-5:15. Cook also</td>
<td></td>
</tr>
</tbody>
</table>
describes that printed circuit wires 32 (traces) may be applied directly along the length of a tube surface and extending to a proximal end. Ex. 1004, 2:51-3:17; 4:25-32; 4:50-59; 6:34-41 (describing placing the wiring between the substrate and the tube surface); Figs. 3, 11A-B (wires 86).

Hon describes that metal paints/inks for forming electrodes and wires may be printed directly on a rounded substrate using “direct writing” techniques. Ex. 1005, p. 601, col. 1, sec. 1 – col. 2, sec. 2; p. 613, col. 2, sec. 7.2; p. 614, col. 2, sec. 7.4; p. 610, col. 2, sec. 5.1-p. 611, col. 1, sec. 5.1; p. 615, col. 1, sec. 8.

Ex. 1009, ¶¶46-49, 57-58, 64-66; Ex. 1012, ¶¶48, 50-51, 56, 58-61, 18-22.

<table>
<thead>
<tr>
<th>conductive pads connected to or integral with the conductive traces, the pads applied directly to the tube surface at the proximal end of the endotracheal tube, and Kartush shows the departure of the wire from the tube at a proximal end thereof (line connecting to output element 40). Ex. 1021, ¶¶[0076]; [0101-02]; Fig. 4. While Kartush does not explicitly describe a “pad” where the wire departs the tube, Cook describes that sensing circuits are constructed such that “[t]he printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34” (emphasis added). Ex. 1004, 4:25-32; Figs. 3 and 11B. Thus, Cook teaches using conductive pads where printed circuits transition to external wires. Cook’s circuitry, including terminal pads 88, are applied directly to the tube surface. Ex. 1004, 6:34-41.</th>
</tr>
</thead>
<tbody>
<tr>
<td>As discussed, Hon describes that metal paints/inks for forming electrical connection points may be printed directly on a rounded surface using “direct writing” techniques. Ex. 1005; p. 601, col. 1, sec. 1-col. 2, sec. 2; p. 613, col. 2, sec. 7.2; p. 615, col. 1, sec. 8; p. 611, col. 2, sec. 5.2.</td>
</tr>
<tr>
<td>Ex. 1009, ¶¶46-49, 56-58, 64-67; Ex. 1012, ¶¶51, 44, 46,</td>
</tr>
</tbody>
</table>
| **electrical leads connected to the pads, said leads adapted to connect to monitoring equipment,** | Kartush describes wires (e.g., leads) connecting to monitoring equipment. Ex. 1021, ¶[0076]; Fig. 4.  
Cook teaches that, when the electrodes are provided on a tube surface, terminal pads 34 (and 88) allow for transmission of electrical signals to leads that connect to monitoring equipment. Ex. 1004, 4:25-32; 5:16-28; 1:16-19 (“placing an electrode in contact with or adjacent the area being monitored and connecting the electrode through a wire to a terminal”). In particular, terminal pads 34 may receive pins 24. Ex. 1004, 5:16-28. Alternatively, a cable 54 may be used as a lead. Ex. 1004, 5:33-47.  
Ex. 1009, ¶¶46-47, 57, 64-67; Ex. 1012, ¶¶48, 50, 66, 68, 18-21. |
|---|---|
| **the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrode plates to a point adjacent the conductive pads** | Kartush acknowledges that insulation is provided over the trace/wire portions, other than at the exposed electrode areas. Ex. 1021, ¶[0013].  
Cook describes that insulation is provided along wires/traces associated with electrodes to protect the signals. Ex. 1004, 1:41-45 (“each discrete wire in such sensing devices normally has separate insulation”); 4:67-5:8-15 (“further insulate and protect the substrate and wiring”); 3:9-11; 6:30-41 (“protective coating”); 2:51-67. In fact, Cook’s substrate may act as the insulation when applied wire side down. Ex. 1004, 6:34-41. In that case, for instance, the insulation extends from adjacent electrodes 82 to adjacent terminal pads 88. Ex. 1004, Fig. 11A and 11B.  
Hon also discloses the direct printing of insulating materials, such as polymers. Ex. 1005, p. 613, col. 2, sec. 7.2; p. 614, sec. 7.4.  
Ex. 1009, ¶¶46-49, 68, 77; Ex. 1012, ¶¶62, 64-65, 18-22, 59-60. |
| wherein a first of said electrode plates is located proximal of the balloon and positioned to contact the vocal cords when placed within the trachea and | Kartush shows sensor/electrodes 14 being located proximal of cuff 118, so as to contact vocal cords 119 when placed in trachea 117. Ex. 1021, Fig. 4; ¶¶[0052-58]; [0068]. Ex. 1009, ¶¶57, 60, 62-63; Ex. 1012, ¶¶69, 18. |
| a second electrode plate is located further proximal thereof and positioned to contact the tongue when the first electrode plate is positioned to contact the vocal cords. | Topsakal describes that electrodes for monitoring EMG signals can be in the form of needle electrodes or surface electrodes integrated on an endotracheal tube. Ex. 1007, p. 47, col. 1, ln. 13-31; p. 50, col. 1, ln. 2-10. Topsakal also describes positioning electrodes at the tongue for monitoring EMG activity. Ex. 1007, p. 47, col. 1, ln. 31-35; p. 50, col. 1, ln. 20-44. Thus, a POSA would have had reason to integrate electrodes for monitoring tongue-based EMG responses with and endotracheal tube for the same reason that electrodes for monitoring vocal cord EMG signals were integrated with the endotracheal tube. Kartush’s tube 12 contacts the patient’s tongue when sensors/electrodes 14 contact vocal cords 119. Ex. 1021, Fig. 4. As discussed above, Kartush also invites the inclusion of additional electrodes for contacting other target muscles. Ex. 1009, ¶¶50-52, 59-64; Ex. 1012, ¶¶71, 73-75, 23, 18, 84. |

<p>| 2. The device of claim 1 wherein said electrically conductive electrode plates, traces and pads comprise a dried conductive paint or printing ink with a liquid carrier removed therefrom. | Kartush states that the electrodes “can be anything that is able to detect nerve activity” and, in preferred embodiments, may flex. Ex. 1021, ¶¶[0060], [0092]. Cook describes printing circuit patterns, including electrodes, traces and pads. Ex. 1004, 4:19-24; 6:47-65. Hon discloses printing conductive components using various dried metallic inks/paints to achieve flexion on medical devices. Ex. 1005, p. 613, col. 2, sec. 7.2 (“Possible routes to metallic deposits include the direct |</p>
<table>
<thead>
<tr>
<th>Claim/Reference</th>
<th>Description/Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>deposition of liquid metals, printing of metallic particles”); p. 606, col. 2, sec. 4.2 (solid precursors); p. 611, sec. 5.2. Hon describes that the dried particles remain after the “evaporation of a solvent” used to deliver the particles. Ex. 1005, p. 603, sec. 3.1; p. 613, col. 2, sec. 7.2. Ex. 1009, ¶¶48-49, 72; Ex. 1012, ¶¶52, 78, 18, 22, 32.</td>
<td></td>
</tr>
<tr>
<td>3. The device of claim 1 wherein the surface of the conductive electrode plates are substantially flush with the outer surface of the endotracheal tube.</td>
<td>Cook explains that the printing techniques for electrodes allow such circuitry to be provided without increasing the “thickness and complexity of the device.” Ex. 1004, 6:17-27. Hon describes that such printing techniques obtain substantially flush heights of electrodes, including less than 25 microns for medical applications. Ex. 1005, p. 611, col. 2, sec. 5.2 (“height from 1.3 to 250 μm.”). Also, Cook suggests thin electrodes. Ex. 1004, 4:67-5:5; 4:7-9; 4:15-17. Ex. 1009, ¶¶46-49, 74-75; Ex. 1012, ¶¶82, 19-22.</td>
</tr>
</tbody>
</table>

1 The ’894 patent gives an example of an electrode height of about 25 microns. Ex. 1001, 5:57-61.
| **providing an endotracheal tube having a retaining balloon at a distal end thereof,** | Kartush describes that endotracheal tube (12) has a balloon/cuff 118 at a distal end. Ex. 1021, ¶¶[0054], [0078]; Fig. 4.  
Topsakal also describes providing an endotracheal tube. Ex. 1007, p. 47, col. 1, ln. 13-19.  
Ex. 1009, ¶¶77-79, 50, 57, 60; Ex. 1012, ¶¶41, 18, 23. |
| **forming on an exterior surface of the endotracheal tube one or more electrode plates,** | Kartush’s tube (12) has multiple sensors/electrodes (e.g., 14, 314, 514, 518) applied proximal of balloon/cuff 118 “directly to the exterior surface of cannula 12.” Ex. 1021, ¶¶[0075], [0068] (“plates”); Fig. 4.  
Cook also describes methods for forming electrodes and other circuitry on surgical tubes. Ex. 1004, Fig. 3; 4:25-32; 2:51-3:17. Cook also describes that the electrodes may be applied directly on the tube surface. Ex.1004, 6:34-41 (applying substrates circuit side down).  
Hon describes forming electrode plates by printing directly on a rounded surface using “direct writing” techniques. Ex. 1005, p. 601, col. 1, sec. 1 – col. 2, sec. 2 (“flat, curvilinear, round, flexible, irregular or inflatable”); p. 613, col. 2, sec. 7.2; p. 614, col. 2, sec. 7.4; p. 611, col. 1, sec. 5.1; p. 615, col. 1, sec. 8.  
| **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,** | Kartush explains that electrodes (e.g., sensors 14) are connected by traces (i.e., wires) to monitoring equipment. Ex. 1021, ¶¶[0076], [0101-02]. The wires can be seen connected to the sensors in Figs. 6, 12 and 15 (including wires 517 and 518). Kartush shows the departure of the wire from the tube in Fig. 1 (line connecting to output element 40). Ex. 1021, ¶¶[0076]; Fig. 4. |
Cook describes a printed sensing circuit that includes traces connected to both electrodes and pads. Ex. 1004, Figs. 3 and 11B; 4:25-32 (“The printed circuit pattern ... consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34.”); 1:41-55; 4:67-5:15. Cook’s traces attach to conductive pads (e.g., pads 34 and 88) at proximal ends of the traces. Ex. 1004, 4:25-32; 6:34-41; 5:33-47.

Ex. 1009, ¶¶46-47, 57-58, 64-66, 77-79; Ex. 1012, ¶¶48, 50-51, 18-21.

Kartush shows sensor/electrodes 14 being located at the distal end of tube 12, and proximal of cuff 118, so as to contact vocal cords 119 when placed in trachea 117. Ex. 1021, Fig. 4; ¶¶[0052-58]; [0068].

Ex. 1009, ¶¶56, 77-79; Ex. 1012, ¶¶37, 69, 18, 41.

Cook’s conductive terminal pads (e.g., 34 and 88) are provided at proximal ends of the devices. Ex. 1004, Figs. 1, 3, and 11A. Those pads connect the traces (e.g., 32) to external leads. Ex. 1004, 4:25-38; 5:33-47. In addition, Kartush shows that the wires depart tube 12 at a proximal end thereof. Ex. 1021, Fig. 4.


Cook describes printing electrodes on medical tubes. Ex. 1004, 4:19-38. Hon describes printing circuits directly on medical tubes using conductive particles in a liquid carrier. Ex. 1005, p. 613, col. 2, sec. 7.2 (“Metallic particles suspended in a suitable fugitive liquid can be printed by inkjet processes”); p. 603, sec. 3.1. Hon also discloses that conductive components can be printed using various metallic inks/paints, including “depositing from gaseous, liquid and solid precursors”. Ex. 1005, p. 606, col. 2, sec. 4.2., p. 613, col. 2, sec. 7.2 (“direct deposition of liquid...
| Metals, printing of metallic particles”). Ex. 1009, ¶¶77-79, 46-49, 65, 69-70; Ex. 1012, ¶¶54-55, 78, 19-22. | Hon describes that the conductive particles remain after the “evaporation of a solvent” used to deliver the printed circuitry. Ex. 1005, p. 603, sec. 3.1. Ex. 1009, ¶¶72, 77-79; Ex. 1012, ¶¶78, 22. |
| 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 | Kartush acknowledges that insulation is provided over the trace/wire portions, other than at the electrodes. Ex. 1021, ¶[0013]. Cook describes that insulation is provided along wires/traces associated with electrodes to protect the signals. Ex. 1004, 1:41-45 (“each discrete wire in such sensing devices normally has separate insulation”); 4:67-5:15 (“further insulate and protect the substrate and wiring”); 3:9-11; 6:30-41 (“protective coating”); 2:51-67. Cook’s substrate may act as the insulation when applied wire side down. Ex. 1004, 6:34-41. In that case, for instance, the insulation extends from adjacent electrodes 82 to adjacent terminal pads 88. Ex. 1004, Fig. 11A and 11B. Hon also discloses the direct printing of insulating materials, such as polymers. Ex. 1005, p. 613, col. 2, sec. 7.2. Ex. 1009, ¶¶47-49, 67-68, 77-79; Ex. 1012, ¶¶62, 64, 55, 58, 18-22. |
| Wherein a second electrode plate is located proximal of said first electrode plate, the first Kartush shows sensor/electrodes 14 being located proximal of cuff 118, so as to contact vocal cords 119 when placed in trachea 117. Ex. 1021, Fig. 4; ¶[0052-58]; [0068]. |
| 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. | Topsakal describes that electrodes for monitoring EMG signals can be in the form of needle electrodes or surface electrodes integrated on an endotracheal tube. Ex. 1007, p. 47, col. 1, ln. 13-31; p. 50, col. 1, ln. 2-10. Topsakal also describes positioning electrodes on/in the tongue for monitoring EMG activity. Ex. 1007, p. 47, col. 1, ln. 31-35; p. 50, col. 1, ln. 20-44. Thus, a POSA would have had reason to integrate electrodes for monitoring tongue EMG responses with and endotracheal tube for the same reason that electrodes for monitoring vocal cord EMG signals were integrated with the tube.

Kartush’s tube 12 contacts the patient’s tongue when sensors/electrodes 14 contact vocal cords 119. Ex. 1021, Fig. 4. As discussed above, Kartush also invites the inclusion of additional electrodes for contacting other muscles. A tongue electrode would be provided where the tube contacts the tongue, proximal of the vocal cords.

Ex. 1009, ¶¶50-52, 57, 59-63, 77-79; Ex. 1012, ¶¶69, 71, 18, 23, 84. |
|---|---|
| 5. The method of claim 4 wherein the conductive ink comprises electrically conductive particles in said liquid carrier. | Hon describes metal particles in, for instance, liquid carriers. Ex. 1005, p. 613, col. 2, sec. 7.2 (“Metallic particles suspended in a suitable fugitive liquid can be printed by inkjet processes”); p. 603, sec. 3.1.

Ex. 1009, ¶81; Ex. 1012, ¶78, 22. |
| 6. The method of claim 5 wherein electrically conductive particles comprise finely divided particles or flakes of silver, silver compounds including but not limited to silver chloride and silver oxide, gold, | Hon’s metal particles may include silver, gold, and copper nanoparticles. Ex. 1005, Table 2; p. 614, col. 1, sec. 7.2.

Ex. 1009, ¶83; Ex. 1012, ¶79-80, 22. |
<table>
<thead>
<tr>
<th>copper, copper chloride, platinum, carbon or graphite.</th>
<th>Ex. 1005, p. 614, col. 2, sec. 7.3 (“a silver ink which contained 57–62 wt.% of Ag [silver] nanoparticles”). Ex. 1009, ¶85; Ex. 1012, ¶81.</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. The method of claim 5 wherein the conductive particles comprises at least about 60% of the ink.</td>
<td></td>
</tr>
</tbody>
</table>

2. **Ground 2: Claims 1-7 are Obvious in View of Goldstone, Teves, Cook, and Hon**

Teves and Goldstone are prior art under 35 U.S.C. §102(b) (pre-AIA) because they published more than one year prior to the ’844 patent’s filing date. Teves was not considered during prosecution.

Goldstone describes an endotracheal tube that includes electrodes 43 at a distal end thereof, which electrodes contact the vocal cords when cuff/balloon 13 is positioned in the patient’s trachea. Ex. 1003, 3:25-52; 5:64-6:16; Figs. 1 and 6. Goldstone’s electrode arrangement is similar to that described and claimed in the ’844 patent, as can be seen with a side-by-side comparison.
Also as in the ’844 patent, Goldstone’s electrodes may be applied directly to the exterior surface of the tube using metal paint. Ex. 1003, 5:18-31. Goldstone’s electrodes monitor EMG activity at the vocal cords to prevent damage to the RLN, which can result in speech loss and breathing disruption. Ex. 1003, 1:5-40.

As discussed above, allowance of the ’844 patent resulted from recitation of an additional electrode, for contacting the tongue, positioned on the tube proximal of the electrode for contacting the vocal cords. Goldstone does not explicitly
describe an additional electrode positioned to contact the tongue. In that regard, the claims of the ’844 patent are directed to “laryngeal electromyography.” Laryngeal monitoring involves detecting signals from laryngeal muscles (e.g., vocal cords). Ex. 1003, 1:10-21; see Ex. 1020, p. 1644, col. 2, ln. 13 – p. 1645, col. 1, ln. 14 (“Laryngeal Musculature”). The ’844 patent does not explain the purpose of the claimed electrode for contacting the tongue, which is not a laryngeal muscle. Ex. 1020, p. 1637, col. 2 (“Larynx”); p. 1644, col. 2, ln. 13–p. 1645, col. 1, ln. 14.

As discussed in the background section, the prior art describes various functions for tongue-contacting electrodes, including temperature measurement. Teves describes integrating a temperature sensor (i.e., wire electrode) on an endotracheal tube because “[b]ody temperature is a vital sign that is monitored closely when a patient is under anesthesia.” Ex. 1013, 1:13-14. Teves states that, “[t]o reduce the number of separate instruments that must be used during a medical procedure, many anesthesiologists would prefer to use an endotracheal tube including a built-in temperature sensor if such were available; thus, insertion of the endotracheal tube through the trachea and into the endotracheal tube would also accomplish insertion of a temperature probe and eliminate the need for a temperature probe in the patient’s ear or other location on the body.” Ex. 1013, 1:23-27. Teves states that the electrode may be a thermocouple, which is an
Teves notes that earlier temperature sensors were often positioned on endotracheal tubes so as to contact the patient’s trachea. Ex. 1013, 3:1-19. Teves found that “a temperature sensor attached to the proximal end of an endotracheal tube at a location where it is in temperature-sensing direct contact with the tongue produces temperature readings that are more accurate than those positioned past the larynx, i.e., on the distal end of the tube.” Ex. 1013, 1:64-2:4; 4:1-15.

For these reasons, Teves describes that proximal end 12 of endotracheal tube 10 includes temperature sensor 42. Ex. 1013, 3:48-68.
In some embodiments, Teves’ electrode/sensor 42 (or 44) is separated from the tongue by a thin film, while other embodiments have the sensor in direct contact with the tongue. Ex. 1013, 2:25-28; 3:61-68; Fig. 5. Like electrodes 43 in Goldstone, in its simplest form, Teves’ sensor 42 is an exposed portion of a wire (i.e., electrode) provided on the exterior surface of an endotracheal tube. Ex. 1013, 2:9-28; Ex. 1003, 5:14-46. Also like Goldstone’s design, Teves’ connecting wire 25 extends along the tube to a point at which it departs the tube and connects to monitoring equipment (through adapter 23). Ex. 1013, 1:4-60; Ex. 1003, 5:14-46; 6:25-33; Fig. 1. Thus, the electrode constructions in Goldstone and Teves are substantially the same, but for Goldstone describing a vocal cord-contacting electrode and Teves describing a tongue-contacting electrode. Ex. 1013, 2:36-41; 1:4-60. Both are used during surgery to ensure the patient’s health.

In both Goldstone and Teves, when the tube is placed in a patient, the patient’s tongue contacts a more proximal position of the endotracheal tube than the vocal cords. Ex. 1003, Fig. 6; Ex. 1013, Fig. 2. Consequently, a POSA would have appreciated that electrodes for contacting the tongue, as described in Teves, would have been positioned proximal of vocal cord-contacting electrodes when integrated with Goldstone’s tube. Ex. 1009, ¶¶86, 100.

A POSA would have been led to combine Teves’ tongue electrode with Goldstone’s endotracheal tube because, at least, Teves states that combining such
an electrode with an endotracheal tube provides a better measurement of body temperature than other arrangements. Ex. 1013, 1:64-2:4; 4:1-15; 1:13-15. Moreover, Teves states that one reason for incorporating a tongue sensor on an endotracheal tube is that anesthesiologists would have wanted to “[t]o reduce the number of separate instruments that must be used during a medical procedure.” Ex. 1013, 1:23-27. Moreover, only one endotracheal tube is used at a time. Teves even states “that an important object of this invention is to advance the art of endotracheal tubes by providing … a temperature sensor that overlies a patient’s tongue.” Ex. 1013, 2:36-41. Thus, the very purpose of Teves is to improve the type of tube described in Goldstone.

A POSA also would have understood that there would have been no technical hurdle to the combination. Ex. 1009, ¶95; Ex. 1012, ¶85. Both Teves and Goldstone explain that multiple electrodes/sensors could (and preferably should) be integrated on a single endotracheal tube, with both references showing virtually identical technology for doing so—exposed wires and/or alternative conductive areas provided on the tube surface. Ex. 1003, 5:18-31; Ex. 1013, 3:41-47; 2:9-18; 4:30-31.

While Goldstone indicates that an electrode for contacting the vocal cords should not be “so long” as to contact other muscles outside the larynx, that does not preclude separate electrodes being positioned to contact other anatomical
structures (e.g., the tongue).\textsuperscript{2} Ex. 1003, 3:40-52. Specifically, Goldstone’s direction is to avoid having a single “uninsulated portion” (or pair, when bipolar electrodes) contact any muscle other than the target muscle, so as to avoid EMG signals from sources other than the nerve of interest. \textit{Id.} However, as discussed above, a POSA would have realized that different electrodes may contact different structures, so long as the electrodes were monitored on different channels. Ex. 1009, ¶95.

\textbf{Electrodes, Traces and Connection Pads Applied to the Tube Surface}

Goldstone also describes that the electrodes and other conductive elements, may be applied directly to the surface of the tube, without any intervening carrier film. Specifically, while describing an embodiment in which a portion of the conductive elements are embedded in the tube wall, Goldstone also describes forming electrodes by applying a metal paint to the tube, without any mention of an intervening film. Ex. 1001, 5:1-46; Figs. 2, 3, 5; see \textit{Ex parte Cheng}, Appeal No. 2007-0959, p. 6 (BPAI 2007) (non-precedential) (stating that silence in a

\textsuperscript{2} Patent Owner asserts in the related litigation that electrodes of a length described in Goldstone (up to 4cm) contact both the vocal cords and tongue in a subset of the patient population. Ex. 1015, pp. 11-16 (identifying a 40mm electrode); Ex. 1003, 5:41-46 (2-4cm electrodes).
reference as to a feature may teach a negative limitation concerning the feature). Teves also states that the electrodes are “mounted on an exterior surface.” Ex. 1013, 2:20-35.

In Fig. 1, Goldstone depicts points at which external wires connect with the traces (wires 42) leading to electrodes 43. While Goldstone does not describe specific “conductive pads” that connect traces (wires 42) to the external wires (16), such connection points would have been obvious to a POSA in light of the prior art. A POSA would have appreciated that there would have been a conductive connection between Goldstone’s paint and the external wires that connect to monitoring equipment. Cook describes such electrical connections, including electrodes, traces, and pads. Ex. 1004, Fig. 3; 4:25-32 (“The printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34.” (emphasis added)); Ex. 1009, ¶¶ 91-92, 101-102.

Cook is directed to sensing electrodes to be used on medical devices—including “tube-shaped” elements—during surgery and other medical procedures. Ex. 1004, 1:6-23 (“Such potentials are normally sensed by placing an electrode in contact with or adjacent to the area being monitored and connecting the electrode through a wire to a terminal”); 2:64-67. A POSA would have appreciated that, when forming circuitry on Goldstone’s endotracheal tube, it would have been
obvious to use Cook’s techniques for circuit formation. Ex. 1009, ¶¶ 67, 101-103. In particular, a POSA would have had reason to use Cook’s pads 34, which enable printed/painted circuits to communicate with associated monitoring equipment.

Because Goldstone calls for the application of electrodes on a tube using metal paints, and a POSA would have looked to suitable techniques to achieve that goal, which techniques are provided in Cook. Ex. 1004, 6:47-65. Consequently, the incorporation of Cook’s disclosure of printing electrodes on medical tubes with Goldstone’s tube having conductive electrodes merely combines prior art elements to yield predictable results by using a “known technique to improve a similar device.” 72 Fed. Reg. 57526. Hon provides even more details for directly printing circuitry on medical tubes. Other bases for further combining Cook and Hon with electrode formation on an endotracheal tube are explained above with respect to Ground 1. For simplicity sake, those explanations will not be repeated here.

In addition, Teves provides additional reasons for combining the technology of Cook and Hon. Teves calls for other electrode configurations “to increase the surface area thereof and thus to increase the accuracy of the information sent to the external temperature read-out device.” Ex. 1013, 3:41-47; 2:9-18; 4:30-31. Based on that statement in Teves, a POSA would have had reason to adopt the electrode printing technology described in Cook and Hon to provide an electrode having a surface area larger than that offered by a simple wire. Ex. 1004, 6:52-58 (“a[n] …
advantage is that the printed circuit technology permits the size, shape and orientation of each electrode to be individually controlled to provide a sensing device which is optimal for each application”).

Provided below is a claim chart that sets forth the manner of applying Goldstone, Teves, Cook, and Hon. The claim chart is for illustrative purposes and it should be understood that the explanation for an element in one claim applies equally to similar elements in other claims, even if not fully repeated. In addition, for the sake of simplicity, where the basis for applying a reference is the same as set forth in Ground 1, reference to the previous claim chart is provided in lieu of repeating citations and discussions.

<table>
<thead>
<tr>
<th>U.S.P. 8,467,844</th>
<th>Goldstone, Teves, Cook, and Hon</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A device for use in monitoring electrical signals during laryngeal electromyography comprising:</td>
<td>Goldstone describes an endotracheal tube that has electrodes for laryngeal electromyography. Ex. 1003, 1:5-8 (“The present invention relates generally to electrodes for detecting electromyographic (EMG) signals of the laryngeal muscles, and more particularly to electrodes which are mounted on an endotracheal tube.”); 3:3-6.</td>
</tr>
</tbody>
</table>

Teves describes an improved endotracheal tube with a sensor electrode integrated in the tube for monitoring internal body temperature. Ex. 1013, 1:8-11; 1:64-2:41.


Ex. 1009 ¶¶88, 94-95, 65, 43-45; Ex. 1012, ¶¶8-9, 38-39, 17, 19-21, 23.
<table>
<thead>
<tr>
<th>Description</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>an endotracheal tube having a retention balloon at or adjacent a distal end thereof,</td>
<td>Goldstone describes an endotracheal tube with a retaining balloon (inflatable cuff 13) “located near distal end 12.” Ex. 1003, 1:5-8; 5:3-13; 5:64-6:16; 1:32-40; see also Ex. 1004, 2:64-67 (“tube-shaped member”); 3:11-17 (“balloon”). Teves also describes endotracheal tube 10 having a balloon (cuff 17) near distal end 14. Ex. 1013, 3:4-11; Fig. 2. Ex. 1009 ¶¶88, 53; Ex. 1012, ¶¶42-43, 17, 23.</td>
</tr>
<tr>
<td>said tube having on its outer surface one or more electrically conductive electrode plates 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 electrode plates,</td>
<td>Goldstone describes conductive electrodes 43 provided on tube 10 proximal of the balloon (cuff 13). Ex. 1003, 5:3-13; 5:41-46; Fig. 1. Those electrodes may be applied directly to the outer surface of the tube using metal paint. Ex. 1003, 5:18-31 (“A second wire portion 43 is located between distal end 12 and first wire portion 42, on outer surface 23 of tube 10.”) (“The term ‘wires’ includes any type of electrically conducting lead suitable for use as an electrode, including metal paint ….”). Goldstone does not describe the use of any carrier film between the painted electrodes and the tube.</td>
</tr>
<tr>
<td></td>
<td>Teves describes that endotracheal tube 30 has electrode 42 positioned proximal of cuff 17 (near proximal end 34). Ex. 1013, 1:26-68; Figs. 2 and 5. Teves states that its electrode portion “is mounted on the exterior surface of the endotracheal tube.” Ex. 1013, 2:20-35; 3:4-19; Figs. 1, 2, and 6. To increase surface contact, Teves acknowledges that electrode/sensor 42 may take various configurations. Ex. 1013, 3:41-47. While Teves describes that insulation may be provided between sensor/electrode 42 and tube 30 as a thermal insulator against gases within the tube, the same is not required. Ex. 1013, 3:51-60. In fact, Teves shows configurations that did not use such an insulating layer, and instead thickened the tube wall in lieu of insulation. Ex. 1013, 3:4-17; Fig. 1.</td>
</tr>
<tr>
<td></td>
<td>Cook describes methods for providing printed conducting electrodes and other circuitry on medical tubes used in surgery, including where the circuitry is directly contacting</td>
</tr>
</tbody>
</table>
the tube surface. Ex. 1004, Fig. 3; 4:25-32 (“The printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34 [connection points].”); 2:51-3:17; 4:25-32; 4:50-59; 6:34-41 (“wiring [can] be placed on the underside” of the substrate).

Hon describes that metal paints/inks for forming electrodes and wires may be printed directly on a rounded surface using “direct writing” techniques. Ex. 1005, p. 601, col. 1-col. 2, sec. 1 (“flat, curvilinear, round, flexible, irregular or inflatable”); p. 613, col. 2, sec. 7.2 (“Possible routes to metallic deposits include the direct deposition of liquid metals, printing of metallic particles ….”); p. 614, col. 2, sec. 7.4; p. 611, col. 2, sec. 5.2; p. 615, col. 1, sec. 8. Hon states that the techniques are suitable for “medical devices.” Ex. 1005, p. 617, col. 2, sec. 10; p. 611, col. 2, sec. 5.2 (“medical balloons”).

Ex. 1009, ¶¶88-89, 93, 44, 46-48; Ex. 1012, ¶¶45-47, 55, 76, 17, 19-22.

<table>
<thead>
<tr>
<th>said tube having on its surface electrically conductive traces connected to or integral with the electrode plates, the traces applied directly to the tube surface and running along the length of the endotracheal tube to a proximal end thereof, Goldstone discloses that traces (wire portions 42) are connected to electrodes 43 and extend along the length of the tube from distal portion 12 to proximal portion 11. Ex. 1003, 5:14-46 (“[e]ach electrode wire has a first portion 42, located between proximal end 11 and distal end 12”); 3:14-18; Fig. 1. While in one embodiment the wires are embedded in the tube, Goldstone states that “[t]he term ‘wires’ includes any type of electrically conducting lead suitable for use as an electrode, including metal paint, metallic tape, or metal strips.” Ex. 1003, 5:18-28.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teves describes a trace in the form of wire 25 that runs along tube 30 to proximal end 32, where it departs the tube outside of the patient’s mouth. Ex. 1013, 3:33-40; Fig. 2. Cook describes a printed sensing circuit that includes traces (e.g., 32) connected to electrodes. Ex. 1004, Fig. 3;</td>
</tr>
<tr>
<td>conductive pads connected to or integral with the conductive traces, the pads applied directly to the tube surface at the proximal end of the endotracheal tube, and</td>
</tr>
<tr>
<td>electrical leads</td>
</tr>
</tbody>
</table>
connected to the pads, said leads adapted to connect to monitoring equipment, equipment. Ex. 1003, Fig. 1; 5:58-63 (describing an EMG processing machine connected to plugs 19A-D of wires 16A-D); 6:25-33.

Cook teaches that terminal pads 34 (and 88) allow for transmission of electrical signals to leads that connect to monitoring equipment. Ex. 1004, 4:25-32; 5:16-28; 1:16-19 (“placing an electrode in contact with or adjacent the area being monitored and connecting the electrode through a wire to a terminal”). In particular, terminal pads 34 may receive pins 24. Ex. 1004, 5:16-28. Alternatively, a cable 54 may be used as a lead. Ex. 1004, 5:33-47.

Teves describes that wire/lead 25 has adapter 23 for connecting to monitoring equipment. Ex. 1013, 3:33-40; Fig. 2.

Ex. 1009, ¶¶43, 92, 99, 86; Ex. 1012, ¶¶49-50, 67-68, 17, 19-21, 23.

the electrically conductive traces covered by an insulating material along their length from a point adjacent the electrode plates to a point adjacent the conductive pads

Goldstone indicates that the electrically conductive traces (wire portions 42) are insulated along their lengths starting from electrodes 43. Ex. 1003, 5:22-25 (“Each electrode wire has a first portion 42, located between proximal end 11 and distal end 12, and insulated against electrical contact.”); 3:14-24 (“insulated against electrical contact”); 5:14-57 (“to insulate wire portions 42 from electrical contact”); 8:7-12; 8:31-34; see Fig. 1 (showing wires 42 (and 16A-D) separated by insulation).

Teves describes that trace/wire 25 is insulated along its length from sensor/electrode 42 to the point where the wire departs the tube. Ex. 1013, 3:33-40; 2:20-31; Figs. 2 and 5.

Cook also describes using insulation along wires/traces to protect the signals transferred to the pads 34. Ex. 1004, 1:41-45 (“each discrete wire in such sensing devices normally has separate insulation”); 5:8-15 (“further insulate and protect the substrate and wiring”); 3:9-11; 6:30-41 (“protective coating”). Cook’s substrate may act
as the insulation when applied wire side down. Ex. 1004, 6:34-41. In that case, the insulation extends between electrodes 82 and terminal pads 88. Ex. 1004, Figs. 11A and 11B.

Hon also discloses the direct printing of insulating materials, such as polymers. Ex. 1005, p. 613, col. 2, sec. 7.2.

Ex. 1009, ¶¶43, 45, 47-48, 54, 90, 86; Ex. 1012, ¶¶63-65, 59-60, 17, 19-23.

<p>| wherein a first of said electrode plates is located proximal of the balloon and positioned to contact the vocal cords when placed within the trachea and | Goldstone’s electrodes 43 are positioned on the tube, proximal of cuff 13, to contact “a set of laryngeal muscles, particularly a vocal cord of that set, when the endotracheal tube is properly positioned.” Ex. 1003, 3:40-46; 5:36-46; 6:12-16 (positioned in the trachea). Ex. 1009 ¶¶43, 88-89, 100; Ex. 1012, ¶70, 17. |
| a second electrode plate is located further proximal thereof and positioned to contact the tongue when the first electrode plate is positioned to contact the vocal cords. | Teves describes a “second electrode plate” in the form of sensor 42 (or 44), which is positioned to contact the tongue. Ex. 1013, 3:33-68; Fig. 2. Both Goldstone and Teves show that an endotracheal tube contacts the patient’s tongue at a more proximal position then the vocal cord–contacting position. Ex. 1003, Fig. 6; Ex. 1013, Fig. 2. A POSA would have understood that the incorporation of Teves’ relative electrode position on Goldstone’s tube would result in Teves’ electrode being further proximal of Goldstone’s electrodes. Ex. 1009, ¶54, 98, 100; Ex. 1012, ¶72-75, 87. |
| 2. The device of claim 1 wherein said electrically conductive electrode plates, traces and | Goldstone describes conductive metal paint that is used to form conductive components on the surface of a tube. Ex. 1003, 5:18-21; Cook describes printing circuit patterns. Ex. 1004, 4:19-24. |</p>
<table>
<thead>
<tr>
<th>pads comprise a dried conductive paint or printing ink with a liquid carrier removed therefrom.</th>
<th>Hon discloses the printing of conductive components using various dried metallic inks/paints. Ex. 1005, p. 613, col. 2, sec. 7.2 (“Possible routes to metallic deposits include the direct deposition of liquid metals, printing of metallic particles”); p. 606, col. 2, sec. 4.2 (solid precursors); p. 611, sec. 5.2. Hon describes that the dried particles remain after the “evaporation of a solvent” used to deliver the particles. Ex. 1005, p. 603, sec. 3.1; p. 613, col. 2, sec. 7.2. Ex. 1009, ¶¶69, 89, 72, 106; Ex. 1012, ¶¶77, 78, 17, 22.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. The device of claim 1 wherein the surface of the conductive electrode plates are substantially flush with the outer surface of the endotracheal tube.</td>
<td>See the explanation in Ground 1, above. See Ex. 1009, ¶108; Ex. 1012, ¶82.</td>
</tr>
<tr>
<td>providing an endotracheal tube</td>
<td>Goldstone describes an endotracheal tube with a retaining balloon (inflatable cuff 13) “located near distal end 12.”</td>
</tr>
<tr>
<td>Description</td>
<td>References</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>having a retaining balloon at a distal end thereof,</td>
<td>Ex. 1003, 1:5-8; 5:3-13; 5:64-6:16; 1:32-40; see also Ex. 1004, 2:64-67 (“tube-shaped member”); 3:11-17 (“balloon”).</td>
</tr>
<tr>
<td></td>
<td>Teves describes an endotracheal tube 30 that has cuff/balloon 17 at distal end 34. Ex. 1013, 1:26-68; Figs. 2 and 5.</td>
</tr>
<tr>
<td></td>
<td>Ex. 1009 ¶¶43-46, 53, 88, 111, 86; Ex. 1012 ¶¶42-43, 17, 23.</td>
</tr>
<tr>
<td>forming on an exterior surface of the endotracheal tube one or more electrode plates,</td>
<td>Goldstone describes providing electrodes 43 on tube 10. Ex. 1003, 5:3-13; 5:41-46; Fig. 1. Those electrodes may be applied to the outer surface of the tube using metal paint. Ex. 1003, 5:29-31 (“A second wire portion 43 is located between distal end 12 and first wire portion 42, on outer surface 23 of tube 10.”); 5:18-21.</td>
</tr>
<tr>
<td></td>
<td>Teves describes forming electrode 42 on endotracheal tube 30. Ex. 1013, 1:26-68; 2:20-35 (“is mounted on the exterior surface of the endotracheal tube.”); 3:4-19; Figs. 2 and 5. To increase surface contact, Teves acknowledges that electrode/sensor 42 may take various configurations. Ex. 1013, 3:41-47.</td>
</tr>
<tr>
<td></td>
<td>Cook describes methods for forming electrodes and other circuitry on surgical tubes. Ex. 1004, Fig. 3; 4:25-32; 2:51-3:17. Cook also describes that the electrodes may be applied directly on the tube surface. Ex.1004, 6:34-41.</td>
</tr>
<tr>
<td></td>
<td>Hon describes forming electrode plates by printing directly on a rounded surface. Ex. 1005, p. 601, col. 1, sec. 1 – col. 2, sec. 2; p. 613, col. 2, sec. 7.2; p. 614, col. 2, sec. 7.4; p. 611, col. 1, sec. 5.1; p. 615, col. 1, sec. 8.</td>
</tr>
<tr>
<td>at least one trace attached to each of</td>
<td>Goldstone describes electrically conductive traces (wire portions 42) extending along tube 10 from (and attached</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Reference</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>the one or more electrode plates and a conductive pad attached to a proximal end of the traces,</td>
<td>to) respective electrodes 43. Ex. 1003, Fig. 1; 3:14-18; 5:14-46. While Goldstone does not explicitly describe a “pad” where portions 42 transition to wires 16, Cook describes that such sensing circuits may be constructed such that electrodes are “connected by a printed circuit wire 32 [trace] to a corresponding <em>terminal pad 34</em>” (emphasis added). Ex. 1004, 4:25-32; Figs. 3 and 11B. Ex. 1004, Fig. 3; 4:25-32 (“The printed circuit pattern … consists of eight electrode pads [electrodes], 12A-12H, each of which is connected by a printed circuit wire 32 [trace] to a corresponding terminal pad 34.”); 1:41-55; 4:67-5:15. Cook’s traces also attach to conductive pads (e.g., pads 34 and 88) at proximal ends of the traces. Ex. 1004, 4:25-32; 6:34-41; 5:33-47.</td>
</tr>
<tr>
<td>a first of said electrode plates located at the distal end of the endotracheal tube proximal of the retaining balloon,</td>
<td>Goldstone’s electrodes 43 are provided at distal end 12 of tube 10, proximal of cuff 13. Ex. 1003, Fig. 1; 5:3-31. Ex. 1009 ¶¶45-46, 65-66, 89-90, 94-95, 111; Ex. 1012, ¶¶49-51, 17, 19-21, 23.</td>
</tr>
<tr>
<td>the conductive pad or pads located at a proximal end of the endotracheal tube,</td>
<td>Cook’s conductive pads (e.g., 34 and 88) are provided at proximal ends of the devices. Ex. 1004, Figs. 1, 3, and 11A. In addition, Goldstone shows the point at which traces depart the tube in the form of wires 16 is at proximal end 11. Ex. 1003, Fig. 1; 5:3-28. Teves shows a similar configuration with respect to where wire 25 departs tube 30. Ex. 1013, Fig. 2.</td>
</tr>
<tr>
<td>Description</td>
<td>Sources</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>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,</td>
<td>Ex. 1009 ¶¶90, 111; Ex. 1012 ¶¶49-50, 19-21, 17, 22</td>
</tr>
<tr>
<td>Goldstone describes use of a metal paint. Ex. 1003, 5:18-21. Cook describes printing electrodes “using any one of a variety of known techniques.” Ex. 1004, 4:19-38. Hon describes printing circuits directly on medical tubes using conductive particles in a liquid carrier. Ex. 1005, p. 613, col. 2, sec. 7.2 (“Metallic particles suspended in a suitable fugitive liquid can be printed by inkjet processes”); p. 603, sec. 3.1. Hon also discloses that conductive components can be printed using various metallic inks/paints, including “depositing from gaseous, liquid and solid precursors”. Ex. 1005, p. 606, col. 2, sec. 4.2., p. 613, col. 2, sec. 7.2 (“Possible routes to metallic deposits include the direct deposition of liquid metals, printing of metallic particles”).</td>
<td></td>
</tr>
<tr>
<td>evaporating the liquid carrier to provide an electrically conductive path from the electrode plates to the endotracheal tube proximal end, and</td>
<td>Hon describes that the conductive particles remain after the “evaporation of a solvent” used to deliver the printed circuitry. Ex. 1005, p. 603, sec. 3.1. Ex. 1009 ¶¶72, 77-79, 103, 111; Ex. 1012 ¶¶78, 22.</td>
</tr>
<tr>
<td>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</td>
<td>Goldstone indicates that the electrically conductive traces (wire portions 42) are insulated along their lengths, starting from electrodes 43 and up to the transition to wires 16. Ex. 1003, 5:22-25 (“Each electrode wire has a first portion 42, located between proximal end 11 and distal end 12, and insulated against electrical contact.”); 3:16-18. Cook describes that insulation may be used along wires/traces associated with electrodes to protect the signals. Ex. 1004, 1:41-45 (“each discrete wire in such sensing devices normally has separate insulation”); 5:8-15 (“furthert insulate and protect the substrate and wiring”). Cook’s substrate may act as the insulation when applied wire side down. Ex. 1004, 3:9-11, 6:34-41. The insulation</td>
</tr>
</tbody>
</table>
extends from, for instance, electrodes 82 to pads 88. Ex. 1004, Fig. 11A and 11B.

Hon also discloses the direct printing of insulating materials, such as polymers. Ex. 1005, p. 613, col. 2, sec. 7.2.

Ex. 1009, ¶¶43-45, 47, 90-91, 99, 77, 111; Ex. 1012, ¶¶63-65, 55, 58, 88, 17, 19-22.

<table>
<thead>
<tr>
<th>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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goldstone’s four electrodes 43 (“first electrode plate”) are positioned around the tube to contact “a set of laryngeal muscles, particularly a vocal cord of that set, when the endotracheal tube is properly positioned.” Ex. 1003, 3:40-46; 5:36-46.</td>
</tr>
<tr>
<td>Teves describes a “second electrode plate” in the form of sensor 42 (or 44), which is positioned to contact the tongue—an anatomical structure contacting the tube proximal of the vocal cords. Ex. 1013, 3:33-68; Fig. 2.</td>
</tr>
<tr>
<td>Goldstone shows that endotracheal tube 10 contacts the patient’s tongue at a more proximal position on the tube then the vocal cord electrodes. Ex. 1003, Fig. 6.</td>
</tr>
<tr>
<td>Ex. 1009 ¶¶44, 54, 92, 111; Ex. 1012 ¶¶70, 72, 17, 23.</td>
</tr>
</tbody>
</table>

5. The method of claim 4 wherein the conductive ink comprises electrically conductive particles in said liquid carrier.

| See the explanation in Ground 1, above. See Ex. 1009, ¶113; Ex. 1012, ¶78. |

6. The method of claim 5 wherein electrically conductive particles comprise finely divided particles or flakes of silver, silver

| See the explanation in Ground 1, above. See Ex. 1009, ¶115; Ex. 1012, ¶79. |
compounds including but not limited to silver chloride and silver oxide, gold, copper, copper chloride, platinum, carbon or graphite.

7. The method of claim 5 wherein the conductive particles comprises at least about 60% of the ink.

See the explanation in Ground 1, above. See Ex. 1009, ¶117; Ex. 1012, ¶81.

3. **Alternative Grounds: Interchanging Kartush and Goldstone**

While the applications of Topsakal and Teves in Grounds 1 and 2 present distinct bases for unpatentability, which establishes that those grounds are not redundant, Petitioner recognizes that Kartush and Goldstone disclose similar subject matter. Given the similar technology in Kartush and Goldstone, Petitioner invites consideration of alternative grounds in which Kartush replaces Goldstone and vice versa, in view of the ruling in *SightSound Technologies, LLC v. Apple Inc.* 809 F.3d 1313-14 (Fed. Cir. 2015). The bases for combining Kartush with Teves or Goldstone with Topsakal are substantially the same as those provided in the existing grounds. To the extent that the Board prefers the use of one of those primary references over the other in either proposed ground, or some other
variation, the content of this Petition and supporting declarations provide sufficient basis for the interchange of references.

VI. Conclusion

For the reasons set forth above, Petitioner submits that claims 1-7 of the ’844 patent are unpatentable under 35 U.S.C. § 103. Accordingly, Petitioner requests institution of Inter Partes Review of these claims for each ground presented herein.

Respectfully submitted,

/Justin J. Oliver/
Justin J. Oliver
Counsel for Petitioner
Registration No. 44,986

FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, New York 10104-3800
Facsimile: (212) 218-2200
CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing document, excluding the portions exempted under 37 C.F.R. § 42.24(a)(1), contains 13,606 words (including in the figures), which is under the limit of 14,000 words set by 37 C.F.R. §§ 42.24(a)(1)(i) and 42.24(b)(1).

Dated: September 19, 2016 /Justin J. Oliver/
Justin J. Oliver
Counsel for Patent Owner
Registration No. 44,986

Fitzpatrick, Cella, Harper & Scinto
1290 Avenue of the Americas
New York, NY 10104
Tel: (212) 218-2100
Fax: (212) 218-2200
CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e)(4) and 42.105, the undersigned certifies that on this date, a true and correct copy of this Petition for Inter Partes Review and all supporting exhibits were served via Express Mail on the Patent Owner at the correspondence address of record for U.S. Patent No. 8,467,844.

Koppel, Patrick, Heybl & Philpott
2815 Townsgate Road
Suite 215
Westlake Village, CA 91361-5827

Dated: September 19, 2016 /Justin J. Oliver/
Justin J. Oliver
Counsel for Petitioner
Registration No. 44,986