UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

iRhythm, Inc.

Petitioner,

v.

Welch Allyn, Inc.

Patent Owner

U.S. Patent No. 8,630,699

EXPERT DECLARATION OF JASON HEIKENFELD

I, Dr. Jason Heikenfeld, hereby declare and state as follows:

I. INTRODUCTION

1. I am submitting this declaration in connection with iRhythm Technologies, Inc.'s ("Petitioner") Petition for Inter Parties Review of claims 1-4 and 8 (collectively, the "Challenged Claims") of U.S. Patent No. 8,630,699 (the "'699 patent") (Ex. 1001), before the Patent Trial and Appeal Board of the United States Patent Office (the "Board"). I have been asked by Petitioner to provide information and opinions regarding the level of skill of a person of ordinary skill in the art ("POSA") for the invention claimed in the '699 patent, the general knowledge of such a person at the time of the filing of the application for the '699 patent, the status of the documents relied upon by the Petition, the scope and content of the documents described by the Petition, technical information relating to the '699 patent, and whether the claimed invention in the '699 patent would have been obvious to a POSA in view of the grounds asserted by the Petitioner.

II. QUALIFICATIONS

2. Information concerning my professional background, including my education, experience, and publications, are set forth below. Additional information is provided in my current curriculum vitae, attached as Exhibit 1004.

3. I received a Bachelor of Science (B.S.) in electrical engineering from the University of Cincinnati in 1998 and a Doctor of Philosophy (Ph.D.) in electrical engineering in 2001, also from the University of Cincinnati.

4. I currently hold the titles of Professor of Electrical Engineering, Professor of Biomedical Engineering, and Director of the Novel Devices Laboratory at the University of Cincinnati. In this capacity, I have taught courses including Semiconductor Devices, Optics for Engineers, Biomedical Engineering Seminar, and other electrical and computer engineering courses.

5. In these capacities, I oversee a range of clinical, research and teaching activities in the field of rapid prototyping, electronic materials, microfluidics, electrofluidics, biosensors, electronic displays, flexible electronics, and optics. I have also published widely on topics related to sweat and to interstitial fluid monitoring in the human body and have developed models for both the technology behind wearable biosensing devices and the physiology that provides signals to wearable biosensing devices. I have both academic and industry experience in flexible and wearable electronics and in biosensors, where I have been a leading academic authority world-wide. In my most recent research, I am focused on biosensors for cardiovascular diseases such as heart failure.

6. In addition, I have extensive published research relating to the design, operation, and performance of medical devices used in the monitoring of

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 3

physiological signals, analytes, and/or biofluids. Specifically, my publication record includes titles such as *Adhesive RFID Sensor Patch for Monitoring of Sweat Electrolytes*, 62 IEEE Trans. Biomed. Eng. 1457 (2015); *Wearable Sensors: Modalities, Challenges, and Prospects*, 18 Lab on a Chip 217 (2018); *Accessing Analytes in Biofluids for Peripheral Biochemical Monitoring*, 37 Nature Biotech. 407 (2019); and *Continuous Molecular Monitoring of Human Dermal Interstitial Fluid with Microneedle-Enabled Electrochemical Aptamer Sensors*, 23 Lab on a Chip 3289 (2023).

7. I have worked on numerous projects involving wearable medical devices that monitor various analytes and physiological signals. Nearly all of my wearable medical device work has involved flexible electronics that place electrodes onto the body, including dry electrodes, gel electrodes, iontophoresis electrodes, working and counter and reference electrodes, ion-selective electrodes, and enzymatic electrodes, and heart-rate measurement electrodes. These devices also require electrode leads or traces and electronics and data processing and communication modules. These projects include, but are not limited to, extensive research and professional publications on topics including various strategies for detecting glucose and ethanol levels in blood-correlated sweat, monitoring phenylalanine, cortisol, and drugs in biofluids such as interstitial fluid, and using adhesive sensor patches for monitoring sweat electrolytes. I have also co-authored

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 4

a book-length treatment of fluid dynamics and engineering principles behind "lab-on-a-chip" devices. The book is entitled ELECTROWETTING (2019) and is a comprehensive introduction to the theoretical and practical aspects of fluid manipulation technologies, written to inform academic and industry interests alike.

8. Beyond this, I have been an invited presenter at innumerable academic and professional conferences around the world, where I have given talks with titles such as: "Eccrine Sweat Biomonitoring: Addressing Fundamental Challenges that Advance the Frontiers of Biosensing," ApplySci's Wearable Tech + Digital Health + NeuroTech Conference in Palo Alto, CA, February 26–27, 2018; and "A Leap Beyond the Wearable's of Today: Non-Invasive Biomarker Sensing Through Sweat" at Point-of-Care Conference, San Diego, CA, USA, 2015. Each of these relates to wearable devices that monitor analytes and other physiological signals.

9. I am also the co-founder of Kilele Health Inc., a company devoted to advancing molecular monitoring devices beyond glucose and diabetes to new applications in cardiovascular diseases such as heart failure. In this role, I regularly interface with cardiologists treating patients with heart disorders. I am also a co-founder of HydroLabs Inc., a private company creating technologies and systems for the measurement and analysis of bodily hydration.

10. In addition, I was a co-founder and Member of the Board and Chair of Scientific Advisory Board for Eccrine Systems, a biotechnology company that was

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 5

developing advanced sweat sensors for personalized medicine. Prior to its intellectual property being acquired by Epicore Biosystems, Eccrine was developing a wearable, "skin-like" microfluidic patch that could capture eccrine sweat and then assay that sweat for various biochemical markers.

11. In addition, during the period of 2000 through 2003, I was actively practicing the development of printed circuit board technologies applied to electronic displays, performing the fabrication myself and in communication with leading industry experts such as Pete Zeigler of Dupont Microcircuit Materials and Charles Price of CW Price Screen Printing equipment. At that time, I was aware of the materials and methods utilized for circuit creation using carbon, silver, copper, insulators, markings, and other printed circuit board materials.

12. I have also been the recipient of numerous awards and honors for my research and teaching. In 2023, I was elected to Fellow Status at both the American Institute for Medical and Biological Engineering and Institute of Electrical and Electronics Engineers. These represent the highest levels of professional recognition for biomedical engineers and also for electrical engineers in their respective fields. In 2019, I received the CEAS Research Award, which is the highest career research award bestowed by the University of Cincinnati's College of Engineering. In 2018, I received the Ohio Faculty Council Technology Commercialization Award, which is given to only one faculty statewide per year. In 2015, I was given the Ernst and

Young Edge Award for the Ohio Valley region and in 2014, I was elected to the rank of Fellow at the National Academy of Inventors.

13. I have been listed as an inventor on over one hundred patents and patent publications in the past ten years, mostly directed to detecting and measuring physiological signals, body analytes, or biofluids.

III. DOCUMENTS AND MATERIAL REVIEWED

14. I have reviewed the ’699 patent and its prosecution history (Exs. 1001 and 1002, respectively). In addition, I have also reviewed the Petition and both current and historical industry documentation related to electrophysiology and cardiac monitoring and related to flexible wearable electronics and on-body electrode materials, including all exhibits filed herewith. In preparation of this declaration, I relied on my knowledge of electrical and biomedical engineering, my professional experience, and the exhibits filed herewith.

15. My work on this case is being billed at a rate of $500 per hour, with reimbursement for actual expenses. My compensation is not contingent upon the outcome of this *inter partes* review.

IV. ELECTROCARDIOGRAPHIC MONITORING AND DEFIBRILLATION TECHNOLOGIES

16. Below I describe the state of electrocardiographic body-worn sensor devices as of November 1, 2006, which is the priority date claimed by the ’699

patent. I also summarize the development of technologies underlying the features and methods recited in the Challenged Claims as of November 1, 2006.

A. Electrocardiograms (ECGs or EKGs) Are a Long-Known, Well-Understood Medical Technique

17. Physicians have analyzed their patients' heart rhythms for centuries—even before they had a way to reliably track and interpret the meaning of that rhythm. Ex. 1010 (Jan Adamec & Richard Adamec, *ECG Holter, Guide to Electrocardiographic Interpretation* (2008)) at vii. Electrocardiograms were captured for the first time in the late 1880s using a mercury capillary electrometer. Ex. 1011 (Gautham Kalahasty et al., *A Brief History of Remote Cardiac Monitoring*, 5 Cardiac Electrophysiology Clinics 275 (2013)) at 275–76. After making a number of improvements to the early ECGs, Dr. Willem Einthoven won a Nobel Prize in Medicine in 1924 for his development of the first practical electrocardiogram monitor. *Id.* at 276.

18. From that point on, physicians have used electrocardiograms to evaluate and monitor patients' heart health. *See, e.g.*, Ex. 1010; Ex. 1012 (Edward K. Chung, *Ambulatory Electrocardiography Holter Monitor Electrocardiography* (1979)) at 3–12; Ex. 1013 (U.S. Patent Publication No. 2006/0224072 ("Shennib") (filed March 31, 2005)) at [0005]–[0006]. The acronyms "ECG" and "EKG" are used interchangeably in the art to refer to an electrocardiogram. Ex. 1014 (Daniel E. Becker, *Fundamentals of Electrocardiography Interpretation*, Anesthesia

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 8

Progress 53 (2006)) at 53 ("Th[e] device is variably referred to as an ECG or as an EKG, the latter based on the Greek term 'kardia' for heart. Many prefer EKG to ECG because it is less likely to be confused verbally with EEG, the abbreviation for electroencephalogram.").

19. ECGs work by measuring the electrical activity which controls the heartbeat. *See, e.g.*, Ex. 1015 (Brian Burkhardt, *The Future of Electrocardiograph Telemetry Systems*, Int'l Telemetering Conference Proceedings (2004)) at 2–3. The atria and ventricles, chambers in the heart, contract in response to specific electrical stimulation in order to pump blood through the body. *Id.* at 1. In a healthy heart, the rhythm caused by these electrical impulses is known as a normal sinus rhythm. *See, e.g.*, Ex. 1012 at 5. The sinus rhythm of a heart with irregularities differs from that of normal, healthy hearts, meaning that ECGs can be used to identify irregularities in heart rate and heart rhythm as well as other potential health concerns. *Id.* at 3–12; Ex. 1001 at 12:40–44 ("[i]rregular or missing waves may be indicators of cardiac issues including: ischemic tissue, e.g. due to myocardial infarction, bundle branch block, atrial problems (specifically P-wave abnormalities), pericarditis, and electrolyte disturbance"); *see also* WO 2008/005015 A1 ("Shennib PCT") (Ex. 1016) at [0005].

20. ECGs measure the movement of these electrical signals using electrodes placed on the surface of a patient's skin. *Id.* Over a half-century before

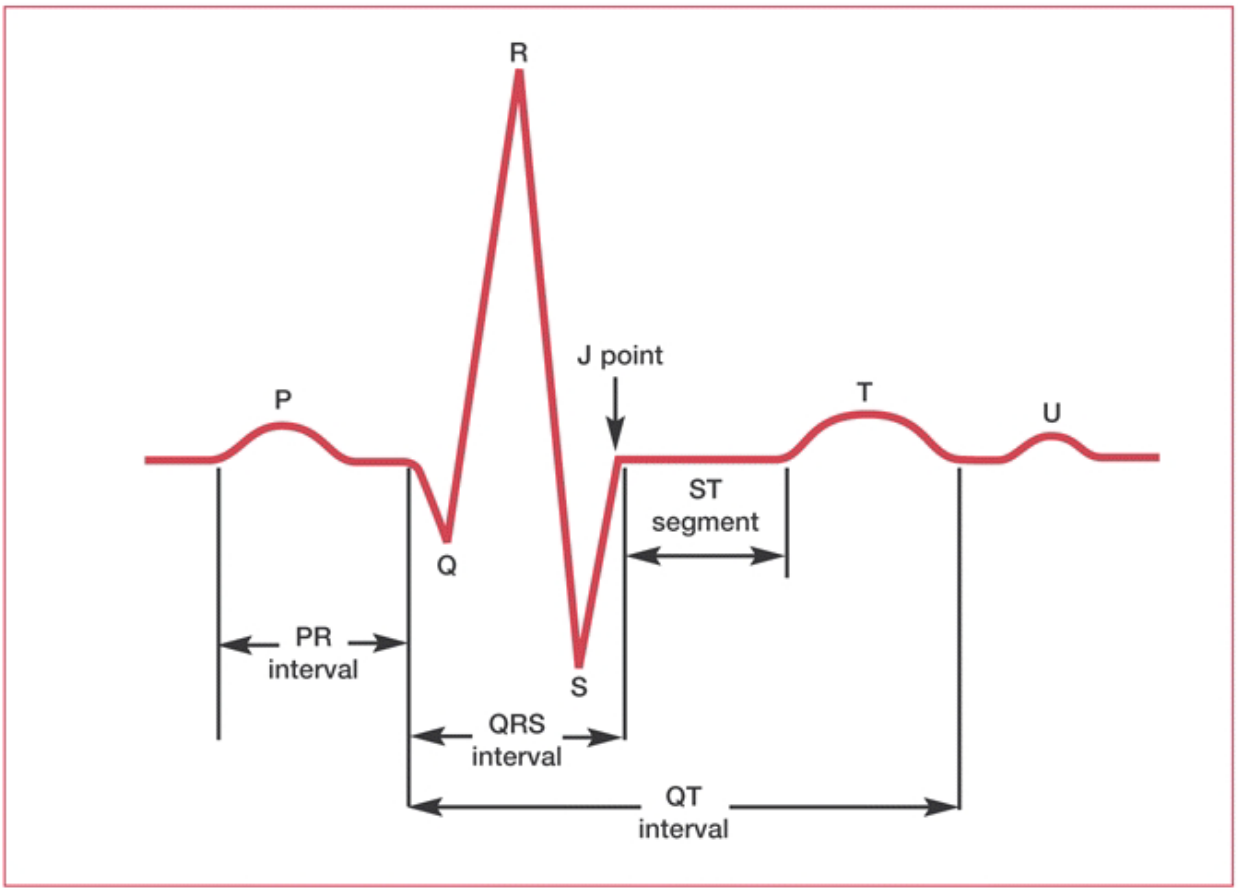
iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 9

the invention date, 12-electrode ECG was standardized. Ex. 1017 (Majd AlGhatrif & Joseph Lindsay, *A Brief Review: History to Understand Fundamentals of Electrocardiography*, 2 J. Community Hosp. & Internal Med. Persps. 14383 (2012)). These earlier, "12-lead" ECGs used ten "electrodes" (a type of conductor) to measure these electrical signals: six on the patient's chest, two on each of the patient's forearms, and two on each of the patient's calves. Ex. 1018 (NLM, In brief: *What is an electrocardiogram (ECG)?*, *available at* https://www.ncbi.nlm.nih.gov/books/NBK536878/). These electrodes are typically disposable and attached to specific locations on the surface of the patients' skin using adhesive. Ex. 1019 (Michael R. Neuman, *Biopotential Electrodes*, Medical Instrumentation (3d ed. 1998)) at 201, Fig. 5.9; *id.* at 204. The specific positioning of the electrodes provides a three-dimensional view of the heart's electrical activity. The positions of the electrodes correspond to ECG vectors that trace the direction, magnitude, and sense of the electrical activity. *See, e.g.*, Ex. 1020 (Robert P. Grant, *Spatial Vector Electrocardiography*, Circulation Vol. II, 676 (Nov. 1950)) at 677. The vectors detected by the electrodes are transmitted via cables to an ECG machine which converts the signals into an ECG readout. Ex. 1018.

21. A typical ECG readout includes several distinct waves: the P-wave, the QRS complex, and the T-wave. *See, e.g.*, Ex. 1021 (ACLS Medical Training, *The Basics of ECG*, *available at* https://www.aclsmedicaltraining.com/basics-of-ecg/).

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 10

Physicians can interpret one of more of these waves to derive a patient's heart rate and rhythm. *Id.* The P-wave represents the atrial electrical activity, while the QRS complex and the T wave all represent ventricular electrical activity. *Id.*



Ex. 1022 (Euan A. Ashley & Josef Niebauer, *Cardiology Explained* (2004), *available at* https://www.ncbi.nlm.nih.gov/books/NBK2204/) at Ch. 3, Fig. 4.

22. Well before the priority date of the '699 patent, physicians used several methods of ECG cardiac monitoring, including screening, short-term monitoring, intermittent monitoring, and long-term monitoring. Ex. 1023 (Am. Coll. Cardiology, Am. Heart Ass'n Task Force on Practice Guidelines, *ACC/AHA*

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 11

Guidelines for Ambulatory Electrocardiography: Executive Summary and Recommendations 100 Circulation 886 (1999), *available at* https://www.ahajournals.org/doi/full/10.1161/01.cir.100.8.886). There are various devices that can be used for each different method of cardiac monitoring. *Id.*

B. The Evolution of Portable Physiological Monitors Decades Prior to the Priority Date

23. The first practical ECG monitor—weighing several hundred pounds—was developed in the 1920s. Ex. 1011 at 276. Recognizing the commercial potential of ECG, the industry quickly sought to reduce and miniaturize these monitors. *Id.* While there were many reasons to reduce the size of stationary ECGs used solely in clinical settings, the commercial and clinical benefits of reducing the size of ECGs became even more salient when long-term, portable ECG recording devices were invented by Dr. Norman Holter in 1949 and released for commercial production in 1962. *Id.*; *see also* Ex. 1012 at 3; Ex. 1010 at xi. These devices became known as "Holter monitors," versions of which are still commonly used today. *Id.* By the early 1960s, the size had decreased enough that Holter monitors were both clinically viable and commercially available. *Id.* One way that this size reduction was achieved was by incorporating transistors, *i.e.*, semiconductor devices that can act as electronic switches and amplifiers that control or alter current or voltage flow, into the Holter monitor. Ex. 1011 at 276. The size of the Holter monitor continued to be reduced throughout the 1960s. By 1969, Holter *mini*monitors (the size of a

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 12

cigarette package) were being commercially produced. Ex. 1024 (Mike Cadogan, *Norman J. Holter* (2022), *available at* https://litfl.com/norman-j-holter/).

24. Holter monitors were widely adopted, in part due to clinical reports demonstrating the usefulness of long-term ECG monitoring. Ex. 1025 (Joel Morganroth, *Ambulatory Holter Electrocardiography: Choice of Technologies and Clinical Uses*, Anals. of Internal. Med. (1985)) at 74. By 1979, there were a number of medical uses, referred to as indications, for the use of Holter monitor electrocardiography. These indications included "[d]iagnosis of cardiac arrhythmias," "[e]valuation of symptoms . . . to correlate with actual arrhythmias," "[d]iagnosis of myocardial ischemia," "[e]valuation of anti-arrhythmic drug therapy," and "[e]valuation of artificial pacemaker function." Ex. 1012 at 228, Table 2. By the early 1980s, the incorporation of transistors and other technologies made it possible for the size of portable ECG monitors to continue to shrink while at the same time their functionality improved. Ex. 1025 at 74; Ex. 1026 (Nitish V. Thakor, *From Holter Monitors to Automatic Defibrillators: Developments in Ambulatory Arrhythmia Monitoring*, IEEE Transactions on Biomed. Eng'g, 770 (1984)) at 775–76 (noting that "[m]icroprocessor technology permitted the design of a compact, even portable, device that analyzed the ECG signal in real time").

25. Importantly, the designs of ECG monitoring devices continued to evolve with the goals of reduced size and increased discreteness, which allowed

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 13

ECG monitoring patients to have reduced interference with their day-to-day lives. Ex. 1001 at 1:28–29 ("[p]ortable patient monitors have evolved that allow patients to enjoy at least some mobility"); *see also* Ex. 1044 (J. Mühlsteff et al., *Wearable Approach for Continuous ECG –and Activity Patient-Monitoring*, 26th Ann. Int'l Conf. of IEEE EMBS, San Francisco, CA, USA (2004)) at 2184 ("An ideal monitoring system should measure relevant medical parameters with almost no impact on quality of life."). Thus, reducing the size and improving the wearability of longer-term ECG monitors, such as the Holter monitor, has been, and continues to be, an industry focus since long-term ECG monitoring was first conceived of decades ago.

C. Wearable ECG Monitors Were Well Known Prior to the Priority Date

26. Prior to November 1, 2006, wearable ECG monitors that allowed for longer monitoring periods were well known in the industry. As the '699 patent and other prior art references explain, most of these devices comprised, *inter alia*, ECG electrodes, electrical traces/wiring, portable batteries, printed circuit boards, and some form of resistor.

1. Electrical Traces/Wiring

27. First, prior to November 1, 2006, wearable devices including electrical traces or wiring (also known as leads) on flexible substrates that connected the electrodes to the device electronics, were widely known. *See, e.g.*, Ex. 1013 at

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 14

[0014] (discussing a prior art patch that is a "flexible, nominally flat planer form having integral gel electrodes, a sticky-back rear surface, [and] an internal flex circuit"), [0035] ("The electronic assembly of the patch is formed of a flexible circuit substrate 20 with trace extensions to the electrodes 21, 22, 23"); U.S. Patent No. 6,454,708 ("Ferguson") (Ex. 1027) (issued September 24, 2002) at 8:57–58 ("[t]he signal processing circuitry 12 receives the sensor data from traces 14"), 9:44–48 ("[r]espiration data . . . may also be collected using a printed carbon on flextrate resistance band sensor 19 located on the left hand side of the chest"), 10:35–40 ("[t]he PCB is connected to a flexible substrate which has printed circuit traces 14 providing connections to the electrodes and the connector 13'"). These electrical traces are small, allowing for the device to be miniaturized without needing to use large or cumbersome individual electrical wires, such as those used in Holter monitors.

2. Microprocessors

28. Second, prior to November 1, 2006, wearable devices including a reusable electronic component used to interpret the signals received by the sensor were widely known. *See, e.g.*, Ex. 1013 at [0011] ("The patches (electrodes) employed with these monitors are disposable. However, the electronic base unit is reusable as it is loaned to patients as part of the diagnostic service provided by the clinic."); Ex. 1027 at 6:12–14 ("the smart card also houses the sensor band's

electronics so that the electronics may be reusable from one sensor band to the next"). Reusing some electronic components of the wearable device is more economical and more environmentally sound.

3. Portable Batteries

29. Third, prior to November 1, 2006, wearable devices including portable batteries were widely known. *See, e.g.*, Ex. 1001 at 1:29–35 ("Typically a battery operated monitor can be hung on a belt, shoulder strap, or carried by a patient using some other similar hanging arrangement. . . . After a fixed interval of time, or at a low battery indication, the batteries can be replaced or recharged"), 1:36–40 (discussing the Micropaq wireless patient monitor, manufactured by Welch Allyn, Inc., as "[*o*]*ne* example of a portable patient monitor") (emphasis added); Ex. 1013 at [0010] ("These monitors may have a display to inform the patient if and how many events have been recorded and the status of the battery life.").

4. Printed Circuit Boards

30. Fourth, prior to November 1, 2006, printed circuit boards (or PCBs) were widely known and used in wearable medical devices as described above in this Section. Ex. 1008 (R.S. Khandpur, *Printed Circuit Boards: Design, Fabrication, Assembly, and Testing* (2006)) at 3 (noting that the screen-printing technique which "ushered in the commercial use of printed circuits" or PCBs was first developed "[t]owards the end of World War II"). PCBs are comprised of a base (or substrate)

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 16

that provides support to the components that will be mounted to the board as well as the conductors (or traces). *Id.* at 4. The traces form electrical connections among and between the various components mounted to the substrate. *Id.* To continue to miniaturize and improve wearable ECG devices, engineers looked to well-known PCB technology. *See, e.g.*, Ex. 1028 (David Prutchi & Michael Norris, Design and Development of Medical Electronic Instrumentation (2005)) at 10, 48, 193–94; Ex. 1027 at 10:31–37; U.S. Patent Publication No. 2005/0096513 to Ozguz ("Ozguz") (Ex. 1029) (filed December 6, 2004) at [0005].

31. It was well known, for example, that flexible materials could be used as the substrate for a PCB in order to improve the design of a wearable device, including because the flexible substrate material allowed the PCB to adapt to and with the human body in motion. Ex. 1029 at [0005]–[0006]; U.S. Patent Publication No. 2003/0149349 to Jensen ("Jensen") (Ex. 1005) (filed December 18, 2002) at [0046].

32. It was also well known that PCBs could be created using a technique known as screen printing. *See, e.g.*, Ex. 1008 at 3 (noting that the screen printing technique was used to print "silver paste conductors and graphite resistors . . . onto ceramic substrate" as early as "the end of World War II"; noting that "[i]t was [the screen-printing] technique that ushered in the commercial use of printed circuits"), 4 ("When the completed board provides mechanical support and all necessary

electrical connections to the components, it is essentially a Printed Wiring Board or Printed Circuit Board. The term *printed* became popular because the conductive areas are often generated by means of a printed process like screen printing . . .”), 283 (explaining that “[t]he majority of PCBs produced worldwide are screen printed” because, while “less precise” than other methods, it is “comparatively cheap and simple”), 659 (defining “Printed Circuit” as a “[c]ircuit where the interconnections between components, terminals, subassemblies, etc., are made by conductive strips (traces) that have been printed or etched onto an insulating board”); *see also* Ex. 1030 (AAMI, *Cardiac monitors, heart rate meters, and alarms*, ANSI/AAMI EC13:2002 (2002)) (“EC-13”) at 4 (referencing a “printed trace”).

33. In order to print a PCB using the screen-printing technique, an ink containing a conductive material (such as silver/silver-chloride) is extruded through a stencil onto the substrate, forming a predetermined pattern as shown below.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 18

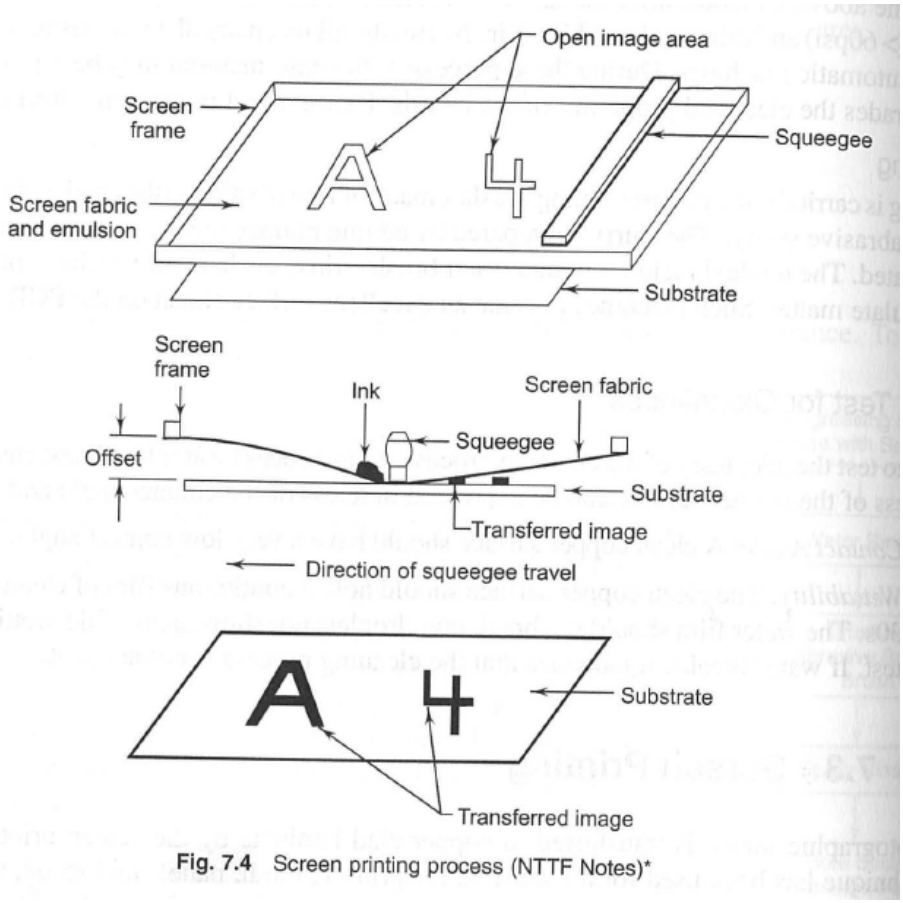


Fig. 7.4 Screen printing process (NTTF Notes)*

Ex. 1008 at 288, Fig. 7.4. It was well known by PCB designers and others in the art that varying the composition of the ink, the length of a trace, and the width of a particular trace would result in traces of varying conductivities/resistivities. *See, e.g.*, U.S. Patent No. 5,169,679 ("Palanisamy") (Ex. 1031) (issued December 8, 1992) at 1:26–32 ("The resistance R of a particular resistor composition is generally tailored by adjusting its aspect ratio, L/W, where L is the length and W [is] the width of the resistive film. R increases directly with L and inversely with W. R also increases inversely with the thickness of the film, but the thickness is generally kept uniform to facilitate processing."); U.S. Patent No. 6,229,098 ("Dunn") (Ex. 1032)

(issued May 8, 2001) at 2:31–36 (providing a process for "forming a resistor whose x (width), y (electrical length) and z (thickness) dimensions can be accurately obtained, thereby yielding a resistor whose resistance value can be precisely obtained even for resistors having dimensions on the order of about 100 micrometers"); *see also* U.S. Patent No. 4,763,660 ("Kroll") (Ex. 1007) (issued August 16, 1998) at 5:29–37.

5. Resistors

34. Fifth, prior to November 1, 2006, wearable devices including resistors, which protected both the patient and the device from unwanted electrical discharge, were widely known. A typical solution was to include "one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor." Ex. 1001 at 1:63–65; *see also* U.S. Patent No. 6,238,338 ("DeLuca") (Ex. 1033) (issued May 29, 2001) at 4:57–64 ("all input stage connections to the ASIC 36 are protected against electrostatic discharge by the circuit formed by the current limiting series resistors Rin and Rdrive with their respective diode connected JFETs, D1, D2, D3. This arrangement maintains a low leakage path under normal operating conditions, while providing a current path during over-voltage conditions"); U.S. Patent No. 4,280,507 ("Rosenberg") (Ex. 1034) (issued July 28, 1981) at 1:19–27 (noting that "[m]ost EKG machines are equipped with internal circuits that bypass the front end amplifiers in the presence of a defibrillation pulse, but full protection

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 20

of the machine requires that voltage limiting means be included in each of the leads from the machine to the electrodes attached to the patient's body"). However, such resistors were "too large for use in a compact monitor application." Ex. 1001 at 1:65–67.

35. It was also well-known that screen printing techniques, such as those described above, could be used to print resistors on the surface of PCBs. There were many well-known ways to do so, including by first screening traces using a highly conductive ink, leaving a gap between the traces for a resistor, and then, in a second layer, screening a span of highly resistive ink over the gap, making contact with both of the traces to form a resistor. U.S. Patent No. 5,093,036 ("Shafe") (Ex. 1035) (issued March 3, 1992) at 5:53–56 (screen printing resistive ink to "connect[] to other electronic components"); *id.* at 1:26 (citing use in circuit protection); U.S. Patent No. 8,334,464 ("Edwards") (Ex. 1036) (issued December 18, 2012) at 2:7–10. Similarly, a trace itself could be screened onto a PCB using an ink that was a mixture of conductive and resistive elements, resulting in a trace with a known resistivity. Ex. 1007 at 5:22–42.

D. Industry Standards as of November 1, 2006

36. Patients often undergo longer-term ECG monitoring because they are suspected to have an increased risk of heart conditions. Because such conditions may require defibrillation, any device used for longer-term ECG monitoring must

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 21

be designed in a way that prevents any adverse effects should defibrillation be necessary while the patient is wearing the ECG monitor. Defibrillation is the application of a dose of electrical current to "reset" the body's natural pacemaker.

37. As acknowledged by the '699 patent, prior to November 1, 2006, a number of industry standards relevant to wearable physiological monitoring devices had been promulgated. *See, e.g.*, Ex. 1001 at 4:31–34 (referencing the European Unions' Medical Device Directive and the EC-13 standard for electrocardiographs), 14:36–39 ("Standard EC13 addresses the ability of an ECG monitor to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electrosurgical device is being used."), 14:39–41 (noting that without the suppression required by EC-13, "the high RF output of an electrosurgical device can render ECG monitoring impossible and or render the monitor unusable"). These standards required that, to achieve compliance, wearable devices contain certain features and/or functionalities that, in the event the device absorbed too much of the electrical energy from a defibrillation shock, the necessary voltage would be limited before it reached the patient, preventing any harm to the patient. As described by the '699 patent, these standards included as requirements, among other things, many of the features that had been well known in the field, such as those described in Sections IV.C–D above.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 22

38. The ’699 patent references the Association for the Advancement of Medical Instrumentation’s (AAMI) EC-13 standard, which was published in 2002. EC-13 describes disposable ECG electrodes, affixed to the patient’s body, as well known in the art. *See, e.g.*, Ex. 1030 at 60 (“The characteristics of disposable electrodes have been studied extensively by UBTL [(a Division of the University of Utah Research Institute under the sponsorship of the U.S. Food and Drug Administration’s then Bureau of Medical Devices)] (Schoenberg, et al., 1979)”); *id.* at 48–49 (“This device is attached to the body through ECG electrodes”); *see also id.* at 68 (citing EC-12, a standard concerning “pre-gelled ECG disposable electrodes,” and dated 1991). Another relevant standard is AAMI’s EC-82 standard, which was published in 1999. Ex. 1037 (AAMI, *Ambulatory Electrocardiographs*, ANSI/AAMI EC38:1998 (1998)) (“EC-38”). For wearable ECGs the Association for the Advancement of Medical Instrumentation (AAMI) standard for diagnostic electrocardiographic devices (AAMI-EC11) notes that “[d]efibrillator overload protection is necessary for most ECG devices, since in the hospital environment any given ECG device might be used on patients potentially requiring defibrillation.” Ex. 1054 (AAMI, *Diagnostic electrocardiographic devices*, ANSI/AAMI EC11:1991 (1991)), Section A.3.2.14.2.

39. The EC-13 standard requires protection of both the patient and the device from electrical shock. Ex. 1030 at 55 (“Defibrillator overload protection is

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 23

necessary for most cardiac monitors" because "***any given monitor might be used on patients potentially requiring defibrillation***.") (emphasis added). In particular, the EC-13 standard specifically requires that wearable devices can survive "multiple defibrillation cycles of at least 360 joules." Ex. 1001 at 1:61–63; Ex. 1030 at 18, Table 4; *see also* Ex. 1037 at 45 (noting the maximum selectable deliverable energy of defibrillators ranges from 250 to 360 joules). The EC-13 standard explains that the device should "continue to function after exposure to the short-duration high voltages of a defibrillator discharge" and discusses mechanisms for doing so. Ex. 1030 at 55.

40. Lastly, "portable and battery-powered ECG monitors" were already so widely known that they were explicitly included in the scope of the EC-13 standard, *id.* at 1, and the EC-38 standard, *see, e.g.*, Ex. 1037 at 8 Table 2, 42.

41. In sum, the EC-13 standard, which the '699 patent understood to require "that a medical grade monitor [could] survive multiple defibrillation cycles," demonstrates that, as of November 1, 2006, it was well understood in the art that if the device absorbed too much of the electrical energy from the defibrillation shock, the necessary voltage would not reach the patient. Further, it was well understood that the voltage increase from defibrillation could damage or destroy the electronics on the wearable heart monitor. Ex. 1001 at 1:61–63.

E. Resistive Protection and Resistive Traces

42. Using electrical resistance for protection of both the device and the patient was also widely known before November 1, 2006. As discussed above, the importance of including such protection in ECG monitors was well-understood because patients who require long-term monitoring are at an increased risk of experiencing a cardiac event, such as a sudden cardiac arrest. *See* Section IV.E, *supra.* It was an industry requirement that ECG monitors were capable of withstanding the surplus electrical discharge associated with defibrillation. *See* Section IV.E., *supra* (discussing the EC-13 standard). This requirement is acknowledged by the background section of the '699 patent, which notes that "[a]nother problem is related to the ***requirement that a medical grade monitor survive multiple defibrillation cycles*** of at least 360 joules." *See, e.g.*, Ex. 1001 at 1:61–63 (emphasis added); see also Ex. 1054, Sections A.3.2.14.2, A.3.2.14.2.1 ("Defibrillator overload protection is necessary for most ECG devices, since in the hospital environment any given ECG device might be used on patients potentially requiring defibrillation. . . . The American National Standard, *Cardiac defibrillator devices*, specifies a maximum selectable deliverable energy in the range of 250 to 360 joules (AAMI, 1989)."). A POSA would understand that 360 Joules is the maximum amount of energy that would be delivered by a defibrillator. *See, e.g.*, Ex.

1030 at 55 ("The American National Standard . . . specifies a maximum selectable deliverable energy [for a defibrillator] in the range of 250 joules (J) to 360 J").

43. There were multiple known ways of incorporating electrical resistance as protection as of November 1, 2006. While the '699 patent notes that "[c]onventionally, this requirement has been met by one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor," this was not the only approach available to a POSA at the time. *See, e.g.*, Ex. 1001 at 1:63–65. One approach was to use leads of "electrically conductive carbon loaded polymer" where the "distributed resistance of each polymer lead" was sufficient to provide protection from any excess electrical current. Ex. 1034 at 1:36–45. A POSA would understand that the terms "lead" and "trace" are often used interchangeably because signal traces connect the components on a printed circuit board much like lead wires functioned in the early days of ECG technology. *See* Ex. 1008 at 642 ("Conductor: A single conductive path in conductive pattern. A PCB has at least one layer of conductors. *Synonyms:* path, trace.").

44. This approach is further highlighted in Kroll, which notes that lead strips are comprised of "a flexible conductive ink compound having a conductive filler . . . [p]referably . . . of a preselected conductivity to provide a certain total lead strip resistance so that each strip 34 serves as a current limiter." Ex. 1007 at 5:4–11, Fig. 4. A POSA reading this disclosure would understand that the flexible

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 26

conductive ink described in Kroll was printed on a flexible circuit board. *See, e.g.*, Ex. 1008 at 255 ("The basic function of the laminate is to provide mechanical support for electronic components and to interconnect them electrically . . . They can be simply described as products obtained by pressing layers of a filler material impregnated with resin under heat and pressure. The resulting thin, insulating material, which is the mixture of filler (reinforcement) and resin on which all conductors and components are mounted, is called *base material* [which] can be either rigid or flexible material."); *see also* Section IV.C, *supra*. Thus, the lead strips in Kroll are electrical traces. *See* Ex. 1008 at 659 (defining a "printed circuit" as one in which the "interconnections" are "made by conductive strips (traces) that have been printed or etched onto an insulating board").

45. Another approach was to use "a small, flat surface mount resistor soldered to input trace 34 on top of circuit board 28." Ex. 1038 (WO 1987/01024 A1) ("Dunseath") (filed August 21, 1986) at 25:24–26:12. This can be used to "provide adequate protection for some types of integrated circuit amplifiers such as CMOS devices which are sensitive to large input voltages rather than currents." *Id.* at 5:31–6:2.

46. Importantly, resistance in the traces on a body-worn physiological device has a twofold protective effect. It helps protect the patient from shock from the device and it helps to protect the device from the effects of an outside shock. In

fact, any approach to limiting current using resistive material to protect the patient from shock would also protect the body-worn device from excess electrical current because the electrical resistance operates to limit the flow of current in *either* direction (flowing from the device toward the patient, or from the patient's skin toward the device). *See, e.g.*, Ex. 1039 (Roger A. Freedman & Hugh D. Young, *University Physics* (15th ed. 2019) at 816–17 (noting that the resistivity of a conductor depends on the properties of the conductor material), 819–20 (noting that current always flows in the direction of decreasing electric potential or voltage). Further, a resistor functions the same regardless of the direction of current flow through it: for a given amount of current through a resistor or voltage drop across the resistor the resulting power dissipation, currents, and voltage drops are identical regardless of direction of current flow. *Id.* Therefore, any resistor that simply has the proper range of resistance would protect the body-worn device from excess electrical current (*e.g.*, Ex. 1001 at 7:58–60 ("in a range between about 1 kilo ohm to about 10 kilo ohms," or other ranges depending on the specific electronics used in an ECG device)).

47. Further, consistent with the industry goal of reducing the size of body-worn monitoring devices, a POSA would have prioritized approaches of limiting current that were small and compact. *See, e.g.*, *id.* at 1:65–67 ("The problem [with the conventional approach of using resistors in series] is that the physical volume of

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 28

conventional power resistors is too large for use in a compact monitor application."). Rosenberg and Kroll have a similar result (*i.e.*, reducing the size of the devices) by incorporating the resistance into the traces or leads or the device, rather than using conventional resistors on the printed circuit board of the device. *See* Ex. 1034 at 1:36–45; Ex. 1007 at 5:4–11.

V. RELEVANT LEGAL STANDARDS

48. I have been asked to provide my opinions as to whether the Challenged Claims of the '699 patent would have been obvious to a POSA at the time of the filing date of the '699 patent.

A. Scope of an *Inter Partes* Review

49. I understand that the scope of issues which are to be considered in an *inter partes* review are limited to those grounds disclosed in the Petition on which it requests the Board institute review.

B. Claim Construction

50. I have been informed and understand that for purposes of this proceeding, the claim terms subject to *inter partes* review are to be "construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by [a POSA] and the prosecution history pertaining to the patent." 37 C.F.R. § 42.100(b). For

purposes of this Petition, the Challenged Claims are interpreted according to their plain and ordinary meaning.

C. Obviousness

51. It is my understanding that a claim is obvious under 35 U.S.C. § 103 if the claimed subject matter as a whole would have been obvious to a POSA at the time of the alleged invention. I also understand that, in an obviousness analysis, the POSA is presumed to have knowledge of all material prior art.

52. In considering obviousness, I understand that one must determine the scope and content of the prior art. I understand that, in order to be considered as prior art to the challenged patent, a prior art reference must be reasonably related to the claimed invention of the challenged patent. A reference is reasonably related if it is in the same field as the claimed invention or is from another field to which a POSA would look to solve a known problem. If a reference relates to the same problem as the claimed invention, that supports use of the reference as prior art in an obviousness analysis.

53. I understand that a patent claim composed of several elements is not proven obvious simply because each of its elements was independently known in the prior art. It is my understanding that, in evaluating obviousness, it is relevant whether there is a reason that would have prompted a POSA to combine the elements or concepts from the prior art in the same way as in the claimed invention. There is

no single way to define the line between true inventiveness on one hand (which is patentable) and the application of common sense and ordinary skill to solve a problem on the other hand (which is not patentable). For example, market forces or other design incentives may be what produced a change, rather than true inventiveness.

54. It is my understanding that several rationales may be applied for combining references or modifying a reference to show obviousness of claimed subject matter. These rationales include: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device (method or product) ready for improvement to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify a prior art reference or to combine prior art teachings to arrive at the claimed invention. Additionally, I understand that the claimed subject matter is obvious if it would have been obvious to a POSA in view of his/her general knowledge, *i.e.*, in light of all knowledge conveyed by the prior art as defined by statute and case law.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 31

VI. PERSON OF ORDINARY SKILL IN THE ART ("POSA")

55. It is my understanding that when interpreting the claims of the patents, I must do so based on the perspective of one of ordinary skill in the art in the same field as the challenged patent at the time of the invention. The earliest claimed priority date for the '699 patent is November 1, 2006.

56. It is my opinion that one of ordinary skill in the art in the field of body-worn physiological monitors in 2006 would have had at least a Bachelor's degree in electrical engineering, electrophysiology, biomedical engineering, or an equivalent degree, and at least two to three years of experience designing wearable monitors that detect physiological signals with mechanical and/or electrical elements. Alternatively, a POSA with respect to the technology described by the challenged patent could have had less education with more experience and vice versa.

VII. THE '699 PATENT

57. The '699 patent is titled "Body Worn Physiological Sensor Device Having a Disposable Electrode Module." It was filed June 5, 2012. The '699 patent claims priority to Application No. 11/591,619 which was filed on November 1, 2006 and which issued as U.S. Patent No. 8,214,007. The stated field of art is "physiological monitor[s]" generally and more specifically "body worn physiological monitor[s]." Ex. 1001 at 1:16–17.

A. Overview of the ’699 Patent

58. As discussed above in Section IV, by the November 2006 priority date, the field of body-worn physiological monitoring was well-established.

59. The ’699 patent describes a physiological monitor that is worn on the patient’s body. According to the ’699 patent, the body-worn monitor includes a “defibrillation protection resistor . . . screened onto a substrate,” which was designed to help protect the body-worn device from damage due to excess electrical current. Ex. 1001 at cl. 1. The “defibrillation protection resistor” is shown in blue below on annotated Figure 4A; the “substrate” is shown in pink below on annotated Figure 4A.

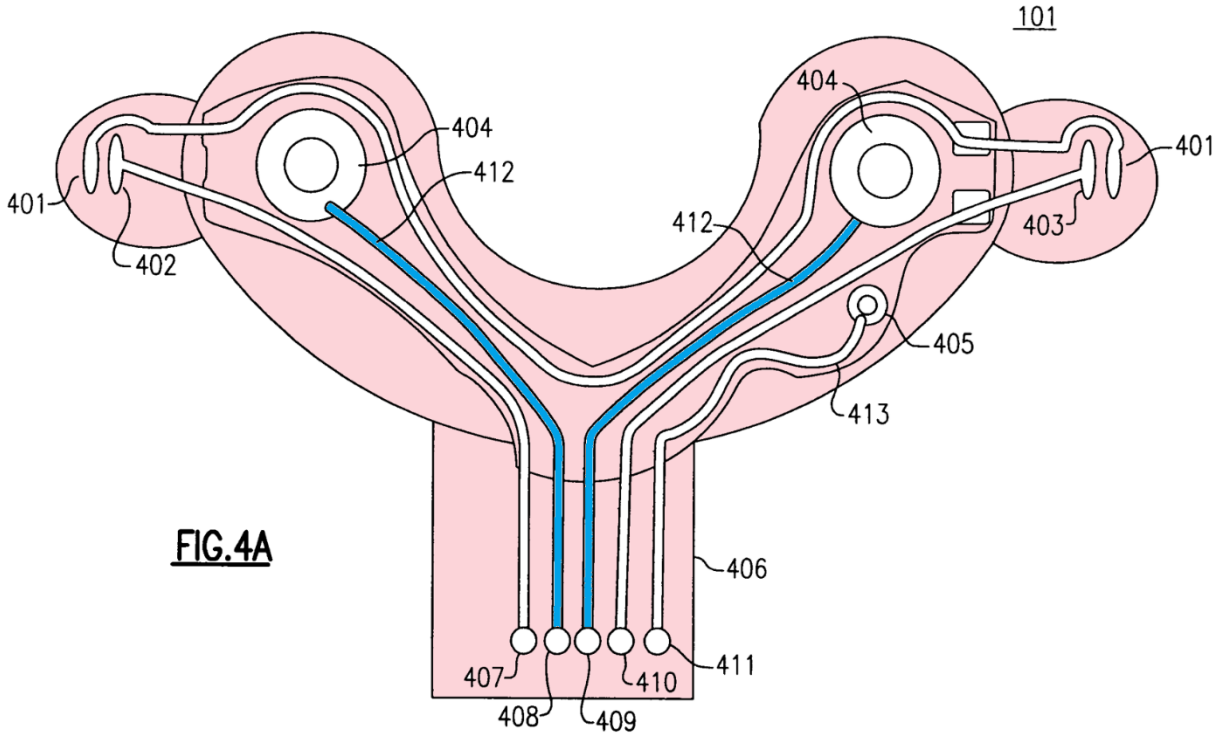


FIG.4A

Id. at Fig. 4A (annotated).

60. The ’699 patent explains that at least some version of current limitation had to be included in the body worn device because there were existing medical standards requiring that “a medical grade monitor survive multiple defibrillation cycles of at least 360 joules.” *Id.* at 1:61–63, 10:17–33. In 2006, a POSA would have understood this to mean that the device was required to have a current limiting mechanism to protect the ECG electronics during a defibrillation shock, which is typically 360 Joules. Ex. 1030 at 18, Table 4; *see also* Ex. 1037 at 45 (noting the maximum selectable deliverable energy of defibrillators ranges from 250 to 360 joules). Further, in my opinion, a POSA would also have been aware of well-known ways to protect electronics against shocks, including by using resistors.

61. The ’699 patent describes the use of “resistive traces” to “replace the bulky power resistors needed by prior art monitors,” which are configured to protect the communication-computation module from “multiple defibrillation cycles.” Ex. 1001 at 7:46–57, 19:26–30.

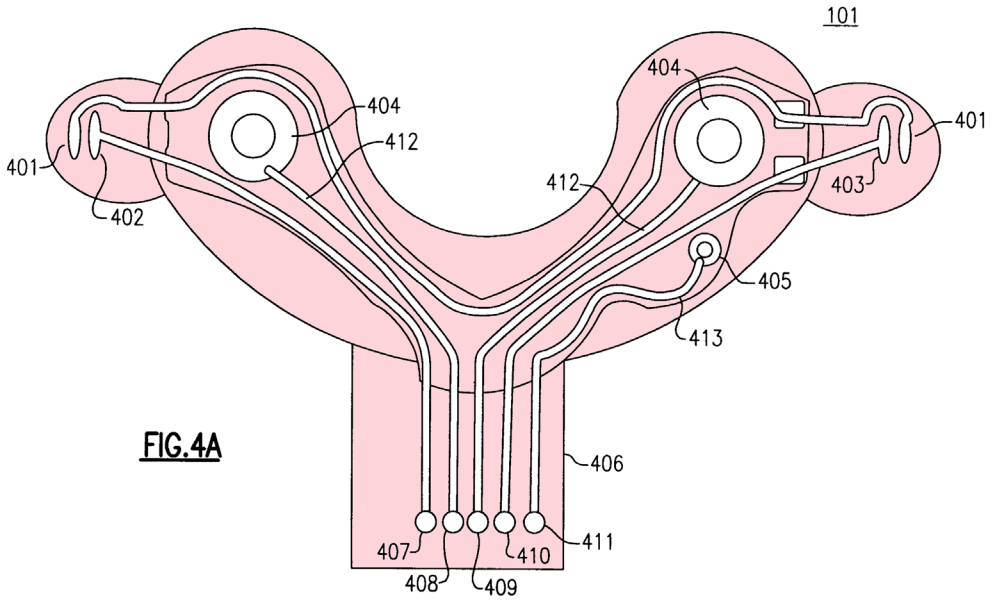


FIG.4A

Id. at Fig. 4A.

62. The ’699 patent further explains that the ideal range of resistances for these traces is between 1 and 10 kΩ (*id.* at 7:58–8:3), and that the desired resistances are achieved by configuring the resistive trace’s width, thickness (height), and length (*id.* at 8:26–30). The ’699 patent explains that, in some cases, “[t]here can be a short overlay distance . . . in which a [conductive] trace overlaps the [resistive] trace to provide a more robust connection between the resistive and conductive portions of the traces.” *Id.* at 8:35–40.

B. Summary of the Claims of the ’699 Patent

63. Claim 1 of the ’699 patent is set forth below with the elements labeled for reference:

Elements Designation	Element
1(pre)	An ECG monitor comprising:
1(a)	a plurality of electrical connections including at least one electrode,
1(b)	the electrical connections being couplable to a skin surface to measure patient heartbeat signals;
1(c)	a power source;
1(d)	at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate; and
1(e)	an ECG electronics module,
1(f)	the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections,
1(g)	wherein the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.

Id. at cl. 1.

64. Claim 2 of the ’699 patent depends from claim 1 and further recites “wherein the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.” *Id.* at cl. 2.

65. Claim 3 of the ’699 patent depends from claim 1 and further recites “wherein a mechanical interface is defined from the at least one series current-

limiting resistor to the at least one ECG electrode, the mechanical interface including a filleted edge." *Id.* at cl. 3.

66. Claim 4 of the '699 patent depends from claim 1 and further recites "wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a plurality of overlapped layers." *Id.* at cl. 4.

67. Claim 8 of the '699 patent depends from claim 1 and further recites "wherein the ECG electronics module includes a microprocessor to process the heartbeat signals, wherein an algorithm running on the microprocessor causes the ECG monitor to enter a lower power mode that disables at least one circuit of the ECG electronics module, from the end of a 'T wave' at the end of one heartbeat to the beginning of a 'P wave' at the beginning of the next heartbeat, in order to reduce said electrical load on the power source." *Id.* at cl. 8.

VIII. PROSECUTION HISTORY OF THE '699 PATENT

68. I have reviewed the file history of U.S. Patent Application No. 13/488,520 (the "'520 Application") from which the '699 patent issued. I provide below a brief (non-exhaustive) summary of its relevant parts.

69. The '520 Application was filed on June 5, 2012. The '520 Application is a continuation of and claims priority from U.S. Application No. 11/591,619, which was filed on November 1, 2006. Ex. 1001.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 37

70. In an Office Action dated March 13, 2013, the Examiner issued a restriction requirement to one of two inventions. Ex. 1002 (U.S. Patent No. 8,630,699 Prosecution History) at 78. The Patent Owner elected to prosecute the claims directed to an ECG monitor (then pending claims 8-15). *Id.* at 70.

71. In a non-final Office Action dated May 16, 2013, the Examiner rejected all pending claims as being anticipated under 35 U.S.C. § 102 by U.S. Pat. Pub. 2003/0171742 ("Tasto"). *Id.* at 52–53.

72. On July 16, 2013, the Examiner and Patent Owner discussed the § 102 rejection over Tasto in an interview requested by Patent Owner. *Id.* at 48. Following the interview, the Examiner noted: "based on the arguments, the examiner agrees with the applicant in that the cited prior art reference, Tasto, fails to disclose the claimed invention. Based on the submitted arguments the Examiner will be required to perform another search." *Id.*

73. Following the interview, on August 16, 2013, Patent Owner submitted an Office Action Response requesting reconsideration of the Examiner's § 102 rejection over Tasto.

74. Patent Owner's Remarks include substantial argument and were focused on the fact that Tasto disclosed "an electrocautery device used for promoting the flow of blood through vessels or to connective tissue of a patient" and not an ECG monitoring device. *Id.* at 40–41. Patent Owner further argued that the device

disclosed by Tasto is a therapeutic device, as opposed to an ECG monitor which utilizes a set of electrodes placed onto a patient for purposes of measuring cardiac activity (QRST and other waveforms) during a scheduled medical examination. *Id.* at 41.

75. The Notice of Allowance for the '520 Application issued on September 6, 2013. *Id.* at 20. In the reasons for allowance, Examiner noted that "***the closest prior art, Tasto***, fails to disclose, suggest, and/or teach an ECG monitor that is configured for receiving and processing patient heart signals from a plurality of disposed connections" despite the Examiner's previous comment that "Tasto[] fails to disclose the claimed invention" and the Patent Owner's adamant argument that "[t]hough both Tasto and [Patent Owner's] monitor are used in connection with the medical field in general and furthermore are directed to a patient, there is almost nothing else similar in terms of a comparison between these references." *Id.* at 26, 40–41, 48.

76. The '520 Application issued as the '699 patent on January 14, 2014. Ex. 1001.

IX. SUMMARY OF PRIOR ART

A. Jensen

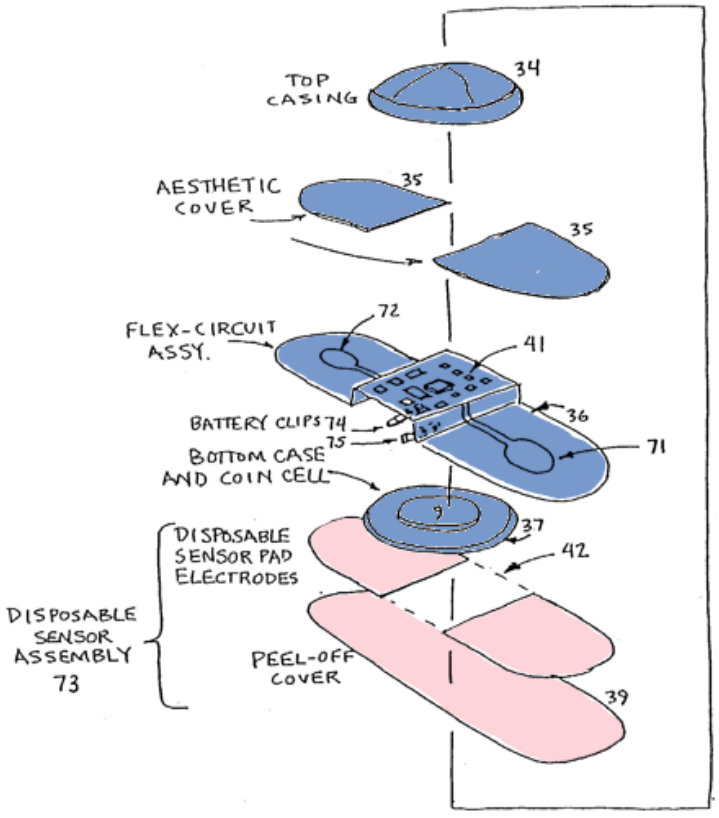
77. Jensen is a U.S. patent application that published on August 7, 2003, and which claims priority to a December 18, 2001, U.S. provisional patent

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 39

application. Ex. 1005. I understand that Jensen is prior art to the '699 patent pursuant to 35 U.S.C. § 102(a), (b), and (e).

78. Like the '699 patent, Jensen teaches a body-worn physiological monitor that collects and wirelessly transmits physiological data, such as ECG or heart rate signals. *Id.* at Abstract, [0014], [0029], [0032]–[0033].

79. The body-worn physiological monitor described in Jensen as a "smart patch" includes a "disposable sensor assembly" (73) and a "re-usable (non-disposable) portion" as shown by Figure 5 below. *Id.* at [0042]–[0043].



Id. at Fig. 5 (annotated) (disposable sensor assembly shown in red and the reusable portion shown in blue).

80. The disposable sensor assembly (73) includes: disposable sensor pad electrodes (1 and 2) which can be coated with a conductive adhesive gel, cover tape (39) used to protect the coated surface of the sensor pads, and connective material (42). *Id.* at [0042].

81. The reusable portion includes a flexible circuit assembly (36), a bottom and top casing (37 and 34, respectively), and two aesthetic covers (35). *Id.* at [0040], [0043].

82. The flexible circuit assembly (36) of the reusable portion contains copper wiring traces that connect the entire circuit (41) to the sensor contacts (71 and 72), as well as to a rechargeable power resource such as a Lithium coin cell (9). *Id.* at [0040]. The Lithium coin cell (9) is attached to the flexible circuit assembly (36) with two small nickel- or gold-plated steel clips (74 and 75). *Id.* at [0043]. Jensen also teaches that the "flexible circuit assembly" (36) includes resistors (24 and 25) and "programmable logic" for "perform[ing] measurement and processing of sensed data." *Id.* at [0014], [0032], [0040], Fig. 2.

83. Jensen also describes a variety of electrical components, such as processors, resistors, and transmitters. For example, Jensen describes that "[t]he resultant signal, at the output of driver 18, may either be input directly to transmitter 7, or may be input into microcontroller 10. Microcontroller 10 runs a conventional program that may perform further analysis and can also encode a data stream output

to the transmitter 7." *Id.* at [0032]. Microcontroller 10 can be used to process data using one or more signal processing algorithms. One signal processing algorithm titled "Beat Reporting" is when a "[m]icrocontroller simply sends transmission that tells of the occurrence of a beat." *Id.* at [0037]. "No data protocol [is] necessary," meaning that this is "[s]imply a transmission to say there was a beat." *Id.* Another signal processing algorithm is titled "Logged Event Reporting" in which the "[m]icrocontroller sends a packet periodically containing a log of all data points since last data transmission." *Id.* Using this algorithm the device can "[s]tore and forward handling yields system efficiencies." *Id.*

84. Jensen also describes that "transmitter 7 may transmit in a variety of modulation and/or keying methods via antenna 8, especially when used in conjunction with microcontroller 10." *Id.* at [0033]. The transmitter may be an "RF transmitter." *Id*.

85. In addition, Jensen teaches that the body-worn monitor may include a piezoelectric respiration sensor (81) with leads (86) that provide the electrical signal output. *Id.* at [0047].

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 42

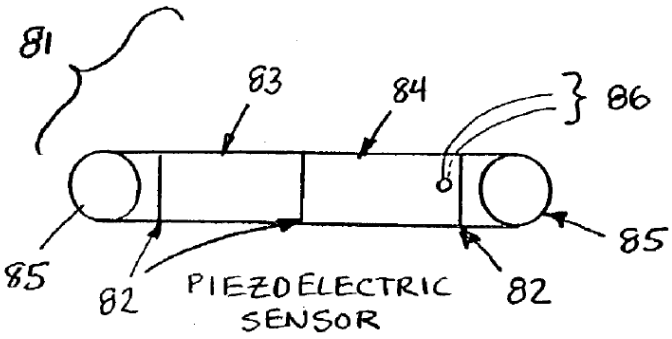


figure 9

Id. at Fig. 9. The sensor (81) is "constructed of insert type rivets or similar fasteners 85 that hold an elastic coupler 83 in tension with a Penwall Corp. Kynar TM piezoelectric strip 84." *Id.* at [0047]. These components of the piezoelectric respiration sensor (81) may be fastened with a suitable adhesive, such as, *e.g.*, epoxy or cyanoacrylate, at glue joints (82). *Id.*

B. Matsumura

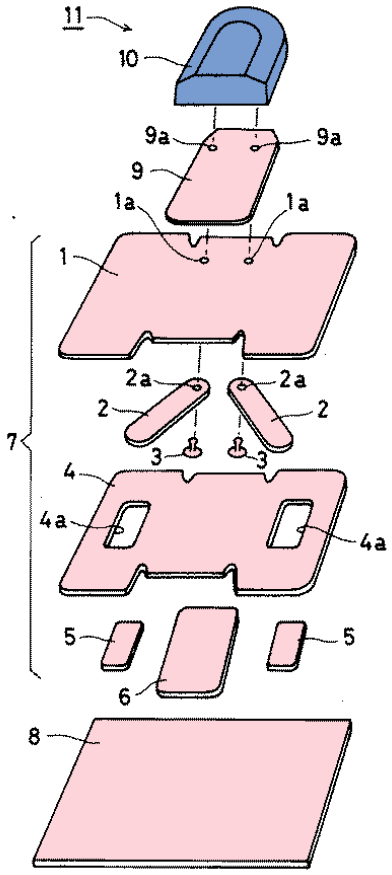
86. Japanese Patent Publication No. 2004-121360 to Matsumura ("Matsumura") (Ex. 1006) (filed September 30, 2002) is a Japanese patent application that published on April 22, 2004. I understand that Matsumura is prior art to the '699 patent pursuant to 35 U.S.C. § 102(a) and (b).

87. Like the '699 patent, Matsumura discloses a body-worn physiological monitor, which it describes as a "bioelectric potential detector having a waterproof structure." *Id.* at [0001]. The bioelectric potential detector described by Matsumura

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 43

"can be used as an electrocardiogram detector that is worn on the subject's chest to detect electrocardiogram signals." *Id.* at [0024].

88. Matsumura's bioelectric potential detector (11) includes two components: "a disposable bioelectrode pad for detecting bioelectric potentials, and a reusable signal processor for processing the bioelectric potential signals detected by the bioelectrode pad." *Id.* at [0007]. Figure 1 below indicates the disposable bioelectrode pad (7) (shown in red) and the reusable signal processor (10) (shown in blue):



Id. at Fig. 1 (annotated). The bioelectrode pad (7) and the signal processor (10) "can be easily attached and detached before and after use." *Id.* at [0016].

89. The disposable bioelectrode pad (7) includes: a first sheet (1), a conductive material (2), a hook (3), a second sheet (4), a conductive gel (5) a third sheet (6), double-sided adhesive tape (9), and a release sheet (8) which is removed before the bioelectric potential detector (11) is attached to the patient's skin. *Id.*

90. The first sheet (1) is made out of an insulating material and has an adhesive applied to the back of the sheet. *Id.* at [0017]. At the center of the first sheet (1) are two holes (1a) through which the protruding portions of the hooks (3) are inserted. *Id.* The second sheet (4) is also made out of an insulating material and has an adhesive applied to the back of the sheet. *Id.* at [0018]. The second sheet (4) has two openings (4a) "into which the conductive gel 5 is inserted." *Id.* An optional third sheet (6) may be used to cover the adhesive surface of the second sheet (4).

91. Two pieces of conductive material (2) and two hooks (3) are arranged between the first sheet (1) and the second sheet (4) "to transmit the bioelectric potentials detected by the conductive gel 5." *Id.* at [0019]. Both ends of the rod-shaped pieces of conductive material (2) have two holes (2a). *Id.* The protruding portions of the hook (3) are inserted into the holes (2a) at one end; the holes at the other end are "for contacting the conductive gel 5." *Id.* This configuration allows

the bioelectric potentials detected by the conductive gel (5) to be transmitted through the two pieces of conductive material (2) and the hooks (3). *Id.*

92. The disposable bioelectrode pad (7) also includes an insulating double-sided adhesive tape (9) which is used to fix the bioelectric pad (7) and the signal processor (1). *Id.* at [0024]. The tape (9) includes a hole (9a) through which the hook (3) can be inserted and a release sheet (9b) that is removed so that the reusable signal processor (10) can be attached to the disposable electrode pad (7). *Id.*

C. Kroll

93. U.S. Patent No. 4,763,660 to Kroll et al. is a United States patent that issued on August 16, 1988. Kroll was filed on March 13, 1987 as a continuation of an application filed December 10, 1985. I understand that Kroll is prior art to the '699 patent pursuant to 35 U.S.C. § 102(a), (b), and (e).

94. Kroll discloses a body-worn disposable and flexible electrode assembly like those found in the '699 patent, which it described as an "electrode belt" that is used to transfer "electrical signals between predetermined patient body locations and the medical therapeutic and diagnostic apparatus." Ex. 1007 at Abstract. The body-worn electrodes described by Kroll may be positioned in a way which would allow for the collection of ECG signals. *Id.* at 10:58–65 (claiming a device in which "contact areas conform with standard pre-cordial positions for 'twelve-lead' electrocardiographic devices"), 14:44–47 (claiming the selection of location of the

device so that its positioning "coincide[s] with standard precordial locations for 'twelve-lead' electrocardiographic applications").

95. The body-worn monitor disclosed by Kroll is described as a "flexible and disposable electrode belt" (20), which is shown below in Figure 4:

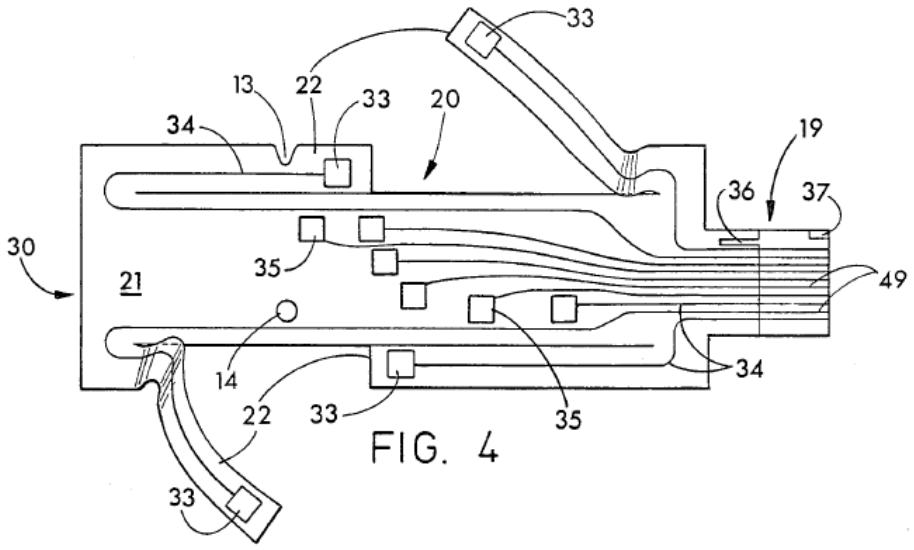


FIG. 4

Id. at Fig. 4. The main body (21) of Kroll's electrode belt has a proximal end (30) and a terminal end (19). *Id.* at 4:48–51. A notch (13) disposed on the top lateral edges of the device (20) or an aperture (14) are used to properly align the electrode belt on the patient's body. *Id.* at 4:52–58.

96. Both the main body (21) and the adjustable side members (22) of the electrode belt described by Kroll include electrodes (35 and 33, respectively). *Id.* at 4:51–52, 4:67–68. Both the main body electrodes (35) and side member electrodes

(33) "transmit and receive electric signals" from the lead strip (34). *Id.* at 5:1–4. Kroll also describes the following:

> The lead strips 34 and electrode portions, discussed below, are of a flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material. Preferably, the ink deposit is of a preselected conductivity to provide a certain total lead strip resistance so that each strip 34 serves as a current limiter to protect a patient from shock due to malfunction of the device 20 or of a complementary medical device.

Id. at 5:4–13; *see also id.* at Fig. 4.

97. As shown in Figure 5 below, Kroll teaches that lead strip 34 (current-limiting resistor) extends from and overlaps electrode 35 that includes a matrix 42 composed of a conductive ink compound. *Id.* at 5:17–19, 23–27. "The conductive ink compound used in the matrix lines 42 is ***generally*** the same as that utilized in the lead strips 34," meaning that Kroll discloses that matrix lines 42 and lead strips both can be or cannot be made of the same material. *Id.* at 5:31–33 (emphasis added). In my opinion, a POSA would have understood "lead strip" to be a strip of the conductive material, which is generally used to connect electronic components and circuit boards. *Id.* at 5:4–11 (teaching that the lead strips "are of a flexible conductive ink compound having a conductive filler having Silver, Aluminum, or compounds thereof, or of a similarly suitable material" and that "the ink deposit is of a preselected conductivity to provide a certain total lead strip resistance so that each strip [ ] serves as a current limiter").

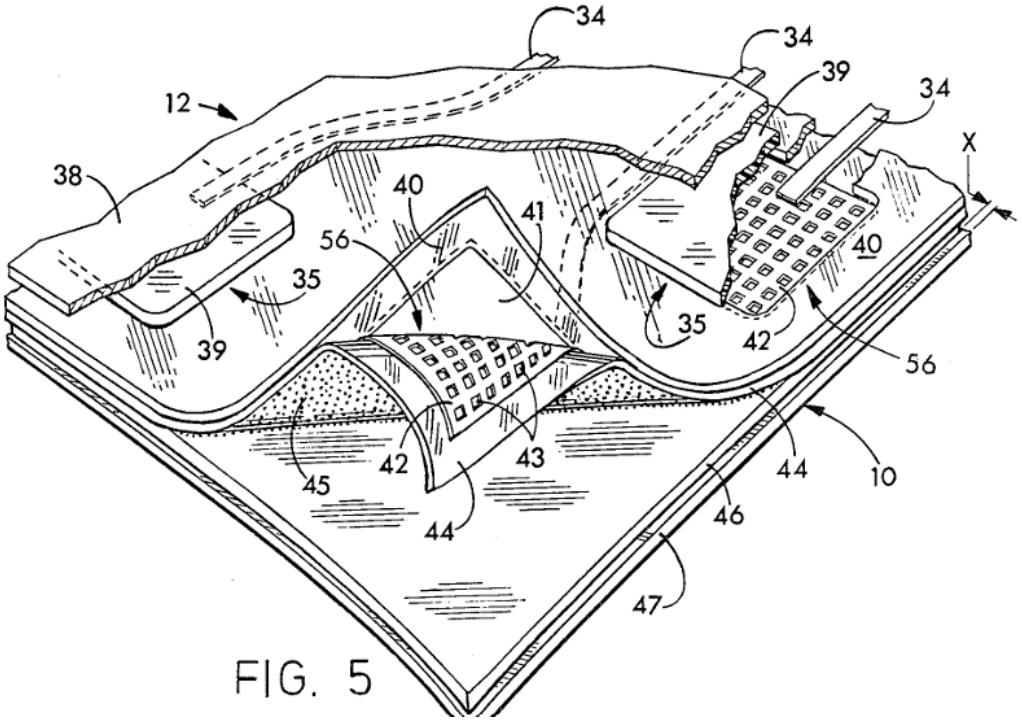


FIG. 5

Id. at Fig. 5. Kroll also teaches that lead strip 34 (current-limiting resistor) is lined with insulation and base support layer 44 and inner patient insulation layer 40. *Id.* at 5:44–50, Fig. 6. Both layers 44 and 40 are made of a polyester laminate which is the same material in the trademarked product Mylar. *Id.*

D. Khandpur

98. A textbook titled "Printed Circuit Boards: Design, Fabrication, Assembly and Testing" and written by Dr. R. S. Khandpur (Ex. 1008) was first published on October 12, 2005. I understand that Khandpur is prior art to the '699 patent pursuant to 35 U.S.C. § 102(a).

99. Khandpur discusses at great length considerations for the design and development process of PCBs. Khandpur teaches that there is generally a "transition

from flexible to rigid material" around the solder pads where conductive areas of components and traces are attached; this area is "highly prone to conductor breakage." *Id.* at 442, 642 (a component is "[a]ny of the basic parts used in building electronic equipment"), 656 (a pad is a "portion of the conductive area of which components, terminals, traces, etc., are mechanically attached"). Khandpur teaches that in order to decrease the chances of breakage, the "general shape of solder pads should be tear-like." *Id.* at 442–43.

E. Thompson

100. U.S. Patent No. 6,223,080 to Thompson ("Thompson") (Ex. 1009) (issued April 24, 2001) was filed on October 28, 1998. I understand that Thompson is prior art to the '699 patent pursuant to 35 U.S.C. § 102 (a), (b), and/or (e).

101. Thompson discloses "solutions to one or more problems existing in the prior art respecting circuitry design having lower power consumption, particularly with respect to implantable medical devices," such as pacemakers. *Id.* at 3:33–37. Specifically, Thompson's invention relates to "the use of multiple digital signal processors in [ ] circuit designs to reduce power consumption." *Id*. at 1:20–23.

102. Thompson discloses a processor that operates in a "high speed processing mode" "[o]nly during [the] QRS complex" of the cardiac cycle. *Id.* at 18:3–5. "During the remainder of the cardiac cycle the [waveform] processor" disclosed by Thompson "may be 'idling along' at a much lower clock frequency."

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 50

Id. at 18:5–7. Thompson notes that the idling of the processor during some interval of the heartbeat allows the supply voltage level to be reduced, meaning "the objective of reduced power consumption is realized." *Id*. at 18:13–14.

X. THE CHALLENGED CLAIMS OF THE '699 PATENT ARE UNPATENTABLE THE PRIOR ART

103. In my opinion, claims 1-4 of the '699 patent are obvious under pre-AIA § 103 over Jensen, Kroll, and the General Knowledge of a POSA.

104. In my opinion, claim 8 of the '699 patent is obvious under pre-AIA § 103 over Jensen, Kroll, Thompson, and the General Knowledge of a POSA.

105. It is my opinion that claims 1, 2, and 4 of the '699 patent are obvious under pre-AIA § 103 over Matsumura, Kroll, and the General Knowledge of a POSA.

106. It is my opinion that claim 3 of the '699 patent is obvious under pre-AIA § 103 over Matsumura, Kroll, Khandpur, and the General Knowledge of a POSA.

107. In my opinion, claim 8 of the '699 patent is obvious under pre-AIA § 103 over Matsumura, Kroll, Thompson, and the General Knowledge of a POSA.

A. Ground 1: Obvious Over Jensen, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art

1. A POSA would have been motivated to combine Jensen and Kroll

108. A POSA would have found it obvious to combine the devices and methods of Jensen with Kroll's teaching of "resistive traces" or "resistive leads."

109. Jensen and Kroll disclose flexible, body-worn devices used to collect and monitor a patient's physiological data, including ECG data. Ex. 1005 at Abstract, [0013]–[0014], [0029]–[0030]; Ex. 1007 at Abstract, 1:11–15, 1:37–45, 1:59–61, 2:41–47.

110. A POSA developing a flexible, body-worn device for monitoring ECG data at this time would have understood the benefits of limiting the current the device could transmit. *See* Section IV.D–E, *supra*. As discussed above, resistive materials which limit the current transmitted would function to limit current in either direction (*i.e.*, either towards or away from the patient's body) and thus would protect both the patient and the device, depending on the source of the excess electrical current. *See* Section IV.E, *supra*.

111. Kroll describes and teaches a solution to the known risk of electrical overload. Specifically, Kroll teaches incorporating electrical lead strips of a known resistivity to limit the current transmitted between the worn device and the patient, thereby preventing excess current from being transmitted between the device and

the patient. Ex. 1007 at 5:1–13. Although Kroll discusses this solution in the context of protecting a patient from electrical "shock" caused by the worn device or a "complementary medical device," a POSA would have understood that it would be advantageous to limit the current transmitted in *either* direction (either toward the body to protect the patient or away from the body to protect the device). *See* Sections IV.E–F, *supra*. Moreover, a POSA would have understood that using a resistive material to limit the current transmitted in one direction (*i.e.*, toward the body, protecting the patient) would also limit the current transmitted in the other direction (*i.e.*, toward the device, protecting the device) depending on the source of the excess current. *Id.* Thus, Kroll's resistive lead strips would protect both the patient and the sensitive electronics inside the device from shock, such as that caused by a defibrillator.

112. Accordingly, a POSA would have understood that the resistive lead strips or traces of Kroll would both (1) protect patients from shock and (2) protect the sensitive electronics inside the device from shock caused by a defibrillator. *See, e.g.*, Ex. 1034 at 1:19–27; *see also* Sections IV.C-E, *supra*.

113. These same considerations taught in Kroll apply to Jensen, which also discloses a wearable monitor; that is, driven by a desire to protect the electronics in the event of defibrillation, ensuring the long-term viability of Jensen's reusable module, and comply with industry standards requiring this very protection, a POSA

would have been motivated to incorporate Kroll's teaching of resistive "lead strips" into Jensen's device.

114. In addition, a POSA developing a flexible, body-worn device at this time would have sought to reduce the size of the device to increase the commercial and clinical viability of the device. *See* Section IV.B., *supra.* Reducing the size of the wearable devices serves two purposes: reduce the costs of monitors and improve their wearability. *See* Ex. 1040 (Bruce R. Bowman & Edward Schuck, "*Medical Instruments and Devices Used in the Home*," CRC Press LLC (2000)) at 87.2 ("Convenience for the user is also extremely important in encouraging use of a device. Applications that require devices to be portable must certainly be light enough to be carried.").

115. Jensen specifically expressed a desire for its device to be thin. Ex. 1005 at [0030] ("It is intended . . . that the present invention act as a totally self-contained sensor that is thin, being less than 6 or 7 mm in thickness, low in mass and may be applied to the skin much like a bandage, with self-adhesive pads and sensor materials on the skin-contact side of the invention."). Modifying Jensen to include Kroll's resistive lead strips formed with ink deposits (rather than the larger, conventional resistors on Jensen's circuit assembly) would further Jensen's stated goal of reducing the size of the device.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 54

116. Further, a POSA would have had a reasonable expectation of success in implementing Kroll's resistive leads on Jensen's device without undue experimentation. A POSA would have expected combining Kroll's teaching of resistive traces/leads with Jensen's device (to produce the intended current-limiting effect) to involve only a minimal modification of Jensen's design. Specifically, only a minimal modification—the addition of a resistive ink—would need to be added to the method and materials used to form electrical traces. It would have been conventional that Jensen would consider printed electronic inks for the amalgam, the insulators, the solder, the solder masking, or for the circuit markings typically found on printed circuits. *See, e.g.*, Ex. 1008 at 3 (noting screen printing had been used to "print[] silver paste conductors and graphite resistors" onto substrates since the end of World War II). Materials such as silver and carbon are typically printed because of cost and/or difficulty in patterning using methods like photolithography. *See id.* at 287 ("The [screen printing] technique is particularly adopted for low cost print and etch plated printed board"). Further, the flexible circuit assembly of Jensen's device would easily be adjusted for the disclosed resistance of Kroll's traces to ensure the traces produce the intended current-limiting effect. Kroll states that the stated resistance of approximately 1000 ohms "allows for signals transmission throughout the lead strip 34 and also ***provid[es] the above-mentioned current limiter qualities*** as is preferred for this invention." Ex. 1007 at 5:13–17 (emphasis added).

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 55

This modification would not only produce a functional device, but it would also further Jensen's stated goals. *See* Ex. 1008 at 2 (noting one advantage of using a printed circuit board is that "[t]he size of component assembly is reduced with a corresponding decrease in weight"). Nothing in the art suggests otherwise. Additionally, this change could be easily implemented using the conventionally known and widely used technique of screen-printing. *See* Section IV.C., *supra.*

2. Independent Claim 1

117. In my opinion, claim 1 of the '699 patent is rendered obvious by Jensen in combination with Kroll.

i. Preamble 1[pre]

118. The preamble of claim 1 recites "[a]n ECG monitor comprising."

119. In my opinion, to the extent that the preamble is limiting, both Jensen and Kroll disclose the preamble of claim 1 of the '699 patent.

120. Jensen discloses an ECG monitor. Ex. 1005 at [0012], [0029]. Kroll discloses an ECG electrode belt for use in EKG monitoring. Ex. 1007, 1:9–15, 1:59–61. As discussed above, the acronyms ECG and EKG are used interchangeably in the art to refer to an electrocardiogram. Ex. 1014 at 53 ("Th[e] device is variably referred to as an ECG or as an EKG, the latter based on the Greek term 'kardia' for heart. Many prefer EKG to ECG because it is less likely to be confused verbally with EEG, the abbreviation for electroencephalogram.").

121. Thus, in my opinion, both Jensen and Kroll disclose an ECG monitor as claimed by the ’699 patent.

ii. Limitation [1a]

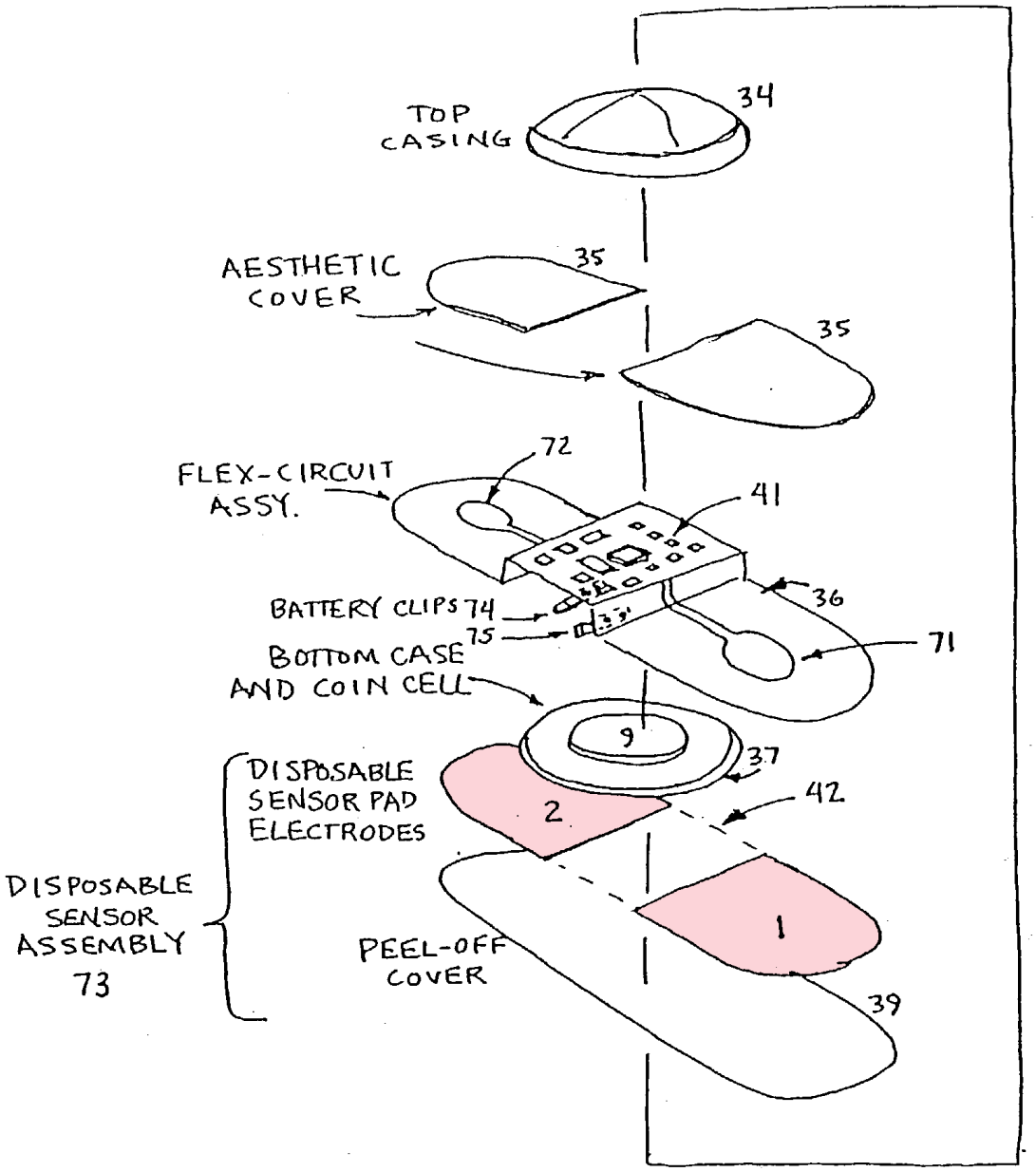
122. Limitation [1a] of the ’699 patent recites “a plurality of electrical connections including at least one electrode.”

123. In my opinion, Jensen discloses limitation [1a] of the ’699 patent.

124. Jensen teaches a “disposable sensor assembly” including “sensor pad electrodes” 1, 2 (shown below in red), also referred to as “sensor pads.” Ex. 1005 at [0041]–[0042]. Jensen further teaches that these disposable sensor electrodes are coated with a “conductive adhesive on the circuit side and a conductive adhesive-gel that is made using a silver amalgam as found in off-the-shelf EKG sensor pads.” *Id.* at [0041]. A silver amalgam, as being taught by Jensen, is a mixture of silver and some other material and, in the case of electrodes used in wearable devices and flexible circuits, is conventionally a screen printed layer of an ink or paste made of silver particles along with a binder material such as acrylic or vinyl that holds the silver particles together and to the substrate on which the amalgam is printed on. Ex. 1008 at 495 (“Composition of Solder Pastes”).

125. The disposable sensor pads form an electrical connection with sensor contacts 71, 72 of the flexible circuit assembly through the conductive adhesive on the circuit side; the disposable sensor pads form an electrical connection with the

skin of the patient through the conductive adhesive-gel on the other side. Ex. 1005 at [0041].



Id. at Fig. 5 (annotated).

126. Thus, in my opinion, a POSA would understand that Jensen's disposable sensor pads are "a plurality of electrical connections including at least one electrode."

iii. Limitation [1b]

127. Limitation [1b] of the '699 patent recites "the electrical connections being couplable to a skin surface to measure patient heartbeat signals."

128. In my opinion, Jensen discloses limitation [1b] of the '699 patent.

129. Jensen teaches a device that "may be applied to the skin much like a bandage, with self-adhesive pads and sensor materials on the skin-contact side of the invention." Ex. 1005 at [0030]. Jensen's device is "couplable to a skin surface" because the disposable sensor pad electrodes of Jensen's device are coated with conductive adhesive-gel. *Id.* at [0041]. Once applied to the patient's skin, "heart-rate signals are collected from left and right sensor [electrodes], 1 & 2." *Id.* at [0031]; *see also id.* at [0032] ("signals from the sensors 1 & 2" reach microcontroller 10 for processing and "further analysis"). Accordingly, a POSA would understand that Jensen's sensor pads, which are adhered to a patient's skin and are conductive, are couplable to a skin surface to measure patient heartbeat signals.

130. Thus, in my opinion, a POSA would understand that Jensen discloses "the electrical connections being couplable to a skin surface to measure patient heartbeat signals."

iv. Limitation [1c]

131. Limitation [1c] of the '699 patent recites "a power source."

132. In my opinion, Jensen discloses limitation [1c] of the '699 patent.

133. Jensen teaches a device that includes a "Lithium coin cell" or "a rechargeable type of power source, or a solar cell" which are both types of "power source[s]." Ex. 1005 at [0040], Fig 5; *id.* at [0014] ("device of the present invention contains all necessary electronic circuitry, including . . . a battery or other power source").

134. Thus, in my opinion, Jensen discloses "a power source."

v. Limitation [1d]

135. Limitation [1d] of the '699 patent recites "at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate."

136. In my opinion, Jensen discloses limitation [1d] of the '699 patent.

137. For the reasons discussed in Section X.A.1, *supra*, a POSA would have looked to combine the resistive (*i.e.*, current-limiting defibrillation protection) traces of Kroll with the ECG monitoring device of Jensen.

138. Jensen teaches a body-worn ECG monitor. Ex. 1005 at [0012], [0029]. As the '699 patent acknowledges, there were existing medical standards requiring that "a medical grade monitor survive multiple defibrillation cycles of at least 360 joules." Ex. 1001 at 1:61–63, 10:17–33; *see also* Section IV.D, *supra*. The device disclosed by Jensen—a medical monitoring device— would be expected to comply with this standard requirement for medical grade monitors. Accordingly, in my opinion, a POSA would understand that Jensen discloses "at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate."

139. Jensen teaches an ECG monitor comprising a substrate in the form of "flexible circuit assembly 36." Ex. 1005 at [0031]–[0033], [0040], [0043], Fig. 5. This substrate includes "copper wiring ***traces*** to connect the entire circuit 41 to the sensor contacts 71, 72 and, for example, Lithium coin cell 9." *Id.* at [0040] (emphasis added). Thus, in my opinion, a POSA would understand that Jensen discloses a substrate containing traces and that Jensen discloses "at least one current-limiting defibrillation protection resistor" as described above. *See* Section X.A.2.vi., *supra.*

140. Kroll teaches the use of "lead strips" which "transmit and receive electric signals to and from the terminal end [ ] of the belt." Ex. 1007 at 5:1–4. Kroll teaches that these "lead strips" are composed of a "flexible conductive ink compound

having a conductive filler" where the ink compound is of preselected conductivity. *Id.* at 5:4–6, 5:8–9. Kroll teaches that the "conductive filler" of the ink compound contains "Silver, Aluminum, or compounds thereof, or [is composed] of a similarly suitable material." *Id.* at 5:4–8. The "lead strips" are printed on an "insulation and base support layer" which is "preferably comprised of a thin . . . polyester laminate and serves as [ ] a base for the silk screened conductive ink used in the matrix lines 42 and lead strips 34." *Id.* at 5:37–42.

141. Kroll further teaches a current-limiting defibrillation protection resistor in the form "of a flexible conductive ink compound . . . of a preselected conductivity to provide a certain total lead strip resistance so that ***each strip*** [ ] ***serves as a current limiter*** to protect a patient from shock due to malfunction of the device [ ] or of a complementary medical device." *Id.* at 5:4–13 (emphasis added). Kroll discloses that the resistive lead strips are screen printed onto a substrate. *See id.* at 5:37–42 (the conductive ink forming the resistive lead strips is "silk ***screened***" onto a substrate (*i.e.*, "insulation and base support layer")) (emphasis added). Thus, in my opinion, a POSA would have understood that Kroll teaches a current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate.

142. In my opinion, it is obvious from Kroll's disclosure that the "lead strips" are created by screening the ink compound onto the device. Screen printing was a preferred method of manufacturing a circuit board at the time. *See, e.g.*, *id.* at

5:23–27, 5:31–33, 5:37–42. Screen printing is preferred because it allows a greater degree of control in printing and thus is cost-effective, which is important when expensive materials such as silver are being used. *See* Ex. 1008 at 296 ("Printing Process. The circuit patterns are screen printed on the substrate by two ways: (1) Manual screen printing process, and (2) Automatic or semi-automatic screen printing process."); *see also* Ex. 1007 at 5:23–42 ("Each electrode 35 has a conductive grid 56 which is comprised of a matrix of approximately 0.050 inch wide lines 42 of conductive ink compound applied to an insulation and base support layer 44 ***preferably by means of a silk screen process.***") (emphasis added); *see also* Ex. 1007 at 5:4–8.

143. A POSA would have easily combined Kroll's teaching of resistive traces which provide current-limiting defibrillation protection with Jensen's teaching of an EKG monitor by replacing the copper wiring traces disclosed by Jensen by screening the resistive ink traces taught by Kroll onto the flexible circuit disclosed by Jensen. This could be easily done using the well-known technique of screen printing. *See* Section IV.C.4, *supra.* This slight modification would result in "at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate." These teachings comport with Jensen's stated desire to create a low form-factor, body worn patient monitoring device. *See* Section X.A.1, *supra.* A POSA would immediately understand that Kroll's conductive "lead strips"

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 63

would function to limit current in *both* directions and not just toward the patient, thereby protecting both the device and its wearer. *See* Section IV.E., *supra.* Moreover, given the demonstrated industry-wide desire to reduce the size of monitoring devices, Kroll's current-limiting solution, which adds little to no extra size, would be preferred by a POSA when designing a body-worn monitoring device.

144. In my opinion, a POSA would have had a reasonable expectation of success in combining Kroll's teaching of resistive traces with Jensen's device because screening the "lead strips" taught by Kroll onto the "flexible circuit assembly" taught by Jensen would be a simple matter of replacing one known component, *i.e.*, the copper traces of Jensen's device, with another, *i.e.*, the conductive ink, which would be routine and predictable for a POSA. *See* Section X.A.1, *supra*.

145. Thus, in my opinion, Jensen and Kroll, in view of the knowledge of a POSA, disclose "at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate."

vi. Limitation [1e]

146. Limitation [1e] of the '699 patent recites "an ECG electronics module."

147. In my opinion, Jensen discloses limitation [1e] of the '699 patent.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 64

148. Jensen teaches "an ECG electronics module" that includes ECG electronics such as a "transmitter" for communication and a "microcontroller" for computation. Ex. 1005 at [0032]. The device disclosed by Jensen includes a microcontroller that "runs a conventional program that may perform further analysis and can also encode a data stream output to the transmitter" and may transmit encoded data messages via "antenna." *Id.* at [0032]–[0033]. The acronyms "ECG" and "EKG" are used interchangeably in the art to refer to an electrocardiogram. Ex. 1014 at 53.

149. Therefore, in my opinion, Jensen discloses the claimed "ECG electronics module."

vii. Limitation [1f]

150. Limitation [1f] of the '699 patent recites "the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections."

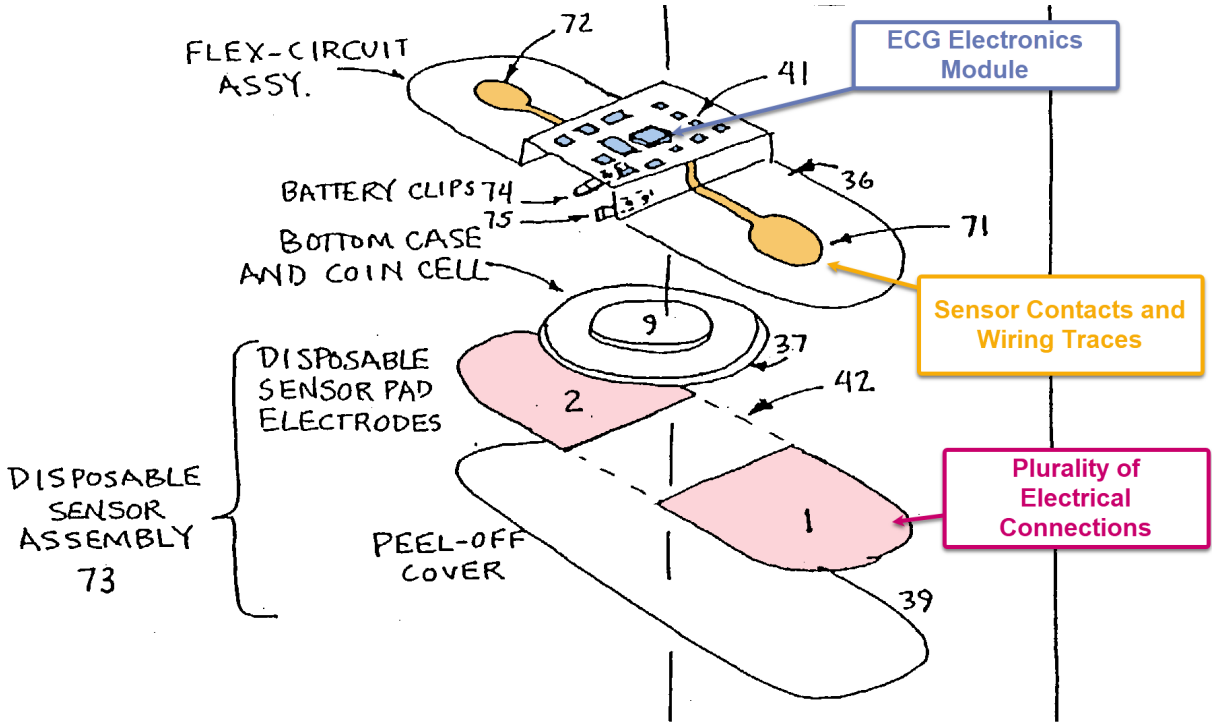
151. In my opinion, Jensen discloses limitation [1f] of the '699 patent.

152. Jensen teaches an ECG electronics module that includes a "transmitter," used for communication, and a "microcontroller," used for computation. Jensen further teaches that the transmitter and microcontroller are part of the "electronic circuit" of Jensen's body-worn physiological sensor. Ex. 1005 at [0036], Fig. 3. The electronic circuit disclosed by Jensen is part of a

"flexible circuit assembly" containing copper wiring to connect the entire circuit to the "sensor contacts 71, 72" and the power source. *Id.* at [0040].

153. As previously discussed, Jensen's plurality of electrical connections includes at least one electrode in the form of "sensor pad electrodes" (or "disposable sensor pads") 1, 2. *Id.* at [0041]; *see* Section X.A.2.ii., *supra*.

154. Heartbeat signals are transmitted from the patient's skin to the conductive adhesive gel on the skin side of sensor pads 1, 2; then through the conductive adhesive on the circuit side of sensor pads 1, 2 to the sensor contacts 71, 72; then through the wiring traces to the "electronics circuit" (*i.e.*, the claimed ECG electronics module). *Id.* at [0039]–[0040], Fig. 5. Jensen teaches that its ECG electronics module further processes the heartbeat signals before transmission: the signal from the heart rate sensor is subject to amplification, bandpass filtering, signal extraction, and signal biasing. Ex. 1005 at [0032]–[0033], [0036]–[0038].



Id. at Fig. 5 (annotated).

155. Thus, in my opinion, Jensen discloses "the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections."

viii. Limitation [1g]

156. Limitation [1g] of the '699 patent recites "wherein the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module."

157. In my opinion, Jensen discloses limitation [1g] of the '699 patent.

158. For the reasons discussed in Section X.A.1, *supra*, a POSA would have looked to combine the resistive (*i.e.*, current-limiting defibrillation protection) traces of Kroll with the ECG monitoring device of Jensen.

159. Because Jensen teaches that "copper wiring traces" ***connect*** the "entire circuit 41," including the ECG electronics module, "to the sensor contacts 71, 72", which make contact with the plurality of electrical connections, Jensen's "copper wiring traces" are disposed between at least one of the plurality of electrical connections and the ECG electronics module. Ex. 1005 at [0040], Fig. 5.

160. As discussed in Section X.A.2.v. *supra*, it would have been obvious to a POSA to incorporate Kroll's teaching of screened current-limiting defibrillation protection traces onto the flexible circuit assembly 36 of Jensen. It would be obvious to place Kroll's resistive traces over, or alternatively in place of, the copper wiring traces disclosed by Jensen. Thus, the modified traces would be disposed between at least one of the plurality of electrical connections (*i.e.*, the ECG electrode) and the ECG electronics module.

161. It is also my opinion that a POSA would recognize that the goal of including a defibrillation protection resistor within a wearable ECG device was to protect the electronics in the device from the potentially destructive flow of current associated with defibrillation. *See* Sections IV.D-E, *supra*. In order to accomplish this goal, a POSA would understand that the defibrillation protection resistor would

need to be placed between where the device would be exposed to defibrillation (*i.e.*, the ECG electrode that contacts the patient's skin) and the ECG electronics module that the resistor is intended to protect.

162. Thus, in my opinion, the combination of Jensen and Kroll discloses that the "at least one current-limiting defibrillation protection resistor is electrically disposed between the at least one of the plurality of electrical connections and the ECG electronics module," as claimed by the '699 patent.

3. Dependent Claim 2

163. Claim 2 of the '699 patent depends directly from claim 1 and additionally requires that "the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate."

164. In my opinion, claim 2 of the '699 patent is rendered obvious by Jensen and Kroll in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Jensen and Kroll teach the additional limitation of claim 2. *See* Section X.A.2, *supra*.

165. For all the reasons explained above, a POSA would have been motivated to combine the ECG monitor of Jensen with Kroll's teaching of current-limiting defibrillation protection resistors screened onto a substrate. *See* Section X.A.2.v., *supra*.

166. Jensen discloses flexible substrates. Jensen's "copper wiring traces," which a POSA would have modified with the resistive, printed-ink traces disclosed by Kroll, are disposed on "flexible circuit assembly 36." Ex. 1005 at [0040].

167. Kroll also discloses a flexible substrate. *See, e.g.*, Ex. 1007 at 4:22–24 (discussing a "**flexible** and disposable electrode belt" onto which the ink for the resistive lead strips is "silk screened"); *see also id.* at 4:36–37, 4:48-51, 5: 37–42.

168. Therefore, Jensen discloses "the plurality of electrical connections to the body compris[ing] at least one of direct electrical connections to the body and indirect electrical connections to the body" and thus that the combination of Jensen and Kroll renders obvious claim 2 of the '699 patent.

4. Dependent Claim 3

169. Claim 3 of the '699 patent depends from claim 1 and further requires that "a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a filleted edge."

170. In my opinion, claim 3 of the '699 patent is rendered obvious by the combination of Jensen and Kroll in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because a POSA would understand that Jensen teaches the additional limitation of claim 3. *See* Section X.A.2, *supra.*

171. For all the reasons discussed above with respect to claim 1, a POSA would have been motivated to modify Jensen's ECG monitor with the teaching of Kroll to include a series current-limiting, defibrillation protection resistor in the form of resistive traces, substituting Kroll's resistive ink traces in place of the "copper wiring traces" disclosed by Jensen. *See* Sections X.A.2.i-viii, *supra*.

172. The '699 patent explains:

> According to one solution to the above noted arcing problem, as shown in FIG. 4B, ***a rounded (fillet) section 430 of carbon trace*** can be added at the interface to conductive surface 404. ***A fillet or "tear drop" shape causes the carbon trace to become gradually wider*** as it connects to conductive surface 404 and relieves the electrical potential stress at the interface.

Ex. 1001 at 8:49–55 (emphases added).

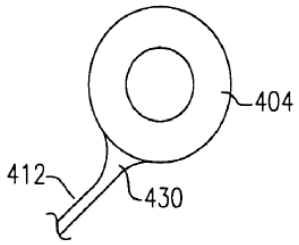


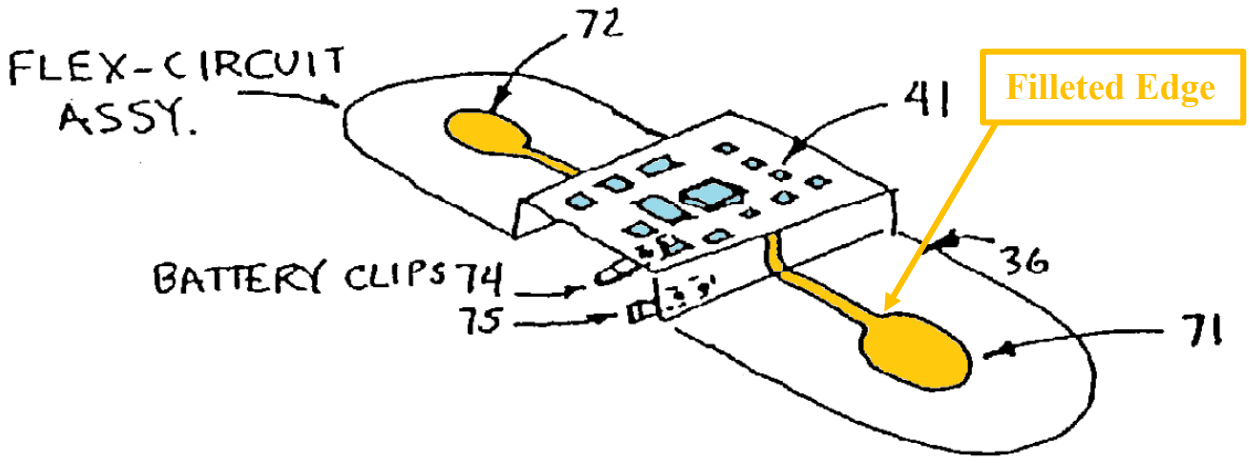
FIG.4B

Id. at Fig. 4B.

173. Because the circuitry/traces of a device mechanically connect "the at least one series current-limiting resistor" and "the EGG electrode," the "mechanical interface" is the circuitry/trace of Jensen's device and the "filleted edge" is the "tear

drop shape" taught by Jensen. Both of these understandings are in line with the disclosure of the '699 patent.

174. Jensen discloses a device comprising a "flexible circuit assembly" which includes "copper wiring traces to connect the entire circuit 41 to the sensor contacts 71, 72" as well as other components. Ex. 1005 at [0040], Fig. 5. In my opinion, a POSA would understand that the traces disclosed by Jensen gradually get wider to mechanically connect to the filleted sensor contacts at least, because, where the end of the trace is connected to the filleted sensor contact 71, the trace is wider than where the trace is connected to circuit 41. This is illustrated in Figure 5 of Jensen:



Id. at Fig. 5 (annotated). Furthermore, it is my opinion that a POSA would recognize that the traces would eventually get wider to mechanically connect to the filleted sensor contact 71, 72, because this was considered a best practice from the perspective of electrical and mechanical reliability at the time of the invention of the

'699 patent. *See, e.g.*, Ex. 1008 at 195 (using the terms "fillet" and "teardrop" synonymously); *id.* at 442–43 (stating that "[t]he general shape of solder pads should be tear-like); *see also id.* at 195, Fig. 5.1(b) (annotated version shown below):

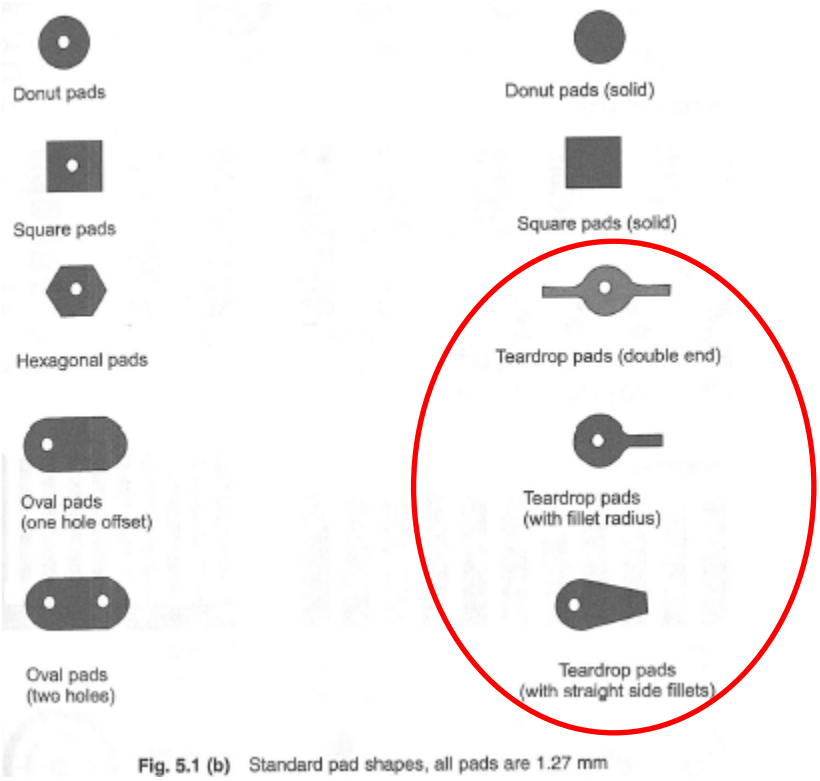


Fig. 5.1 (b) Standard pad shapes, all pads are 1.27 mm

In my opinion, a POSA would choose the teardrop shape when constructing a PCB whenever possible because it increases the surface area for contact, thereby increasing the reliability/performance of the printed circuit board. *Id.*

175. For these reasons, it is my opinion that a POSA would understand that Jensen, modified as discussed above with respect to claim 1, renders obvious "the body worn patient monitoring device compris[ing] an ECG monitor and at least two of the electrical connections are ECG electrodes" and, therefore, that the combination of Jensen and Kroll renders obvious claim 3 of the '699 patent.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 73

5. Dependent Claim 4

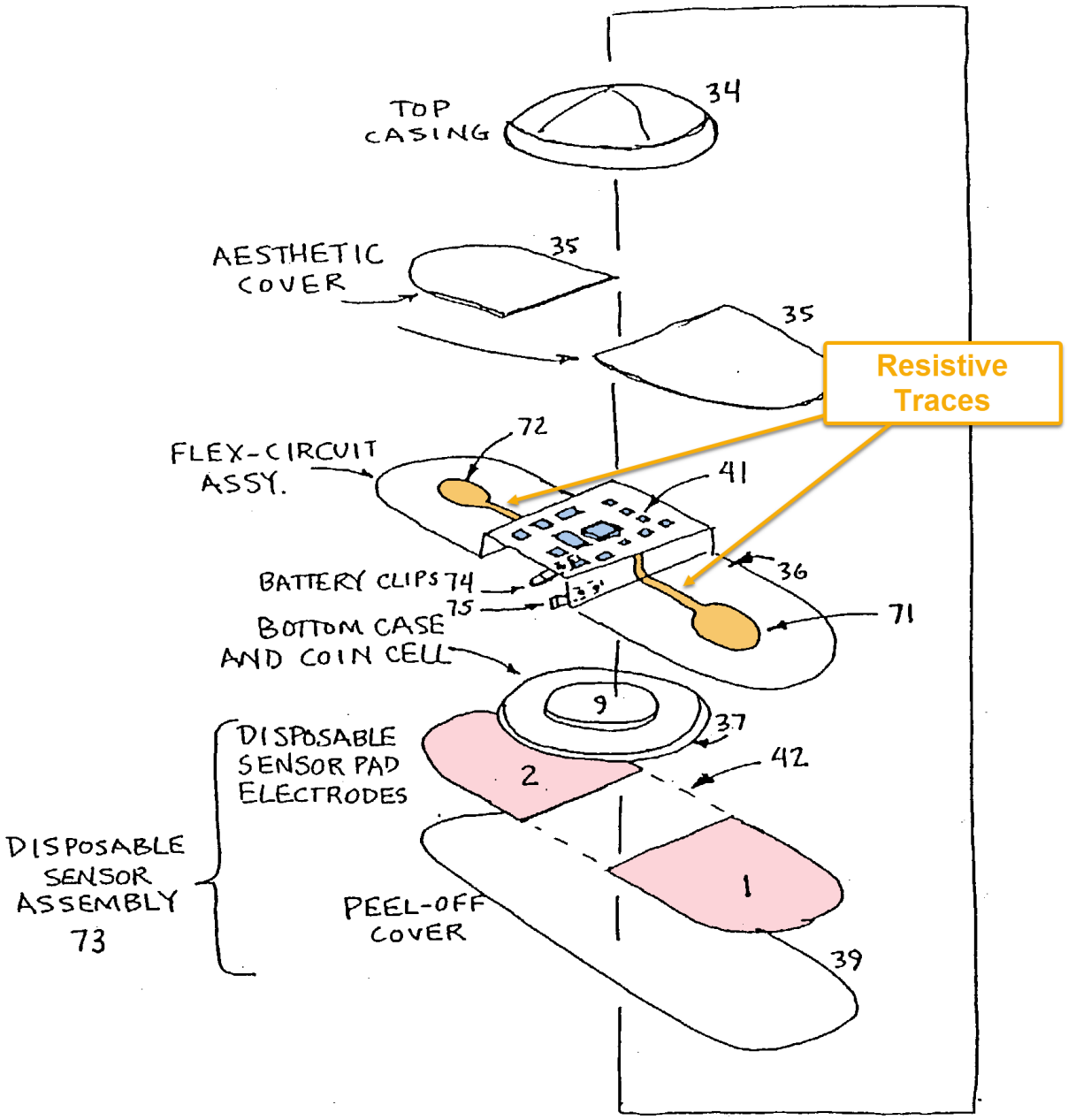
176. Claim 4 of the '699 patent depends from claim 1 and additionally requires that "a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a plurality of overlapped layers."

177. In my opinion, claim 4 of the '699 patent is rendered obvious by the combination of Jensen and Kroll in view of the knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because the combination of Jensen and Kroll renders obvious the additional limitation of claim 4. *See* Section X.A.2, *supra*.

178. As previously discussed, a POSA would have been motivated to modify Jensen's ECG monitor with Kroll's series current-limiting, defibrillation protection resistor in the form of resistive traces by substituting Kroll's resistive ink traces in place of the "copper wiring traces" disclosed by Jensen. *See* Sections X.A.2.i-viii, *supra.* So modified, Jensen's device includes a "mechanical interface" between the series current-limiting resistor and the ECG electrode. Specifically, Jensen's sensor contacts 71, 72 (part of the resistive traces that would be screened onto the surface of Jensen's circuit assembly) form a mechanical interface with sensor pads 1, 2, which as explained above, are the claimed ECG electrodes. *See* Section X.A.3, *supra.*

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 74

179. The mechanical interface of the modified Jensen device comprises a "plurality of overlapping layers." As Figure 5 below illustrates, Jensen discloses electrodes (in the form of sensor pads 1, 2), which form one layer, and a flexible substrate 36, which contains the series current-limiting defibrillation protection resistor (traces) and forms another layer. Ex. 1005 at [0040]–[0041], Fig. 5. In my opinion, a POSA would understand that for "sensor contacts 71, 72" to "make electrical contact with sensor pads 1 and 2," the two layers would necessarily be overlapping. *See, e.g.*, Ex. 1001 at 8:35–38 ("[t]here can be a short overlay distance, on the order of 5 to 10 mm, in which a silver trace ***overlaps*** the carbon ***trace to provide a more robust connection*** between the resistive and conductive portions of the traces") (emphases added).



Ex. 1005 at Fig. 5 (annotated).

180. A POSA would have been motivated to implement Kroll's resistive traces on Jensen's device, *see* Section X.A.1, and it would have been obvious to a POSA to implement the resistive traces in a way which defined a mechanical

interface between them and the electrodes, thereby forming a plurality of overlapping layers. For example, Kroll specifically contemplates such an arrangement; it discloses that the mechanical interface between its current-limiting defibrillation protection resistors (lead strips) and its electrodes comprises a plurality of overlapping layers. Ex. 1007 at 5:17–21, 5:37–42, Fig. 5. This is shown by annotated Figure 5 below, which illustrates that Kroll's lead strips 34 (in blue) are screened onto the flexible substrate, overlapping the electrodes 35 (in green). A POSA would implement these resistive lead strips in the same way—overlapping the electrodes— in Jensen's device, as would be standard using the screen-printing technique. *See* Section IV.C.4, *supra.*

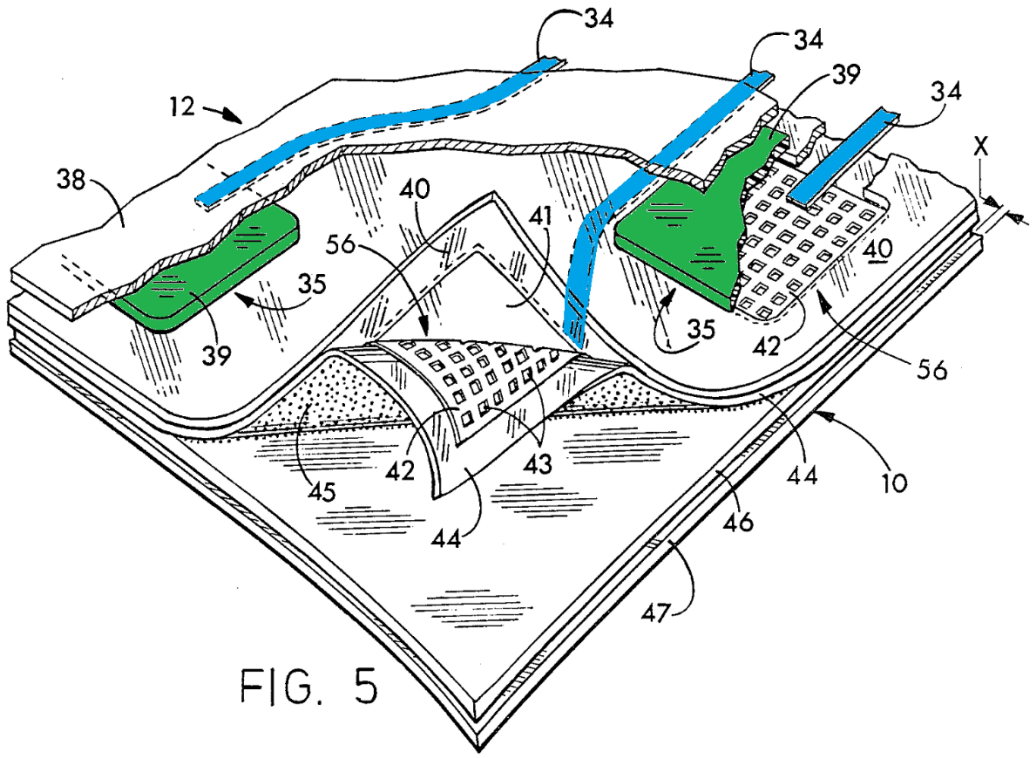


FIG. 5

Ex. 1007 at Fig. 5 (annotated).

181. For these reasons, it is my opinion that a POSA would understand that Jensen, modified as discussed with respect to claim 1, renders obvious "ECG electrodes compris[ing] a material screened onto the flexible substrate" and, therefore, that the combination of Jensen and Kroll renders obvious claim 4 of the '699 patent.

B. Ground 2: Obvious Over Jensen in view of Kroll, Thompson, and General Knowledge of a POSA

1. A POSA would have combined Jensen, Kroll, and Thompson

182. For the same reasons as discussed above, a POSA would have been motivated to combine Kroll's teaching of resistive traces with Jensen's device. *See* Section X.A.1, *supra.* Furthermore, for the same reasons as discussed above, a POSA would have had a reasonable expectation of success in combining Kroll's teaching of resistive traces with Jensen's device. *Id.*

183. In my opinion, a POSA would have also looked to incorporate Thompson's teaching of a periodic low power mode based on the electrical signals of a heartbeat with Jensen's device. The utility of a battery-powered, wearable device is limited by its battery-life and the size and composition of the battery is limited by the dimensional requirements of a body-worn physiological monitor. Therefore, in my opinion, a POSA would seek to optimize power consumption as a means of prolonging the battery life of the device and extending the period for which the device can collect data. In fact, a "low power mode" was already built into many

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 78

microchips before Nov. 1, 2006, including the PIC12C508 taught by Jensen. Ex. 1005 at Fig. 2 (element 10); Ex. 1045 (Jameco Electronics, *8-Pin, 8-Bt CMOS Microcontrollers Data Sheet*, https://web.archive.org/web/20031126132956/http://www.jameco.com/Jameco/Products/ProdDS/200475.pdf (available as of Nov. 26, 2003)).

184. Jensen presents one of the possible solutions for optimizing power consumption of the device by limiting the depletion of the battery: using a "switched supply voltage driver 29" so that "power from the system power source 9 is conserved whenever the sensors 1, 2 are not in contact with the user's skin." Ex. 1005 at [0031]. In addition to Jensen's solution, however, there were many other techniques for optimizing battery life of which a POSA would have been aware, including the use of a periodic low power mode. *See, e.g.*, U.S. Patent Publication No. 2003/0055460 ("Owen") (Ex. 1041) (filed May 31, 2002) at [0019] ("By having the processor operate in a low-power consumption mode, the invention reduces the amount of power consumed by the defibrillator. As a result, a power supply will last longer in the defibrillator of the present invention than in its conventional counterparts.").

185. In my opinion, a POSA would by default always consider, and where feasible adapt, additional power conservation solutions that would conserve power while the device was operational. Such solutions would allow battery usage to be

even more efficient, thereby allowing for a reduction in the overall size of the batteries—and thus the size of the devices—as desired by the industry. *See* Section IV.B., *supra.*

186. Thompson discloses an approach to power conservation by limiting processing time to certain portions of the heartbeat waveform. In one embodiment, Thompson discloses that "[o]nly during a QRS complex, for example, does waveform analysis processor 520 operate in a high speed processing mode at a relatively high frequency. During the remainder of the cardiac cycle [*i.e.*, during the TP interval] the DSP processor 520 may be 'idling along' at a much lower clock frequency. . . . In addition to the lower clock speed utilized for different portions of the cardiac cycle, one skilled in the art will recognize that in accordance with the other aspects of the present invention, as the speed is reduced, the supply voltage level (V_{DD}) may also be reduced accordingly. Thus, the objective of reduced power consumption is realized." Ex. 1009 at 18:3–14.

187. In my opinion, a POSA would have had a reasonable expectation of success in implementing Thompson's low power mode on Jensen's device without undue experimentation. It would only require reprogramming of onboard firmware and/or software to do so. Therefore, it is my opinion that a POSA would know how to combine Thompson's low power mode with Jensen's design with little to no

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 80

design impact. Further, there is nothing in the art to suggest that this modification would not work.

2. Dependent Claim 8

188. Claim 8 of the '699 patent depends from claim 1 and additionally requires that "the ECG electronics module includes a microprocessor to process the heartbeat signals, wherein an algorithm running on the microprocessor causes the ECG monitor to enter a low power mode that disables at least one circuit of the ECG electronics module, from the end of a 'T wave' at the end of one heartbeat to the beginning of a 'P wave' at the beginning of the next heartbeat, in order to reduce said electrical load on the power source."

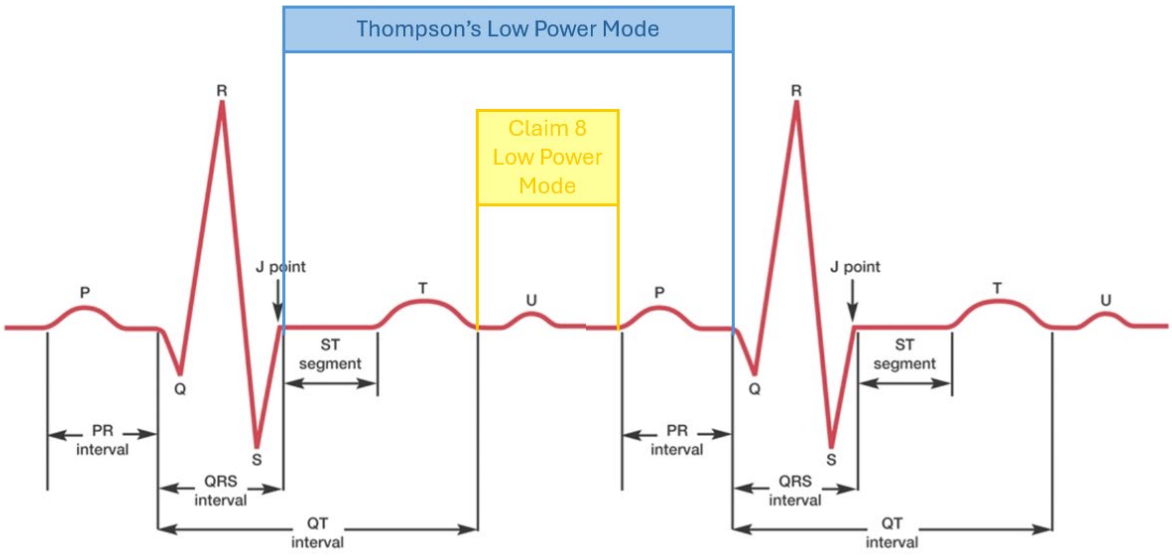
189. In my opinion, claim 8 of the '699 patent is rendered obvious by Jensen in combination with Kroll and Thompson for all the reasons discussed above with respect to claim 1 as well as because each of Jensen and Thompson teaches the additional limitation of claim 8. *See* Section X.A.2, *supra.*

190. Jensen teaches a microprocessor to process heartbeat signals and a "microcontroller" for computation. Ex. 1005 at [0032]. "The microcontroller has the capability of performing [ ] programmatic signal analysis to create and transmit different data records" such as beat reporting, logged event reporting, beat to beat internal, and rolling heart rate average. *Id.* at [0037], Table 1. Because Jensen's microcontroller is designed to and capable of "performing conventional and

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 81

programmatic signal analysis" Jensen discloses "a microprocessor to process heartbeat signals."

191. The device discloses by Thompson conserves power by operating in a low power mode from the end of one S-wave of the patient's heartbeat until the commencement of the next Q-wave. *See* Ex. 1009 at 18:3–14. In my opinion, a POSA would understand that Thompson's low power mode (which spans the broader period "from the end of an S-wave to the next Q-wave) includes the narrower period from the end of a 'T wave' at the end of one heartbeat to the beginning of a 'P wave' at the beginning of the next heartbeat," as shown by the annotated figure below.



192. Furthermore, it is my opinion that a POSA would recognize that this low power mode could be implemented on Jensen's microprocessor for all the reasons discussed above in Section X.B.1, *supra.*

193. For these reasons, it is my opinion that a POSA would understand that Jensen, Kroll, and Thompson render obvious claim 8 of the '699 patent.

C. Ground 3: Obvious Over Matsumura, Kroll, and General Knowledge of a Person of Ordinary Skill in the Art

1. A POSA would have been motivated to combine Matsumura and Kroll

194. In my opinion, a POSA would have found it obvious to combine the devices and methods of Matsumura and Kroll.

195. Matsumura and Kroll both disclose body-worn devices used to collect and monitor a patient's physiological data, including specifically EKG data. Ex. 1006 at [0024], [0031], Fig. 2; Ex. 1007 at Abstract, 1:11–15, 1:37–45, 1:60. Kroll explicitly teaches that its disclosed device is "flexible." Ex. 1007 at 4:27–30 (describing the "***flexible*** and disposable electrode belt 10 [ ] used to receive and transmit an electric current or voltage from and to the body of a patient") (emphasis added). In my opinion, a POSA would understand that Matsumura's "bioelectrode pad" is flexible. Matsumura teaches that its "bioelectrode pad" is preferably composed of sheets made from "polyethylene foam, polyurethane foam, or polyurethane sheet," which are all materials that a POSA would recognize as

"flexible." Ex. 1006 at [0017]. Indeed, the use of flexible polyethylene and polyurethane to create flexible, wearable medical devices was well known in the art at the time of the purported invention. *See, e.g.*, Ex. 1042 (Patrick J. Nolan, *Sterile Medical Device Package Development*, Standard Handbook of Biomedical Eng'g & Design (2004)) at 23.11; Ex. 1043 (Tilak Shah, *Polyurethane Thin-Film Welding for Medical Device Applications*, Med. Device and Diagnostic Indus. (2002)) at 2.

196. Matsumura teaches a "bioelectric potential detector," which is "worn on the subject's chest to detect electrocardiogram signals," Exhibit 1006 at [0024], and which "determines whether the detected electrocardiogram of the subject (patient) is abnormal, such as an arrhythmia or an abnormal heart rate," *id.* at [0037]. Accordingly, Matsumura discloses a medical-grade, body worn ECG monitor, which a POSA would understand would need to meet the existing applicable medical standards, such as the ability to "survive multiple defibrillation cycles of at least 360 joules," a requirement which was specifically acknowledged by the '699 patent. Ex. 1001 at 1:61–63; *see also id.* at 10:17–33. Specifically, Matsumura's device "wirelessly transmits the bioelectric potential detected . . . to inform medical staff or family members of the bioelectric potential information, so that they can quickly treat and cope with a sudden change in condition." Ex. 1006 at [0041].

197. In my opinion, a POSA developing a flexible, body-worn device for monitoring ECG data at this time—such as the device disclosed in Matsumura—

would have sought to incorporate the "resistive trace" of Kroll for at least two reasons.

198. A POSA would recognize that Kroll's teaching of a solution to electrical overload would be beneficial for Matsumura's device. Specifically, Kroll discloses using electrical lead strips of a known resistivity to limit the current transmitted between the worn device and the patient. Ex. 1007 at 5:1–13. Kroll discusses the use of the lead strips in the context of protecting a patient from "shock," from the worn device or "a complementary medical device." *Id.* In my opinion, a POSA would have understood that it would be beneficial to limit the current transmitted in either direction (whether towards or away from the patient's body). Ex. 1054 at Section A.3.2.14 (stating "[t]he intent of the ac overload specification is to verify that the ECG device will not be permanently damaged if a large input signal is accidentally applied" as well as that "[d]efibrillator overload protection is necessary for most ECG devices, since in the hospital environment any given ECG device might be used on patients potentially requiring defibrillation"). Kroll's resistive lead strips would help to (i) protect the patient from shock due to electricity from the device, and (ii) protect the sensitive electronics inside the device from shock due to electricity outside of the device, such as that caused by a defibrillator.

199. Matsumura's device is a "bioelectric potential detector 11," which can "be used as an electrocardiogram detector that is worn on the subject's chest to detect

electrocardiogram signals," Exhibit 1006 at [0024], and which "determines whether the detected electrocardiogram of the subject (patient) is abnormal, such as an arrhythmia or an abnormal heart rate," *id.* at [0037]. As acknowledged by the '699 patent, it was required by existing medical standards at the time that "a medical grade monitor survive multiple defibrillation cycles of at least 360 joules." Ex. 1001, 1:61–63; *id.* 10:17–33. Thus, in my opinion, a POSA would have been motivated to incorporate Kroll's teaching of resistive "lead strips" with the body-worn monitoring device disclosed by Matsumura in order to include features that would allow the device to survive multiple defibrillation cycles.

200. Matsumura also explicitly states that that the system "wirelessly transmits the bioelectric potential detected . . . to inform medical staff or family members of the bioelectric potential information, so that they can quickly treat and cope with a sudden change in condition . . ." Ex. 1006 at [0041]. In my opinion, a POSA would recognize that one such treatment for a sudden change in condition is defibrillation, which involves the application of high voltage electrical current to the patient's body. A POSA would know that Kroll's resistive strips would help to protect the sensitive electronics contained in Matsumura's signal processor from the high voltage in the event of a defibrillation. Further, a POSA would have known that Kroll's resistive lead strips would lead to the additional benefits of helping protect patients from potential shock from the monitor itself and reducing the size of

Matsumura's device. Thus, in my opinion, a POSA would have been motivated to incorporate Kroll's teaching of resistive "lead strips" to the circuitry in Matsumura.

201. Further, it is my opinion that a POSA would have had a reasonable expectation of success in combining the teachings of Matsumura and Kroll because doing so would involve using the screen-printing technique which was well-known for printed circuit board manufacture. *See* Section IV.C, *supra.* In fact, Matsumura already discloses a "PET sheet coated with conductive Ag/AgCl" and to adapt Matsumura to Kroll would only require changing the ink printed onto the PET from Ag/AgCl ink to conventional and widely-available carbon inks. Ex. 1006, at [0020]. At the time of invention of the '699 patent, printing ink—such as disclosed by Kroll—onto a circuit board was well known. *See* Ex. 1008 at 296 ("Printing Process. The circuit patterns are screen printed on the substrate by two ways: (1) Manual screen printing process, and (2) Automatic or semi-automatic screen printing process."); *see also* Section IV.C, *supra*. Specifically, it was also known that screen printing was well-suited to printing circuits on *flexible substrates*, and had long been used to do so. *See, e.g.*, Ex. 1007 at 9:36–48 (Kroll, claiming a conduction network printed onto a flexible non-conductive base layer); Ex. 1029 at cl. 26 ("sensor module comprises a flexible thin sheet of silicon comprising circuitry for collecting physiological data, a flexible power source and a flexible substrate"). Nothing in the art suggests that this modification would not work, as screen printing was a

standard way to manufacture many types of printed circuit boards. Further, this modification would not be difficult to implement using well-known manufacturing techniques because, as discussed above, screen-printing of printed circuit boards was well-known.

2. Independent Claim 1

202. In my opinion, claim 1 of the ’699 patent is rendered obvious by Matsumura and Kroll in view of the knowledge of a POSA.

i. Preamble 1[pre]

203. The preamble of claim 1 recites “[a]n ECG monitor comprising.”

204. In my opinion, to the extent that the preamble is limiting, Matsumura discloses the preamble of claim 1 of the ’699 patent.

205. Matsumura teaches a body-worn patient monitoring device described as a “bioelectric potential detector.” Ex. 1006 at Abstract, [0006], [0014]. The device described by Matsumura receives and processes electrocardiogram (ECG) data. *Id.* at [0033]. Kroll teaches an ECG electrode belt for use in ECG monitoring. Ex. 1007 at 1:9–15, 1:59–61.

206. Thus, in my opinion, Matsumura and Kroll disclose “[a]n ECG monitor.”

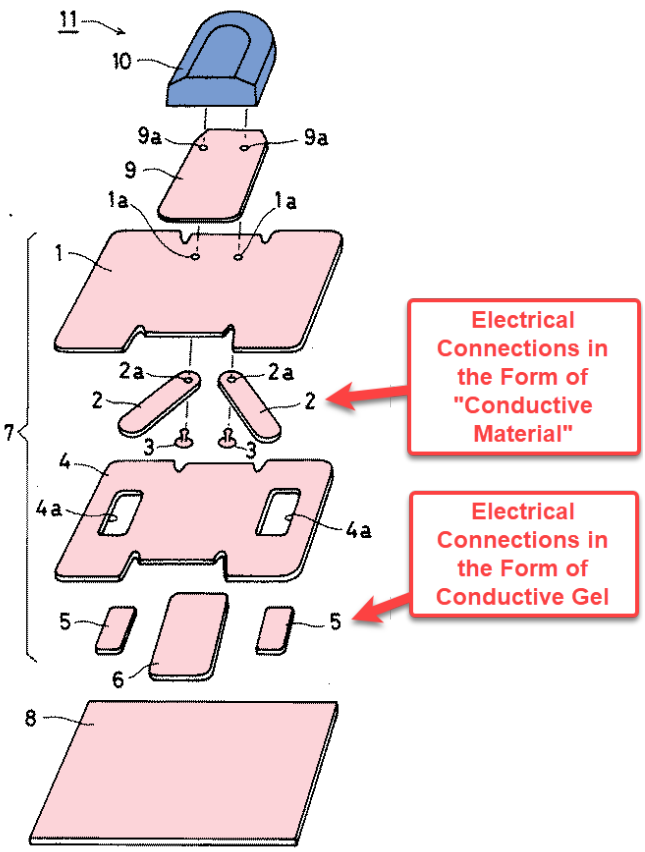
iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 88

ii. Limitation [1a]

207. Limitation [1a] of the ’699 patent recites “a plurality of electrical connections including at least one electrode.”

208. In my opinion, Matsumura discloses limitation [1a] of the ’699 patent.

209. Matsumura’s body-worn device (*i.e.*, “bioelectric potential detector”) includes a “***disposable*** bioelectrode pad” which uses “conductive gel 5” to detect bioelectric potentials and form electrical connections with the patient’s skin. Ex. 1006 at [0016] (emphasis added); *see also id.* at [0007]–[0008], [0014], [0019], Figs. 1–2. As shown by annotated Figure 1 below, Matsumura discloses two pieces of “conductive material 2” which form electrical connections to the signal processor through the interface between holes 2a and hooks 3. *Id.* at [0019]. Matsumura also discloses two pieces of “conductive gel 5” which form electrical connections with the patient’s skin and detect bioelectric potentials. *Id.*



Id. at Fig. 1 (annotated).

210. Matsumura discloses that the "conductive gel" may be produced from components such as "acrylic hydrophilic polymer, glycerin, and water." *Id.* at [0018]. The conductive gel contacts "conductive material 2," which may be "coated with conductive Ag/AgCl." *Id.* at [0019]–[0020]. In my opinion, a POSA would understand that conductive gels comprising an acrylic hydrophilic polymer, glycerin, and water, and contacting a silver/silver-chloride conductive surface comprise a "half cell." Ex. 1001 at 6:62–65 (explaining that the term "electrode" is used interchangeably with "half cell" within the disclosure and that an electrode—

i.e., a half cell—typically comprises (1) a conductive surface and (2) an electrode gel).

211. Thus, in my opinion, a POSA would understand Matsumura to disclose "a plurality of electrical connections including at least one electrode."

iii. Limitation [1b]

212. Limitation [1b] of the '699 patent recites "the electrical connections being couplable to a skin surface to measure patient heartbeat signals."

213. In my opinion, Matsumura discloses limitation [1b] of the '699 patent.

214. As discussed above, Matsumura discloses "conductive gel[s] 5" which detect and transmit bioelectric potentials detected at the patient's skin surface and "conductive material 2" which transmits the detected bioelectric potential to the signal processor 10." *See* Section X.C.2.ii, *supra*; Ex. 1006 at [0018]–[0019].

215. Matsumura teaches that its "bioelectric potential detector" is couplable to the patient's skin to measure physiological signals and teaches a protocol for doing so. Ex. 1006 at [0024]. The "conductive gel 5" is inserted through "two openings 4a on the left and right sides" of second sheet. *Id.* at [0018]. Then, an "adhesive, such as acrylic adhesive for example, is applied to the back surface of the second sheet 4." *Id.* In order to attach the bioelectric potential detector to a patient, "the release tape 8 is peeled off from the bioelectrode pad 7 and the detector is attached to the subject." *Id.* at [0024]. Peeling off the release tape 8 exposes second

sheet 4 (*i.e.*, the bottom of bioelectric pad 7), which allows the adhesive layer to adhere the bioelectric pad to the patient's skin. *See also id.* at [0022] (describing making second sheet 4 "less adhesive to the living body" by covering center with optional third sheet 6).

216. In my opinion, a POSA would understand that "conductive gel" enables Matsumura's device to detect "bioelectric potentials," which are then transmitted "through the conductive material 2 and the hooks 3." *Id.* at [0019]. In my opinion, a POSA would understand that the conductive gel 5 can detect "bioelectric potentials" for transmission "through the conductive material 2 and the hooks 3" because the conductive gel 5 is embedded in second sheet 4.

217. Thus, in my opinion, Matsumura discloses "the electrical connections being couplable to a skin surface to measure patient heartbeat signals."

iv. Limitation [1c]

218. Limitation [1c] of the '699 patent recites "a power source."

219. In my opinion, Matsumura discloses limitation [1c] of the '699 patent.

220. As previously discussed, the use of onboard power sources in wearable monitoring devices was well-known at the time of the invention of the '699 patent. *See* Section IV.C.3, *supra*. Matsumura explains that wireless ECG monitors include a "power source." Ex. 1006 at [0004] (describing a prior art device comprising a "conduction portion (equivalent to an electrode element), a power source, a potential

difference detection portion, and a wireless transmitting/receiving portion"). In my opinion, a POSA would have understood that Matsumura's device ***must*** include an onboard power source because without one, the device would be unable to make the wireless transmissions discussed. For example, Matsumura teaches that its device wirelessly transmits bioelectric potential signals from the signal processor to another device. *See, e.g.*, *id.* at Abstract, [0011], [0025] (monitor transmits "processed bioelectric potential signal . . . wirelessly"). Absent a power source integrated into the device, measuring ECG would not be possible.

221. Thus, in my opinion, Matsumura in view of the General Knowledge of a POSA discloses "a power source."

v. Limitation [1d]

222. Limitation [1d] of the '699 patent recites "at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate; and."

223. In my opinion, limitation [1d] of the '699 patent is obvious in view of Matsumura, Kroll, and a POSA's general knowledge. As discussed above in Section X.C.1, a POSA would have looked to combine Kroll's "resistive traces" with Matsumura's ECG monitoring device. Matsumura's device is a "bioelectric potential detector 11," which can "be used as an electrocardiogram detector that is worn on the subject's chest to detect electrocardiogram signals," Exhibit 1006 at

[0024], and which "determines whether the detected electrocardiogram of the subject (patient) is abnormal, such as an arrhythmia or an abnormal heart rate," *id.* at [0037]. As acknowledged by the '699 patent, it was required by existing medical standards at the time that "a medical grade monitor survive multiple defibrillation cycles of at least 360 joules." Ex. 1001 at 1:61–63, 10:17–33. Thus, in my opinion, a POSA would have been motivated to incorporate Kroll's teaching of resistive "lead strips" with the body-worn monitoring device disclosed by Matsumura in order to include features that would allow the device to survive multiple defibrillation cycles.

224. Kroll teaches a series current-limiting defibrillation protection resistor in the form of a "flexible conductive ink compound . . . of a preselected conductivity to provide a certain total lead strip resistance so that each strip [ ] serves as a current limiter to protect a patient from shock due to malfunction of the device [ ] or of a complementary medical device." Ex. 1007 at 5:4–13. Further, Kroll teaches that the conductive ink forming the resistive lead strips is "silk screened" onto a substrate (*i.e.*, "insulation and base support layer"). *Id.* at 5:37–42. Thus, in my opinion, a POSA would understand that Kroll teaches a current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate.

225. Matsumura discloses a flexible disposable bioelectrode pad, *i.e.*, a substrate, that is composed of materials such as "polyethylene foam, polyurethane foam, or polyurethane sheet" which are all materials that a POSA would recognize

as "flexible." Ex. 1006 at [0017]–[0018], [0022]. Indeed, the use of flexible polyethylene and polyurethane to create flexible, wearable medical devices was well known in the art at the time of the purported invention. *See, e.g.*, Ex. 1042 at 23.11; Ex. 1043 at 2. Matsumura further teaches that the "two pieces of conductive material 2" and "two hooks 3" are "arranged to transmit the bioelectric potentials" from the electrodes to the ECG electronics, Exhibit 1006 at [0019], and that the "conductive material [ ] can be a carbon sheet or a PET sheet" "coated with conductive Ag/AgCl." *Id.* at [0020]. Accordingly, in my opinion, a POSA would understand that Matsumura discloses a flexible substrate that incorporates traces.

226. Matsumura discloses that these "two pieces of conductive material 2," *i.e.*, the traces, "can be a carbon sheet or a PET sheet [which is an insulating material] coated with conductive Ag/AgCl." *Id.* at [0019]–[0020], Fig. 1. In my opinion, a POSA would know that the Ag/AgCl would be applied to the insulating material using a screen-printing technique. As discussed above, screen printing is one of the preferred processes for manufacturing circuits in the industry. *See* Section IV.C, *supra*.

227. In order to implement Kroll's printed traces in Matsumura's device, a POSA would simply replace the Ag/AgCl ink disposed on Matsumura's conductive material 2 with Kroll's resistive ink, *i.e.*, the POSA would use the same screen-printing process to manufacture Matsumura's device, substituting one type of

resistive ink for another such as widely available resistive carbon inks for Ag/AgCl ink.

228. Thus, in my opinion, it would have been obvious to a POSA to combine Matsumura's teaching of conductive silver ink screened on a substrate with Kroll's teaching of resistive traces screened on a substrate, resulting in a device that includes "at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate."

vi. Limitation [1e]

229. Limitation [1e] of the '699 patent recites "an ECG electronics module."

230. In my opinion, Matsumura discloses limitation [1e] of the '699 patent.

231. Matsumura teaches "an ECG electronics module" as well as a "reusable signal processor." Ex. 1006 at [0016]; *see also id.* at [0008], [0014], [0025], Figs. 1–2. The reusable signal processor disclosed by Matsumura incorporates a "processing circuit for filtering and amplifying detected bioelectric potential signals," "a memory for storing the processed bioelectric potential signal," "a circuit for modulating the processed bioelectric potential signal and transmitting it wirelessly, and a loop antenna." *Id.* at [0025].

232. Thus, in my opinion, a POSA would understand Matsumura discloses "an ECG electronics module."

vii. Limitation [1f]

233. Limitation [1f] of the ’699 patent recites “the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections.”

234. In my opinion, Matsumura discloses limitation [1f] of the ’699 patent.

235. Matsumura teaches that “the bioelectric potentials detected by the conductive gel 5 are transmitted through the conductive material 2 and the hooks 3” to the signal processor 10. Ex. 1006 at [0019], [0024]. In Matsumura’s “signal processor 10 . . . it is determined whether or not the detected electrocardiogram of the subject (patient) is in an abnormal state, such as an arrhythmia or an abnormal heart rate measured from the electrocardiogram.” *Id.* at [0032]. Based on this, POSA would understand that Matsumura’s ECG electronics module (signal processor 10) receives and processes “patient heartbeat signals from the plurality of electrical connections.”

236. Thus, in my opinion, Matsumura in view of the knowledge of a POSA discloses “the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections.”

viii. Limitation [1g]

237. Limitation [1g] of the ’699 patent recites “wherein the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.”

238. In my opinion, Matsumura and Kroll render obvious limitation [1g] of the ’699 patent.

239. As previously discussed POSA would have looked to combine the resistive traces of Kroll with the ECG monitor of Matsumura. *See* Section X.C.1, *supra*.

240. As explained above, Matsumura teaches “conductive material 2” and “hooks 3” that interconnect the “conductive gel 5” (the ECG electrodes) and the signal processor 10 (the ECG electronics). Ex. 1006 at [0019], [0024]; *see also* Section X.C.2.vii., *supra*. Matsumura’s “conductive material” is therefore disposed between at least one of the plurality of electrical connections and the ECG electronics module.

241. It would have been obvious to a POSA to incorporate Kroll’s teaching of screened current-limiting defibrillation protection traces onto the conductive material of Matsumura for all the reasons discussed with respect to the prior limitations. A POSA would understand that Kroll’s resistive ink would be form an

electrical connection between electrodes contacting the patient's skin and the ECG electronics module. *See* Sections IV.C.1, X.C.2.v, *supra.*

242. A POSA would understand that the goal of including a defibrillation protection resistor in a wearable ECG device would be to protect the electronics in the device from the potentially destructive flow of current associated with defibrillation. In order to achieve this goal, a POSA would understand that the defibrillation protection resistor must be placed between where the device would be exposed to defibrillation and the ECG electronics module that the resistor is intended to protect.

243. Thus, in my opinion, a POSA would understand that the combination of Matsumura and Kroll disclose "the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module."

3. Dependent Claim 2

244. Claim 2 of the '699 patent depends from claim 1 and additionally requires that "the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate."

245. In my opinion, claim 2 of the '699 patent is rendered obvious by Matsumura, Kroll, and the General Knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Matsumura teaches the

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 99

additional limitation of claim 2. *See* Section X.C.2, *supra.* The combination of Matsumura, Kroll and a POSA's general knowledge renders obvious "wherein the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate."

246. Both Matsumura and Kroll teach flexible substrates. The "conductive material 2" taught by Matsumura can be a carbon sheet or a PET sheet coated with Ag/AgCl which conventionally means that the Ag/AgCl is screened onto the PET sheet. Ex. 1006 at [0020]. In my opinion, a POSA would understand that carbon or PET sheets would be "flexible" substrates. Ex. 1042 at 23.11. Kroll discloses a "flexible and disposable electrode belt" onto which the ink for the resistive lead strips is "silk screened." *E.g.*, Ex. 1007, 4:22–24, 4:36–37, 4:48–51, 5:37–42.

247. As discussed above with respect to limitation [1d], it is my opinion that a POSA would have been motivated to combine the ECG monitor disclosed by Matsumura with Kroll's current-limiting defibrillation protection resistors screened onto a substrate. Specifically, Kroll teaches that the conductive ink forming the resistive lead strips is "silk screened" onto an "insulation and base support layer." *Id.* at 5:37–42.

248. When modified as discussed above with respect to claim 1, a POSA would understand that the combination of Matsumura and Kroll would meet the dependent limitation of claim 2. *See* Section X.C.2.v.*, supra*.

249. For these reasons, it is my opinion that Matsumura, Kroll, and the General Knowledge of a POSA render obvious "the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate" and, therefore, renders obvious claim 2 of the '699 patent.

4. Dependent Claim 4

250. Claim 4 of the '699 patent depends from claim 1 and additionally requires that "a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a plurality of overlapped layers."

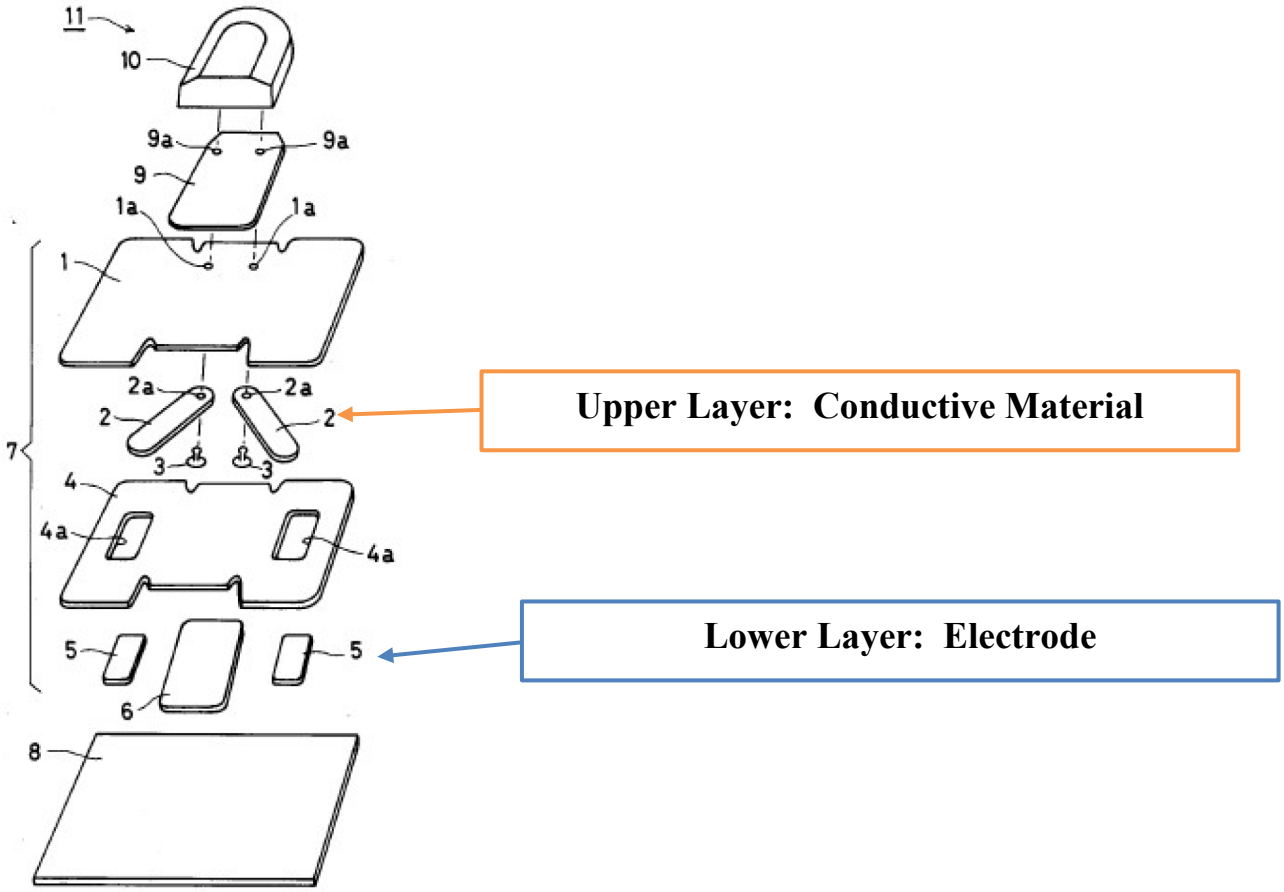
251. In my opinion, claim 4 of the '699 patent is rendered obvious by Matsumura, Kroll, and the General Knowledge of a POSA for all the reasons discussed above with respect to claims 1 as well as because Matsumura, Kroll, and the General Knowledge of a POSA also teach the additional limitation of claim 4. *See* Sections X.C.2, *supra.*

252. In my opinion, a POSA would have been motivated to modify Matsumura's ECG monitor with the teaching of Kroll to include a series current-limiting, defibrillation protection resistor in the form of resistive traces, for all the same reasons as discussed above with respect to claim 1. Sections X.C.2.i-viii, *supra*.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 101

253. It is further my opinion that a POSA would recognize that the interface between conductive material 2, as modified, and conductive gel pad 5 (the ECG electrode) is a mechanical interface because the lower surface of the conductive material 2 is electrically and physically connected to the bottom surface of the conductive gel pad. Ex. 1006 at [0019].

254. Further, in my opinion, a POSA would further understand that this mechanical interface necessarily includes a plurality of overlapped layers, wherein the conductive material 2 is an upper layer, and the conductive gel electrode 5 is a lower layer. An overlapping layer structure is how the "bioelectric potentials detected by the conductive gel 5 are transmitted through the conductive material 2 and the hooks 3." *Id.*



Id. at Fig. 1 (annotated).

255. Further, making this small modification, it would have been obvious to a POSA to implement the resistive traces so as to define a mechanical interface between them and the electrodes, thereby forming a plurality of overlapping layer. For example, Kroll discloses that the mechanical interface between its current-limiting defibrillation protection resistors (lead strips) and its electrodes comprises a plurality of overlapping layers: Kroll's lead strips 34 are screened onto the flexible substrate, overlapping the electrodes (which are also applied to the substrate using a screening process). Ex. 1007 at 5:17–21, 5:37–42, Fig. 5. In my opinion, a POSA

would implement these resistive lead strips in the same way—overlapping the electrodes— in Jensen's device. *See also, id.* at Fig. 5 (annotated):

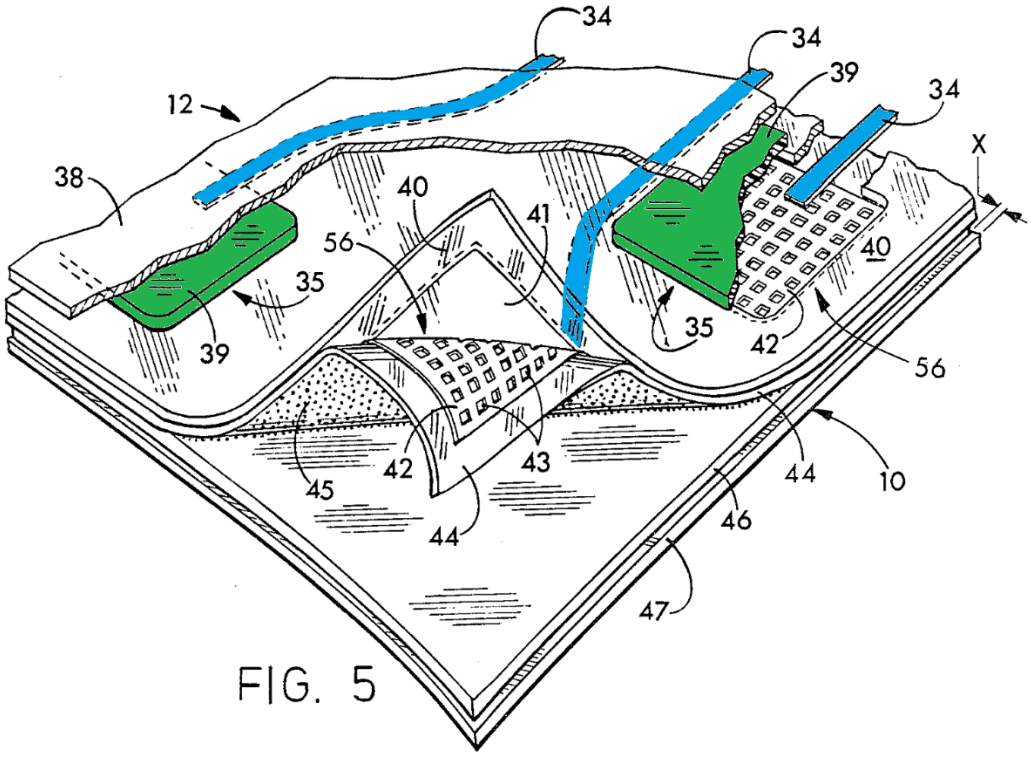


FIG. 5

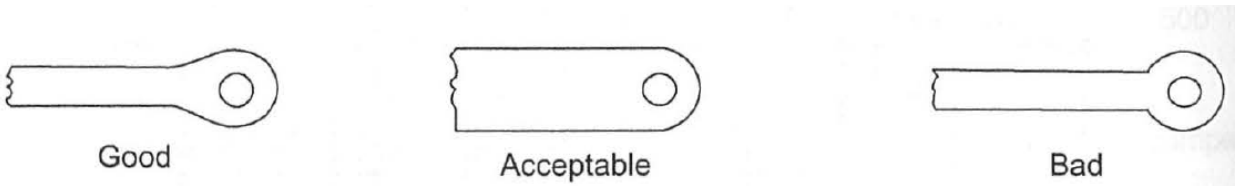
256. For these reasons, it is my opinion that Matsumura, Kroll, and the General Knowledge of a POSA render obvious that "a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a plurality of overlapped layers" and, therefore, renders obvious claim 4 of the '699 patent.

D. Ground 4: Obvious over Matsumura, Kroll, Khandpur, and General Knowledge of a POSA

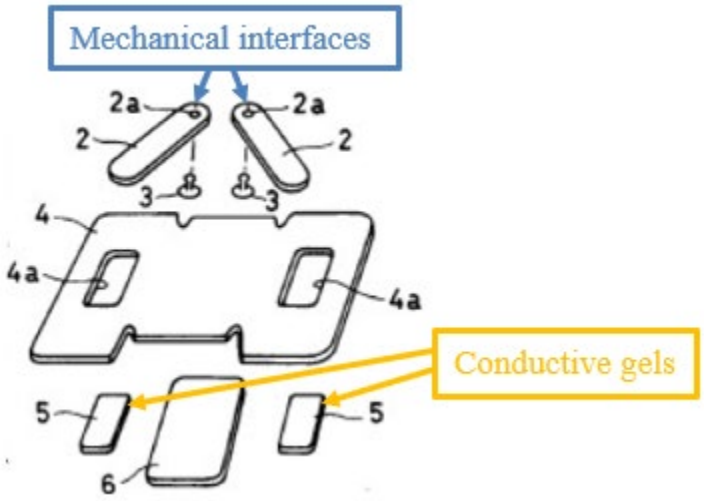
1. A POSA would have been motivated to combine Matsumura, Kroll, and Khandpur

257. A POSA would have been motivated to combine, and would have had a reasonable expectation of success in combining, Kroll's teaching of "resistive traces" with Matsumura's device for all the same reasons set forth above in Section X.C.1.

258. In my opinion, a POSA would have also been motivated to incorporate Khandpur's teachings of a "tear-like" or "filleted" edge to the interface between the more rigid conductive material 2, on which the "resistive traces" of Kroll are printed, and the flexible "conductive gel" 5 of Matsumura. Ex. 1008 at 195, 442–43. The terms "tear-like "and "fillet" are used synonymously to refer to the shape of components or layers on the PCB. *Id.* at 195. Khandpur teaches that this is the preferred approach because the transition between flexible and rigid materials means that zone is "highly prone to conductive breakage." *Id.* at 442–43. Khandpur discloses that having a "tear-like" or "filleted" transition between the flexible and rigid materials helps to solve this problem. *Id.* As shown below, Khandpur identifies the "filleted" edge as "good," while identifying other shapes as "acceptable" or "bad." *Id.*



Id. at Fig. 12.10. The shape of Matsumura's disclosed mechanical interface connecting conductive material 2 to conductive gel 5 is only "acceptable" according to Khandpur. In my opinion, a POSA would have sought to improve that shape from "acceptable" to "good" as taught by Khandpur.



Ex. 1006 at Fig. 1 (annotated).

259. In my opinion, a POSA seeking to implement Khandpur's transition to Matsumura's device with Kroll's "resistive traces" would have a reasonable expectation of success without undue experimentation. This combination only requires a simple design change: altering the "acceptable," straight edge design of Matsumura's interface to the "good," "filleted" edge design of Khandpur. Nothing in the art suggests that this modification would not work.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 106

2. Dependent Claim 3

260. Claim 3 of the ’699 patent depends from claim 1 and further requires that “a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a filleted edge.”

261. In my opinion, claim 3 of the ’699 patent is rendered obvious by Matsumura, Kroll, Khandpur, and the General Knowledge of a POSA for all the reasons discussed above with respect to claim 1 as well as because Khandpur renders obvious the additional limitation of claim 3. *See* Section X.C.2, *supra.*

262. As discussed above, a POSA would have been motivated to modify Matsumura’s ECG monitor with the teaching of Kroll to include a series current-limiting, defibrillation protection resistor in the form of resistive traces. *See* Sections X.C.2.i-viii, *supra*. In my opinion, a POSA would recognize that the interface between conductive material 2, as modified, and conductive gel pad 5 (the ECG electrode) is a mechanical interface because the lower surface of the conductive material 2 is physically connected to the top surface of the conductive gel pad. Ex. 1006 at [0019]. In my opinion, a POSA would know that, when printing ink traces on a flexible circuit board, it is desirable that contacts be “tear-like” or “filleted” to ensure a good conductive connection. *See* Ex. 1008 at 195 (including, as “[s]tandard pad shapes,” “Teardrop pads (with fillet radius),” and “Teardrop pads

(with straight side fillets)"); *id.* at 442–43 (noting that "[t]he general shape of solder pads should be tear-like"); *id.* at 195 (using the terms "fillet" and "teardrop" synonymously); *id.* at 442–43 (stating that "[t]he general shape of solder pads should be tear-like" to prevent conductive breakage). In my opinion, POSA would have recognized that this "filleted" shape not only prevents conductor breakage, as taught in Khandpur, but also increases the reliability and performance of the printed circuit board.

263. Further, it would have been obvious to a POSA to re-shape conductive material to have a "filleted edge" at both ends. Doing so would help to reduce the amount of flexible substrate material (*e.g.*, PET or carbon) in use, and, by reducing the surface area to cover in silver and/or resistive ink, helped to reduce the amount of ink used. Thus, a POSA could potentially reduce the cost of manufacturing by significantly reducing the cost of materials needed to be used.

264. For these reasons, it is my opinion that the General Knowledge of a POSA renders obvious "a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a filleted edge" and, therefore, that the combination of Matsumura, Kroll, and the General Knowledge of a POSA renders obvious claim 3 of the '699 patent.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1003
Page 108

E. Ground 5: Obvious Over Matsumura in view of Kroll, Thompson, and General Knowledge of a POSA

1. A POSA would have been motivated to combine Matsumura, Kroll, and Thompson

265. In my opinion, a POSA would have looked to incorporate Thompson's teaching of a periodic low power mode based on the electrical signals of a heartbeat with Matsumura's device. The utility of a battery-powered, wearable device is limited by its battery-life and the size and composition of the battery is limited by the dimensional requirements of a body-worn physiological monitor. Therefore, in my opinion, a POSA would seek to optimize power consumption as a means of prolonging the battery life of the device and extending the period for which the device can collect data.

266. Due to this concern, a POSA would have been aware of techniques for optimizing battery life, including the use of a periodic low power mode. *See, e.g.*, Ex. 1041 at [0019] ("By having the processor operate in a low-power consumption mode, the invention reduces the amount of power consumed by the defibrillator. As a result, a power supply will last longer in the defibrillator of the present invention than in its conventional counterparts."). In my opinion, a POSA would have sought out additional power conservation solutions that would conserve power while the device was operational. Such solutions would allow battery usage to be even more

efficient allowing for a reduction in the overall size of the batteries—and thus the size of the devices—as desired by the industry. *See* Section IV.C–D, *supra.*

267. Thompson discloses an approach to power conservation by limiting processing time to certain portions of the heartbeat waveform. In one embodiment, Thompson discloses that "[o]nly during a QRS complex, for example, does waveform analysis processor 520 operate in a high speed processing mode at a relatively high frequency. During the remainder of the cardiac cycle [*i.e.*, during the TP interval] the DSP processor 520 may be 'idling along' at a much lower clock frequency. . . . In addition to the lower clock speed utilized for different portions of the cardiac cycle, one skilled in the art will recognize that in accordance with the other aspects of the present invention, as the speed is reduced, the supply voltage level (V_{DD}) may also be reduced accordingly. Thus, the objective of reduced power consumption is realized." Ex. 1009 at 18:3–14.

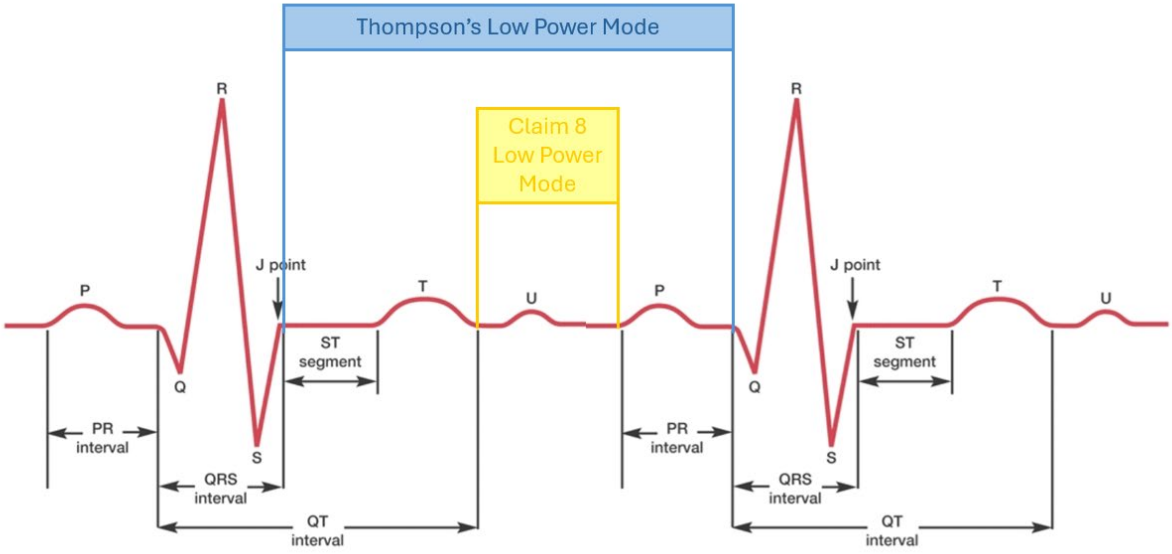
268. In my opinion, a POSA would have had a reasonable expectation of success in implementing Thompson's low power mode on Matsumura's device without undue experimentation. It would only require reprogramming of onboard software to do so. Therefore, it is my opinion that a POSA would know how to combine Thompson's low power mode with Matsumura's design with little to no design impact. Further, there is nothing in the art to suggest that this modification would not work.

2. Dependent Claim 8

269. Claim 8 of the ’699 patent depends from claim 1 and additionally requires that “the ECG electronics module includes a microprocessor to process the heartbeat signals, wherein an algorithm running on the microprocessor causes the ECG monitor to enter a low power mode that disables at least one circuit of the ECG electronics module, from the end of a ‘T wave’ at the end of one heartbeat to the beginning of a ‘P wave’ at the beginning of the next heartbeat, in order to reduce said electrical load on the power source.”

270. In my opinion, claim 8 of the ’699 patent is rendered obvious by Matsumura in combination with Kroll and Thompson for all the reasons discussed above with respect to claim 1 as well as because Thompson teaches the additional limitation of claim 8. *See* Section X.C.2, *supra.*

271. Thompson teaches that a device can conserve power by operating in a low power mode from the end of one S-wave of the patient’s heartbeat until the commencement of the next Q-wave. Ex. 1009 at 18:3–14. Therefore, in my opinion, a POSA would recognize that Thompson’s low power mode (which spans the broader period, from the end of an S-wave to the next Q-wave) includes the narrower period “from the end of a ‘T wave’ at the end of one heartbeat to the beginning of a ‘P wave’ at the beginning of the next heartbeat,” as shown by the annotated figure below:



272. It is further my opinion that a POSA would recognize that this low power mode could be implemented on Matsumura's "signal processor" for the reasons discussed above. *Id.*; Ex. 1006 at [0025], [0032]; *see* Section X.D.1., *supra.*

273. For these reasons, it is my opinion that Thompson teaches "an algorithm running on a microprocessor in the body worn device causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a 'T wave' at the end of one heart beat to the beginning of a 'P wave' at the beginning of the next heartbeat, to save power" and, therefore, that the combination of Matsumura, Ozguz, Kroll, and Thompson renders obvious claim 8 of the '699 patent.

XI. CONCLUSION

274. For all of the reasons I discussed above, it is my opinion that claims 1-4 and 8 of the ’699 patent are unpatentable.

275. I reserve the right to change, amend, and/or supplement my opinions as necessary in response to new information and evidence made available to me, additional scientific analysis that leads me to conclude that supplementation is necessary, new issues that may arise, and any additional discovery, arguments, evidence, or testimony presented in this matter.

276. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises and to consider new information as it becomes available to me.

277. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the full knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code.

Dated: May 30, 2025

Jason Heikenfeld