

1 Bryan J. Sinclair (SBN 205885)  
2 bryan.sinclair@klgates.com  
3 K&L GATES LLP  
4 630 Hansen Way  
5 Palo Alto, CA 94304  
6 Telephone: 650.798.6700  
7 Facsimile: 650.798.6701

8 Sara N. Kerrane (SBN 259239)  
9 sara.kerrane@klgates.com  
10 K&L GATES LLP  
11 1900 Main Street, Suite 600  
12 Irvine, California 92614-7319  
13 Telephone: 949.253.0900  
14 Facsimile: 949.253.0902

15 Attorneys for Plaintiff,  
16 Patient Safety Technologies, Inc.

17 UNITED STATES DISTRICT COURT  
18 CENTRAL DISTRICT OF CALIFORNIA  
19 SOUTHERN DIVISION

20 Patient Safety Technologies, Inc.,  
21 Plaintiff,  
22 vs.  
23 ClearCount Medical Solutions, Inc.,  
24 Defendant.

Case No. **SACV12-00937 DOC (MLGx)**

**COMPLAINT FOR PATENT  
INFRINGEMENT**

**JURY TRIAL DEMANDED**

FILED  
2012 JUN 12 PM 2:21  
CLERK U.S. DISTRICT COURT  
CENTRAL DIST. OF CALIF.  
SANTA ANA

1 **ORIGINAL COMPLAINT**

2 Plaintiff, Patient Safety Technologies, Inc. ("Patient Safety"), by and through its  
3 undersigned counsel, files this Original Complaint against ClearCount Medical  
4 Solutions, Inc. ("ClearCount") and alleges as follows:

5 **NATURE OF THE ACTION**

6 1. This is an action for infringement of U.S. Patent No. 5,931,824 C1  
7 entitled "Identification and Accountability System for Surgical Sponges" which was  
8 duly issued by the U.S.P.T.O on August 3, 1999 (the "'824 Patent"). A copy of the  
9 "'824 Patent is attached as Exhibit A.

10 **THE PARTIES**

11 2. Patient Safety is a Delaware corporation with its principle place of  
12 business at 2 Venture Plaza, Suite 350, Irvine, California. Patient Safety is the  
13 assignee of the '824 Patent and holds all right, title and interest in the '824 Patent.

14 3. ClearCount is a Delaware corporation with its principal place of business  
15 at 101 Bellevue Rd # 300, Pittsburgh, Pennsylvania.

16 **JURISDICTION AND VENUE**

17 4. This Court has subject matter jurisdiction over this Complaint pursuant to  
18 28 U.S.C. §§ 1331 and 1338(a) because this matter arises under the patent laws of the  
19 United States, Title 35 of the United States Code.

20 5. ClearCount is subject to the personal jurisdiction of this Court because it  
21 used, sold and/or offered for sale its infringing SmartSponge Products in this district  
22 and, as such, acts of infringement are occurring in this district.

23 6. Venue of this action is proper in the Central District of California  
24 pursuant to 28 U.S.C. §§ 1391 and 1400(b).

25 **BACKGROUND**

26 7. Patient Safety's, through its wholly owned operating subsidiary,  
27 SurgiCount Medical, Inc. ("SurgiCount"), manufactures and sells the Safety-Sponge®  
28 System, a solution proven to improve patient safety and reduce healthcare costs by

1 preventing one of the most common errors in surgery, retained foreign objects. The  
2 Safety-Sponge® System embodies one or more of the claims of the '824 Patent.

3 8. ClearCount has actual knowledge of the existence of the '824 Patent.

4 9. ClearCount manufactures, uses, offers for sale, and sells products called  
5 the SmartSponge System and the SmartSponge Flex (the "SmartSponge Products").  
6 ClearCount has used, offered for sale, and sold the SmartSponge Products within this  
7 judicial district.

8 10. The SmartSponge Products infringe at least one claim of the '824 Patent.

9 Specifically, the SmartSponge Products infringe at least claims 1, 5, 17, 21, and 31 of  
10 the '824 Patent.

11 **FIRST CLAIM FOR RELIEF**

12 **Infringement of U.S. Patent No. 5,931,824 C1**

13 11. Patient Safety repeats and realleges each and every allegation contained in  
14 paragraphs 1 through 10, inclusive, of this Complaint with the same force and effect as  
15 if set forth at length herein.

16 12. Patient Safety is the owner of all rights, title, and interest in and to the  
17 '824 Patent and possess all rights of recovery under the '824 Patent including the right  
18 to sue for infringement and recovery of past damages.

19 13. In violation of 35 U.S.C. § 271(a), ClearCount has infringed and  
20 continues to infringe one or more claims of the '824 Patent by making, have made,  
21 using, offering for sale and selling directly or through intermediaries, in this district or  
22 elsewhere in the United States, the SmartSponge Products.

23 14. In violation of 35 U.S.C. § 271(b), ClearCount has actively and  
24 knowingly encouraged and induced infringement and possessed specific intent to  
25 encourage another's infringement which has led to direct infringement by a third party  
26 of one or more of the claims of the '824 patent through the use of the SmartSponge  
27 Products in an infringing manner.  
28

1           15. As a result of ClearCount's direct infringement of, and inducement to  
2 infringe, one or more claims of the '824 Patent, Patient Safety has suffered, and will  
3 continue to suffer, substantial damages in amounts to be proven at trial. Patient Safety  
4 will also suffer irreparable harm unless ClearCount's infringement is enjoined by this  
5 Court.

6           16. ClearCount has knowledge of the '824 Patent and its past and future  
7 infringement of the '824 Patent is willful.

8  
9 WHEREFORE, Patient Safety requests that:

- 10           1. Judgment be entered in favor of Patient Safety against ClearCount;
- 11           2. Patient Safety be awarded costs of this suit;
- 12           3. Patient Safety be awarded compensatory and special damages for the  
13 infringement of the '824 Patent in an amount to be determined at trial;
- 14           4. ClearCount be preliminarily and permanently enjoined from infringing or  
15 inducing others to infringe the '824 Patent;
- 16           5. The Court determine that ClearCount's infringement is willful and that  
17 Patient Safety is entitled to collect enhanced damages;
- 18           6. The Court declare this an exceptional case under 35 U.S.C. § 285 and  
19 award Patient Safety its attorneys' fees and costs incurred in connection with this  
20 action;
- 21           7. The Court otherwise award Patient Safety its attorneys' fees; and
- 22           8. The Court grant such further relief as the Court deems just and proper.

23                   **JURY DEMAND**

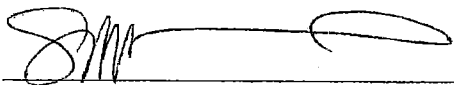
24           Patient Safety demands a trial by jury on all issues so triable.

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

Respectfully submitted,

K&L GATES LLP

Dated: June 12, 2012

By:   
Bryan J. Sinclair  
Sara N. Kerrane

Attorneys for Plaintiff, Patient Safety  
Technologies, Inc.

---

# **EXHIBIT A**



US005931824A

**United States Patent** [19]

Stewart et al.

[11] Patent Number: **5,931,824**[45] Date of Patent: **Aug. 3, 1999**[54] **IDENTIFICATION AND ACCOUNTABILITY  
SYSTEM FOR SURGICAL SPONGES**

[76] Inventors: William W. Stewart, 426 N. Foy's Rd.,  
Kalispell, Mont. 59901; Brian E.  
Stewart, 11982 Kiowa 306, Los  
Angeles, Calif. 90049

[21] Appl. No.: 08/921,430

[22] Filed: Aug. 29, 1997

**Related U.S. Application Data**

[60] Provisional application No. 60/025,629, Sep. 4, 1996.

[51] Int. Cl.<sup>6</sup> A61F 13/15; A61F 13/20

[52] U.S. Cl. 604/358; 604/362

[58] Field of Search 604/358, 362,  
604/385.1[56] **References Cited****U.S. PATENT DOCUMENTS**

3,941,132 3/1976 Lenaghan 604/377  
3,965,907 6/1976 Hardy et al.  
4,098,728 7/1978 Rosenblatt  
4,114,601 9/1978 Abels

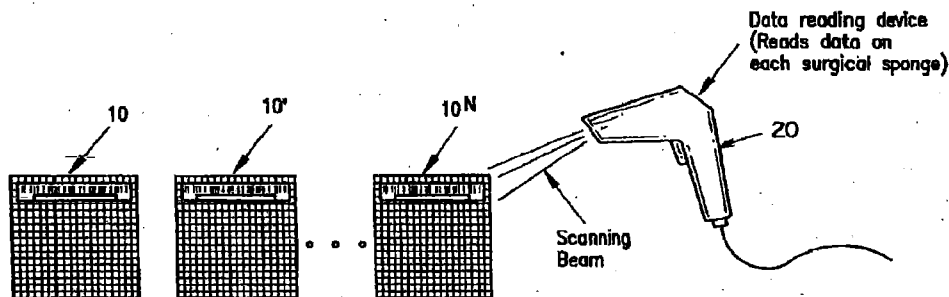
4,244,369 1/1981 McAvinn et al. 604/362  
4,477,256 10/1984 Hirsch 604/362  
4,626,251 12/1986 Shen 604/362  
4,639,253 1/1987 Dyer et al. 604/362  
4,645,499 2/1987 Rupinkas 604/362  
4,658,818 4/1987 Miller et al. 604/362  
4,718,897 1/1988 Elves 604/362  
4,832,198 5/1989 Ali Khan 206/438  
4,917,694 4/1990 Jessup 604/362  
5,031,642 7/1991 Nosek 128/906  
5,041,103 8/1991 Rupinkas 604/362  
5,045,080 9/1991 Dyer et al. 604/362  
5,049,219 9/1991 Johns et al. 156/73.1  
5,112,325 5/1992 Zachry 604/362

Primary Examiner—Mark O. Polutta

[57] **ABSTRACT**

An automatic identification system for accounting for and identifying a plurality of surgical sponges used during a surgical procedure. Machine-readable information is located on a plurality of surgical sponges. Each sponge of the plurality of surgical sponges has unique machine-readable information located thereon. The unique machine-readable information is unique for at least one surgical procedure.

28 Claims, 2 Drawing Sheets

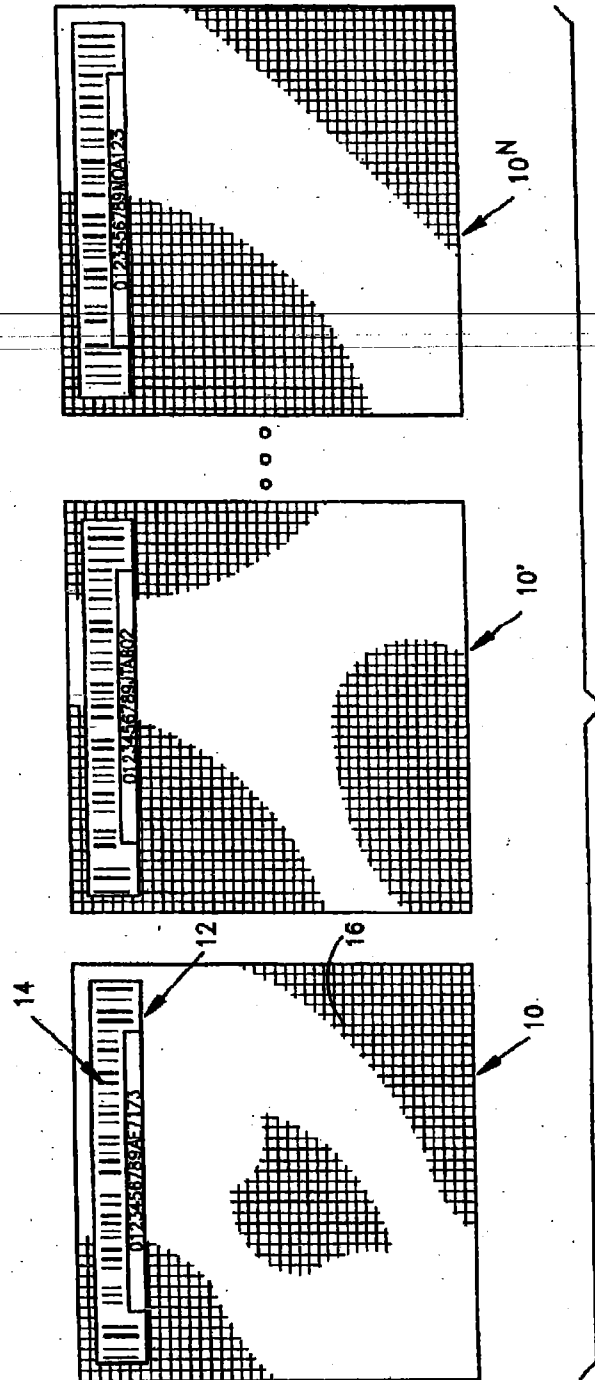


U.S. Patent

Aug. 3, 1999

Sheet 1 of 2

5,931,824





U.S. Patent

Aug. 3, 1999

Sheet 2 of 2

5,931,824

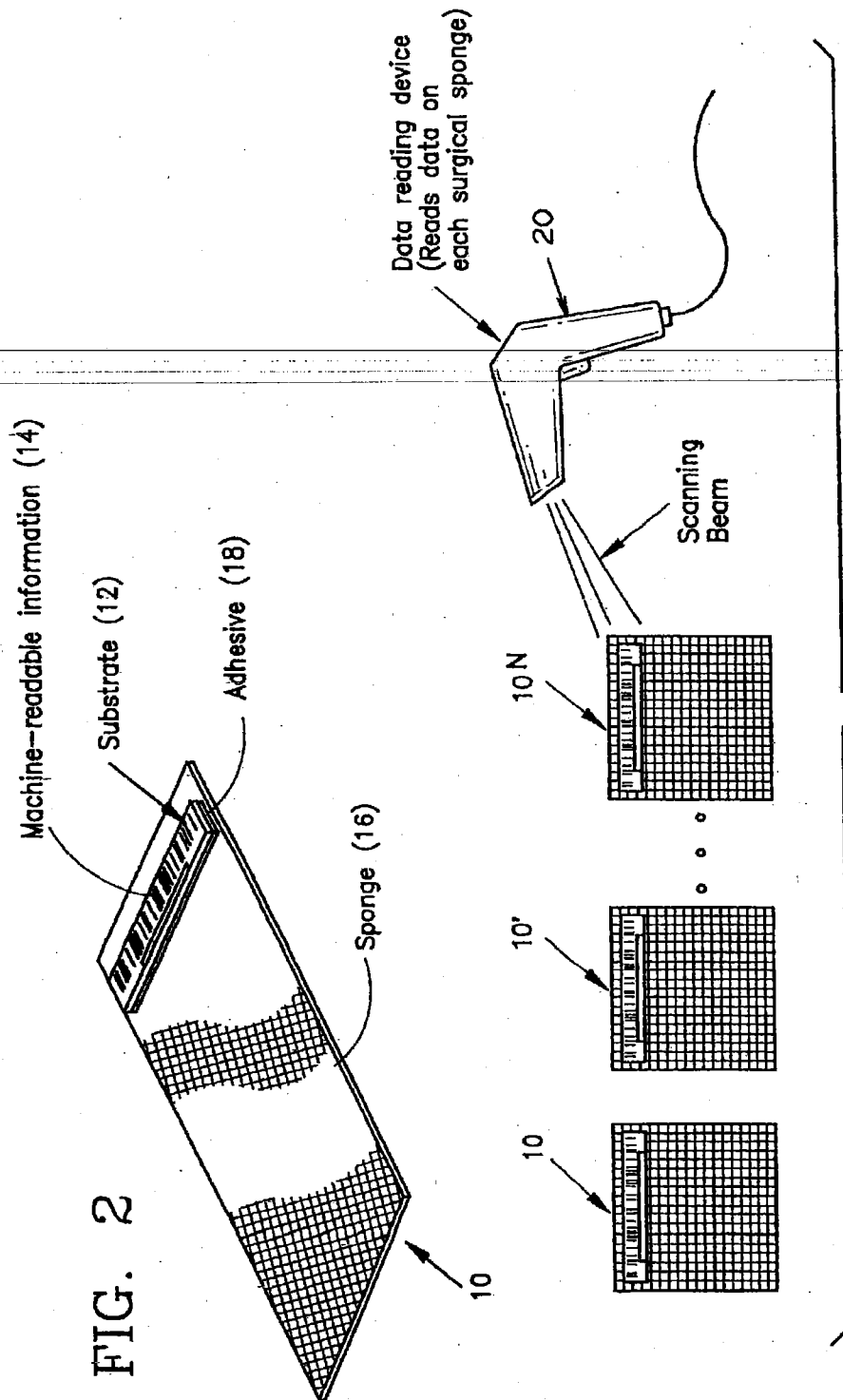


FIG. 3

5,931,824

1

## IDENTIFICATION AND ACCOUNTABILITY SYSTEM FOR SURGICAL SPONGES

This application is a provision of Ser. No. 60/025,629 filed Sep. 4, 1994.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates to an identification and accountability system for surgical sponges and more particularly to an identification and accountability system for surgical sponges, which utilizes machine-readable information to identify and account for surgical sponges.

#### 2. Description of the Related Art

Surgical sponges are commonly used during surgical procedures to absorb body fluids, mostly blood, of the patient both inside the incision and around the site of surgery. Sponges of this nature are usually made of an open ended absorbent fabric, such as woven cotton. When used, surgical sponges become saturated with blood, alter in size and shape and therefore become hard to distinguish from body tissue and each other. For this reason surgical sponges are hard to identify and account for both during and after a surgical procedure. This problem becomes magnified in larger surgical procedures where there are a large number of sponges used.

Before any particular surgical procedure all surgical items must be meticulously counted. After the procedure all items used in that particular surgery must be identified and accounted for. Surgical sponges are a difficult item to account for before, during and especially after a surgical procedure. The current method of identification and accountability relies on medical personnel to count these items by hand, relying on human visual detection and counting ability to differentiate one sponge from another and account for all the sponges, leaving this method open to a degree of human error. If a sponge count taken during or after a surgical procedure does not match a sponge count taken during or after the same procedure, the sponges are impregnated with an x-ray detectable element so that the patient can be x-rayed to see if the missing sponge or sponges are inside the patient and where.

The current system of accountability and identification for surgical sponges has proven itself unreliable and inefficient. Not only does the large amount of time involved to differentiate the sponges from one another and account for them all lead to large costs, but also the unreliable nature of the method leads to an alarming number of miscounted sponges resulting in retained surgical sponges inside the patient. These unfortunate incidents adversely affect not only the health of the patient, but also prove costly to the nurses, technicians, doctors, hospitals and insurance companies involved.

Past attempts have been made to increase the chances of accurate visual counting of surgical sponges. U.S. Pat. No. 4,917,694 addressed this problem by including, in the sponge, an elongated visually detectable element at a visible location on the sponge comprising a pair of elongated twisted strands. One of the strands contrasts with the color of the sponge, and the other with the color of blood. This is done to facilitate visual detection of the sponge whether it is dry or soaked with blood. This is done to facilitate visual detection of the sponge and counting ability and is therefore subject to a high degree of human error. There is no attempt to differentiate one individual sponge from another.

U.S. Pat. No. 4,114,601 attempts to solve the problem of medical item detection. It describes a method by which

2

surgical implants, instruments, sponges, implantable devices and indwelling therapeutic devices and materials may be detected within the human body, or other area of interest, by incorporating or adding a radio frequency transponder. Non-linear mixing of two frequencies in a radio transponder is used. This transponder may be a small film deposition of ferrite material exhibiting gyro-magnetic resonance at selected frequencies or a solid state device. When the transponders are incorporated in the items, the detection of the transponder is equivalent to the detection of the implant.

U.S. Pat. No. 5,031,642 also attempts to address the issue of medical item accountability. The invention is an "Integrator Collector" containing a time-correlated digital receiver for measuring, displaying and recording fluid loss from surgery and for maintaining, displaying and recording a count of secured items, such as needles and sponges by means of an electronic beam, which upon activation by a surgical sponge, triggers the automatic conversion of the weight of the items into cubic centimeters of blood loss.

The '642 patent calls for the placement of indicia on external packaging of the containers holding the surgical sponges as a means to count the number of sponges before a surgical procedure, but makes no attempt to include this indicia on the individual sponges themselves. No attempt is made to differentiate one individual sponge from the next by means of indicia.

### OBJECTS AND SUMMARY OF THE INVENTION

It is therefore a principal object of the present invention to account for and identify surgical sponges in an efficient, reliable manner.

It is another object to provide an identification and accountability system for surgical sponges which is not obscured by the conditions that the system will be exposed to in its use, particularly exposure to body fluids including but not limited to blood.

It is another object to provide an identification and accountability system for surgical sponges which does not compromise any medical requirements thereof, particularly but not limited to requirements of sterility.

It is another object to provide this identification and accountability system in a way as not to compromise the function of the surgical sponges.

These and other objects are achieved by the present invention that, in one broad aspect, comprises machine-readable information located on individual surgical sponges. The machine-readable information is unique to each individual surgical sponge, making each and every sponge automatically differentiable from the next for at least a given surgical procedure. Each surgical sponge further preferably includes an x-ray detectable element.

Means are provided for automatically reading the individually unique surgical sponges and creating an inventory of the surgical sponges to be used for a particular procedure. An automated check of the inventory of surgical sponges can be obtained at any desired time before, during or after a surgical procedure.

The present invention provides for the improved identification and accountability of surgical sponges by the incorporation of automatic identification technology to these sponges in a manner that allows for the differentiation of the individual sponges from each other. This is done through the impregnation of unique machine-readable information to each individual sponge that is unique for at least a surgical

5,931,824

3

procedure. By the incorporation of automatic identification and recognition technology described herein, the human error factor which so negatively affects the current method of identification and accountability and differentiation will be greatly reduced.

By replacing the need to rely solely on human visual detection and counting ability to differentiate the individual sponges from one another and account for their presence or lack thereof with a system as presented here, the medical community will be empowered with the ability to identify and account for individual surgical sponges in a vastly superior way.

In accordance with the present invention, each surgical sponge is made individually unique for a given surgical procedure and preferably from every other surgical sponge by assigning unique machine-readable information to each individual surgical sponge. The sponges therefore become distinguishable from each other in an automated manner providing for a more accurate and efficient system of identification and accountability of these medical items. The inventory of unique surgical sponges created by the automated system before a surgical procedure via a scanning device which reads the machine-readable information off the sponges and inputs that information into a computer system can be compared to an inventory created either during or after the same procedure and an instant comparison of inventories be made to determine the presence, or lack thereof, of all the individual sponges.

Through the use of the herein described system, medical personnel will be able to not only determine if a sponge or sponges are missing faster and more reliably, but exactly which sponge or sponges are missing. This process may lessen the need for needlessly exposing a patient to x-ray radiation and further trauma by needless closing and reopening of an incision. This system will have the potential to vastly reduce the occurrence of retained surgical sponges. Furthermore, the automatically created inventories of surgical sponges can be logged, becoming a permanent addition to a patient's medical file, and referenced at a later time for such needs as legal or medical reference. This herein described system will empower the medical community with the ability to raise the overall standard of health care while potentially saving costs for all parties involved from the patient, medical personnel, hospitals and insurance companies.

Other objects, advantages, and novel features will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a preferred embodiment of the surgical sponge system of the present invention.

FIG. 2 is a side perspective view of a sponge incorporating the features of the present invention.

FIG. 3 illustrates the use of a scanner for reading the data on the surgical sponges.

The same reference characters designate the same parts or elements throughout the drawings.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings and the characters of reference marked thereon, FIG. 1 illustrates the preferred embodiment of the surgical sponge system of the present

4

invention, the sponges being designated generally by numeral designations 10, 10', . . . 10<sup>N</sup>. Each sponge 10 includes a substrate 12 having unique machine-readable information 14 located thereon. This sponge material 16 may be conventional surgical sponge material, typically, folded woven cotton.

The substrate 12 is formed of inert, sterilizable material, which is capable of maintaining the machine-readable information 14. It may be, for example, cotton, polyester or a blend thereof. These materials do not inhibit the basic function of the sponge 16. Various label designers and manufacturers which may fabricate suitable labels for use as substrates 12 may include Computype Inc., St. Paul, Minn.; Information Plus Corp., Texas; and Polymark, Inc., Cincinnati, Ohio.

Referring now to FIG. 2, it can be seen that the lower surface of the substrate 12 includes a layer of adhesive material 18 for attaching the substrate 12 to the sponge material 16. The adhesive material 18 is preferably of the type that provides attachment by application of heat thereto. The above-mentioned label manufacturers typically use such adhesive materials. However, the present invention preferably involves the addition of an x-ray detectable element in the adhesive material 18. Such an x-ray detectable element may include barium sulfate.

It is understood that although the x-ray detectable element has been described as being contained within the adhesive material 18, it may alternately be included on the sponge material 16.

The machine-readable information 14 on each sponge is unique for at least one surgical procedure. The machine-readable information 14 is preferably presented in bar code form. It may be presented by commercially available inkjet technology or thermal transfer processes. Examples of companies providing these capabilities include, for example, Computype, Inc.; Zebra, Inc., Vernon Hills, Ill.; and Information Plus Corporation.

Although the machine-readable information 14 is unique for at least one surgical procedure, it is preferably absolutely unique; i.e. no two sponges will contain the same information, even in different surgical procedures.

The machine-readable information 14 may be present in either one, two or three-dimensional technologies in one of various commercially viable forms.

A sponge may include unique human-readable information thereon associated with its respective unique machine-readable information. This human-readable information is provided as a backup method if there is a machine failure in reading the information in its machine-readable form.

Referring now to FIG. 3, sponges 10, 10', . . . 10<sup>N</sup>, are shown being scanned by a data reading device 20. The data reading device 20 is connected to a computer (not shown). The data reading device 20 may be, for example, a bar code scanner. Before each surgical procedure, an inventory is created of the surgical sponges to be used for that particular procedure. To account for and identify the surgical sponges either during or after this surgical procedure another inventory can be created by scanning the sponges to check and see if they are all accounted for. The missing sponge(s) can be identified.

Obviously, many modifications and variations of the present invention are possible in light of the above teachings. It is, therefore, to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

5,931,824

5

What is claimed and desired to be secured by Letters Patent of the United States is:

1. An automatic identification system for use with a reading device, said automatic identification system for accounting for and identifying a plurality of surgical sponges used during a surgical procedure, comprising:

machine-readable information located on a plurality of physically unconnected surgical sponges, wherein each sponge of said plurality of surgical sponges has its own differentiating machine-readable information located thereon which will not repeat on any other sponge used in a given surgical procedure, said machine-readable information being readable by a reading device, wherein the physically unconnected surgical sponges can be recognized and accounted for during a surgical procedure without reliance on human visual detection and counting ability to identify, differentiate and account for the surgical sponges.

2. The automatic identification system of claim 1, wherein said unique machine-readable information is located on a substrate, said substrate positioned on a respective surgical sponge.

3. The automatic identification system of claim 1, wherein each said surgical sponge further includes an x-ray detectable element.

4. The automatic identification system of claim 1, wherein said machine-readable information is contained within said surgical sponge.

5. The automatic identification system of claim 1, wherein said machine-readable information is contained on said surgical sponge.

6. The automatic identification system of claim 1, wherein each of said plurality of surgical sponges further comprises unique human-readable information thereon associated with its respective unique machine-readable information.

7. The automatic identification system of claim 1, wherein said information is made to be body fluid repellant to prevent obscuration thereof during reading.

8. The automatic identification system of claim 7, wherein said substrate comprises a thin film.

9. The automatic identification system of claim 2, wherein said substrate is formed of inert material.

10. The automatic identification system of claim 1, wherein said machine-readable information comprises bar code information.

11. The automatic identification system of claim 1, wherein said machine-readable information comprises compressed symbology.

12. The automatic identification system of claim 1, wherein said unique machine readable information is located on a substrate, said substrate positioned on a respective sponge, said substrate comprising an adhesive for attaching said substrate to the surgical sponge.

13. The automatic identification system of claim 12, wherein said adhesive comprises an x-ray detectable element.

6

14. The automatic identification system of claim 13, wherein said x-ray detectable element comprises barium sulfate.

15. The automatic identification system of claim 12, wherein said adhesive is of a type which provides attachment by the application of heat thereto.

16. The automatic identification system of claim 1, wherein said machine readable information is located on a substrate, said substrate being positioned on a respective sponge, said substrate comprising biologically inert material.

17. A surgical sponge system for accounting for and identifying a plurality of surgical sponges used during a surgical procedure, comprising:

a plurality of surgical sponges, each sponge having unique machine readable information located thereon, wherein said unique machine readable information is unique for at least one surgical procedure.

18. The automatic identification system of claim 17, wherein said unique machine-readable information is located on a substrate, said substrate positioned on a respective surgical sponge.

19. The automatic identification system of claim 17, wherein each said surgical sponge further includes an x-ray detectable element.

20. The automatic identification system of claim 17, wherein said machine-readable information is contained within said surgical sponge.

21. The automatic identification system of claim 17, wherein said machine-readable information is contained on said surgical sponge.

22. The automatic identification system of claim 17, wherein each of said plurality of surgical sponges further comprises unique human-readable information thereon associated with its respective unique machine-readable information.

23. The automatic identification system of claim 17, wherein said information is made to be body fluid repellant to prevent obscuration thereof during reading.

24. The automatic identification system of claim 23, wherein said substrate comprises a thin film.

25. The automatic identification system of claim 18, wherein said substrate is formed of inert material.

26. The automatic identification system of claim 17, wherein said machine-readable information comprises bar code information.

27. The automatic identification system of claim 17, wherein said machine-readable information comprises compressed symbology.

28. The automatic identification system of claim 17, wherein said unique machine readable information is located on a substrate, said substrate positioned on a respective sponge, said substrate comprising an adhesive for attaching said substrate to the surgical sponge.

\* \* \* \* \*

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 5,931,824

DATED : 08/03/99

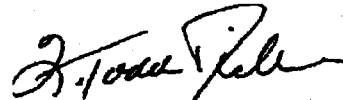
INVENTOR(S) : WILLIAM W. STEWART and BRIAN E. STEWART

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 5, Line 17, after "identify" delete "." and substitute therefor --, --.

Signed and Sealed this  
Twenty-fifth Day of April, 2000

Attest:



Q. TODD DICKINSON

Attesting Officer

Director of Patents and Trademarks



US005931824C1

(12) **EX PARTE REEXAMINATION CERTIFICATE** (6311th)  
**United States Patent**  
**Stewart et al.**

(10) Number: **US 5,931,824 C1**  
 (45) Certificate Issued: **Jul. 22, 2008**

(54) **IDENTIFICATION AND ACCOUNTABILITY  
 SYSTEM FOR SURGICAL SPONGES**

(76) Inventors: **William W. Stewart, 426 N. Foy's Rd.,  
 Kalispell, MT (US) 59901; Brian E.  
 Stewart, 11982 Kiowa 306, Los  
 Angeles, CA (US) 90049**

**Reexamination Request:**  
 No. 90/007,051, May 21, 2004

**Reexamination Certificate for:**

Patent No.: **5,931,824**  
 Issued: **Aug. 3, 1999**  
 Appl. No.: **08/921,430**  
 Filed: **Aug. 29, 1997**

4,943,939 A	*	7/1990	Hoover	702/128
5,057,095 A	*	10/1991	Fabian	
5,074,840 A	*	12/1991	Yoon	604/15
5,231,273 A	*	7/1993	Caswell et al.	235/385
5,374,813 A	*	12/1994	Shipp	235/375
5,443,082 A	*	8/1995	Mewburn	
5,456,718 A	*	10/1995	Szymaitis	
5,554,841 A	*	9/1996	Kost et al.	235/494
5,610,811 A	*	3/1997	Honda	705/2
5,629,498 A	*	5/1997	Pollock et al.	177/15
5,637,850 A	*	6/1997	Honda	235/454
5,650,596 A	*	7/1997	Morris et al.	177/25.13
5,678,569 A	*	10/1997	Chew et al.	128/897
5,805,451 A	*	9/1998	Speas et al.	700/110
5,923,001 A	*	7/1999	Morris et al.	177/245
5,991,728 A	*	11/1999	DeBusk et al.	705/2
5,996,889 A	*	12/1999	Fuchs et al.	235/375
2002/0049650 A1	*	4/2002	Reff	705/29

Certificate of Correction issued Apr. 25, 2000.

**Related U.S. Application Data**

(60) Provisional application No. 60/025,629, filed on Sep. 4, 1996.

(51) Int. Cl.  
**A61F 13/15** (2006.01)  
**A61F 13/20** (2006.01)

(52) U.S. Cl. .... 604/368; 604/362

(58) Field of Classification Search .... 604/362  
 See application file for complete search history.

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

3,481,462 A	*	12/1969	Chapel	206/438
3,915,172 A	*	10/1975	Wichterle et al.	604/8
3,948,390 A	*	4/1976	Ferreri	206/370
4,105,115 A	*	8/1978	Horvath et al.	206/370
4,105,800 A	*	8/1978	Jahns et al.	426/61
4,264,575 A	*	4/1981	Zimmerman et al.	424/432
4,355,020 A	*	10/1982	Kuy	424/404
4,477,256 A	*	10/1984	Hirsch	604/362
4,711,996 A	*	12/1987	Drexler	235/468
4,889,230 A	*	12/1989	Zachry	206/362

**FOREIGN PATENT DOCUMENTS**

EP	948940 A1	*	10/1999
FR	2580172 A1	*	10/1986
GB	884143 A		12/1961
GB	1274061	*	5/1975
WO	WO 9115159 A1	*	10/1991
WO	WO 9417767 A1	*	8/1994
WO	WO 9422580 A1	*	10/1994
WO	WO 9527252 A1	*	10/1995
WO	WO 9830166 A1	*	7/1998

**OTHER PUBLICATIONS**

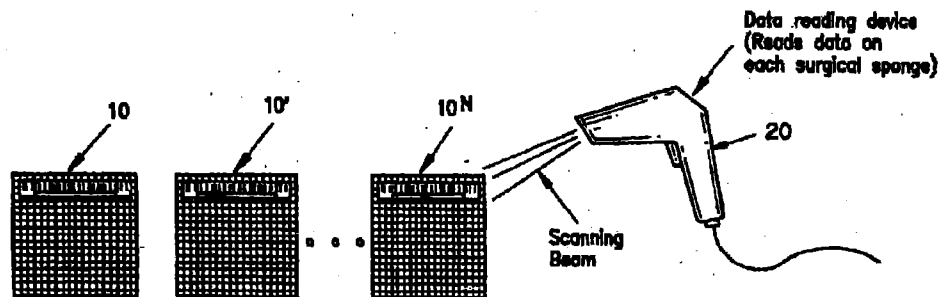
Translation of 94/17767.\*

\* cited by examiner

Primary Examiner—David O. Reip

(57) **ABSTRACT**

An automatic identification system for accounting for and identifying a plurality of surgical sponges used during a surgical procedure. Machine-readable information is located on a plurality of surgical sponges. Each sponge of the plurality of surgical sponges has unique machine-readable information located thereon. The unique machine-readable information is unique for at least one surgical procedure.





US 5,931,824 C1

1

**EX PARTE  
REEXAMINATION CERTIFICATE  
ISSUED UNDER 35 U.S.C. 307**

THE PATENT IS HEREBY AMENDED AS  
INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

ONLY THOSE PARAGRAPHS OF THE  
SPECIFICATION AFFECTED BY AMENDMENT  
ARE PRINTED HEREIN.

Column 1, lines 4-5:

This application is a [provision] provisional of Ser. No. 60/025,629 filed Sep. 4, [1994] 1996.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claims 4 and 20 are cancelled.

Claims 1, 8, 17 and 24 are determined to be patentable as amended.

Claims 2, 3, 5-7, 9-16, 18, 19, 21-23 and 25-28, dependent on an amended claim, are determined to be patentable.

New claims 29-40 are added and determined to be patentable.

1. An automatic identification system for use with a reading device, said automatic identification system for accounting for and identifying a plurality of surgical sponges used during a surgical procedure, comprising:

machine-readable information located on a plurality of physically unconnected surgical sponges, wherein each sponge of said plurality of surgical sponges has its own differentiating machine-readable information located thereon *and which is different from and which will not repeat on any other sponge used in a given surgical procedure*, said machine-readable information being readable by a reading device, wherein the physically unconnected surgical sponges can be recognized and accounted for during a surgical procedure without reliance on human visual detection and counting ability to identify, differentiate and account for the surgical sponges.

8. The automatic identification system of claim [7] 2, wherein said substrate comprises a thin film.

17. A surgical sponge system for accounting for and identifying a plurality of surgical sponges used during a surgical procedure, comprising:

a plurality of surgical sponges, each sponge having a unique [machine readable] machine-readable information located thereon *and which is not repeated on any*

2

*other of the plurality of sponges, wherein said unique [machine readable] machine-readable information is unique for at least one surgical procedure.*

24. The automatic identification system of claim [23] 18, wherein said substrate comprises a thin film.

29. An automatic identification system, said automatic identification system for accounting for and identifying a plurality of surgical sponges used during a surgical procedure, comprising:

an automatic identification system according to claim 1; and

a data reading device capable of reading the machine-readable information located thereon each surgical sponge.

30. The automatic identification system of claim 29, wherein the data reading device comprises a scanner having a scanning beam.

31. A surgical sponge system, comprising:

a plurality of surgical sponges in a number sufficient to perform a given surgical procedure;

wherein each surgical sponge in said plurality has unique machine-readable information located thereon and which distinguishes each individual surgical sponge from all other individual sponges in said plurality of sponges, wherein such machine-readable information is adapted to allow surgical sponges used in said given surgical procedure to be automatically scanned before the procedure and again during or after the procedure to identify missing surgical sponges.

32. The surgical sponge system of claim 31, wherein said unique machine-readable information is located on a substrate, said substrate positioned on the surface of a respective surgical sponge.

33. The surgical sponge system of claim 31, wherein each said surgical sponge further includes an x-ray detectable element.

34. The surgical sponge system of claim 31, wherein each of said plurality of surgical sponges further comprises unique human-readable information thereon associated with its respective unique machine-readable information.

35. The surgical sponge system of claim 31, wherein said information is made to be body fluid repellant to prevent obscuration thereof during reading.

36. The surgical sponge system of claim 32, wherein said substrate comprises a thin film.

37. The surgical sponge system of claim 32, wherein said substrate is formed of inert material.

38. The surgical sponge system of claim 31, wherein said machine-readable information comprises bar code information.

39. The surgical sponge system of claim 31, wherein said machine-readable information comprises compressed symbology.

40. The surgical sponge system of claim 31, wherein said unique machine-readable information is located on a substrate, said substrate positioned on a respective sponge, said substrate comprising an adhesive for attaching said substrate to the surgical sponge.

\* \* \* \* \*

**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA**

**NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY**

This case has been assigned to District Judge David O. Carter and the assigned discovery Magistrate Judge is Marc Goldman.

The case number on all documents filed with the Court should read as follows:

**SACV12- 937 DOC (MLGx)**

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

=====

**NOTICE TO COUNSEL**

*A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).*

Subsequent documents must be filed at the following location:

☐ **Western Division**  
312 N. Spring St., Rm. G-8  
Los Angeles, CA 90012

☒ **Southern Division**  
411 West Fourth St., Rm. 1-053  
Santa Ana, CA 92701-4516

☐ **Eastern Division**  
3470 Twelfth St., Rm. 134  
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.



**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA**  
**CIVIL COVER SHEET**

<b>I (a) PLAINTIFFS</b> (Check box if you are representing yourself <input type="checkbox"/> PATIENT SAFETY TECHNOLOGIES, INC.		<b>DEFENDANTS</b> CLEARCOUNT MEDICAL SOLUTIONS, INC.	
<b>(b) Attorneys</b> (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)  Sara N. Kerrane (SBN 259239), K&L Gates LLP 1900 Main Street, Ste. 600, Irvine, CA 92614 Tel: 949-253-0900		Attorneys (If Known)	

<b>II. BASIS OF JURISDICTION</b> (Place an X in one box only.)  <input type="checkbox"/> 1 U.S. Government Plaintiff <input checked="" type="checkbox"/> 3 Federal Question (U.S. Government Not a Party)  <input type="checkbox"/> 2 U.S. Government Defendant <input type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)	<b>III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only</b> (Place an X in one box for plaintiff and one for defendant.) <table style="width:100%; border: none;"> <tr> <td style="width:33%; border: none;">Citizen of This State</td> <td style="width:10%; border: none; text-align: center;">PTF DEF</td> <td style="width:10%; border: none; text-align: center;"><input type="checkbox"/> 1 <input type="checkbox"/> 1</td> <td style="width:33%; border: none;">Incorporated or Principal Place of Business in this State</td> <td style="width:10%; border: none; text-align: center;">PTF DEF</td> <td style="width:10%; border: none; text-align: center;"><input type="checkbox"/> 4 <input type="checkbox"/> 4</td> </tr> <tr> <td style="border: none;">Citizen of Another State</td> <td style="border: none; text-align: center;">PTF DEF</td> <td style="border: none; text-align: center;"><input type="checkbox"/> 2 <input type="checkbox"/> 2</td> <td style="border: none;">Incorporated and Principal Place of Business in Another State</td> <td style="border: none; text-align: center;">PTF DEF</td> <td style="border: none; text-align: center;"><input type="checkbox"/> 5 <input type="checkbox"/> 5</td> </tr> <tr> <td style="border: none;">Citizen or Subject of a Foreign Country</td> <td style="border: none; text-align: center;">PTF DEF</td> <td style="border: none; text-align: center;"><input type="checkbox"/> 3 <input type="checkbox"/> 3</td> <td style="border: none;">Foreign Nation</td> <td style="border: none; text-align: center;">PTF DEF</td> <td style="border: none; text-align: center;"><input type="checkbox"/> 6 <input type="checkbox"/> 6</td> </tr> </table>	Citizen of This State	PTF DEF	<input type="checkbox"/> 1 <input type="checkbox"/> 1	Incorporated or Principal Place of Business in this State	PTF DEF	<input type="checkbox"/> 4 <input type="checkbox"/> 4	Citizen of Another State	PTF DEF	<input type="checkbox"/> 2 <input type="checkbox"/> 2	Incorporated and Principal Place of Business in Another State	PTF DEF	<input type="checkbox"/> 5 <input type="checkbox"/> 5	Citizen or Subject of a Foreign Country	PTF DEF	<input type="checkbox"/> 3 <input type="checkbox"/> 3	Foreign Nation	PTF DEF	<input type="checkbox"/> 6 <input type="checkbox"/> 6
Citizen of This State	PTF DEF	<input type="checkbox"/> 1 <input type="checkbox"/> 1	Incorporated or Principal Place of Business in this State	PTF DEF	<input type="checkbox"/> 4 <input type="checkbox"/> 4														
Citizen of Another State	PTF DEF	<input type="checkbox"/> 2 <input type="checkbox"/> 2	Incorporated and Principal Place of Business in Another State	PTF DEF	<input type="checkbox"/> 5 <input type="checkbox"/> 5														
Citizen or Subject of a Foreign Country	PTF DEF	<input type="checkbox"/> 3 <input type="checkbox"/> 3	Foreign Nation	PTF DEF	<input type="checkbox"/> 6 <input type="checkbox"/> 6														

**IV. ORIGIN** (Place an X in one box only.)

☒ 1 Original Proceeding    
 ☐ 2 Removed from State Court    
 ☐ 3 Remanded from Appellate Court    
 ☐ 4 Reinstated or Reopened    
 ☐ 5 Transferred from another district (specify):    
 ☐ 6 Multi-District Litigation    
 ☐ 7 Appeal to District Judge from Magistrate Judge

**V. REQUESTED IN COMPLAINT:** JURY DEMAND: ☒ Yes ☐ No (Check 'Yes' only if demanded in complaint.)

**CLASS ACTION under F.R.C.P. 23:** ☐ Yes ☒ No    
 **MONEY DEMANDED IN COMPLAINT:** \$ \_\_\_\_\_

**VI. CAUSE OF ACTION** (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

<b>VII. NATURE OF SUIT</b> (Place an X in one box only.)					
<b>OTHER STATUTES</b> <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce/ICC Rates/etc. <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Act <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Info. Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes	<b>CONTRACT</b> <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loan (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise <b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>TORTS</b> <b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Fed. Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury-Med Malpractice <input type="checkbox"/> 365 Personal Injury-Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <b>IMMIGRATION</b> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 463 Habeas Corpus-Alien Detainee <input type="checkbox"/> 465 Other Immigration Actions	<b>TORTS</b> <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability <b>BANKRUPTCY</b> <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 <b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 American with Disabilities - Employment <input type="checkbox"/> 446 American with Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 Habeas Corpus <input type="checkbox"/> 535 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus/Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <b>FORFEITURE/PENALTY</b> <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related <input type="checkbox"/> 625 Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number:

**SACV12-00937 DOC (MLGx)**

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA**  
**CIVIL COVER SHEET**

**VIII(a). IDENTICAL CASES:** Has this action been previously filed in this court and dismissed, remanded or closed? ☒ No ☐ Yes  
 If yes, list case number(s): \_\_\_\_\_

**VIII(b). RELATED CASES:** Have any cases been previously filed in this court that are related to the present case? ☒ No ☐ Yes  
 If yes, list case number(s): \_\_\_\_\_

**Civil cases are deemed related if a previously filed case and the present case:**

- (Check all boxes that apply) ☐ A. Arise from the same or closely related transactions, happenings, or events; or  
☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or  
☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or  
☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

**IX. VENUE:** (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.  
☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Orange County	

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.  
☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	Pennsylvania

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.  
**Note: In land condemnation cases, use the location of the tract of land involved.**

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Orange County	

\* Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties

**Note:** In land condemnation cases, use the location of the tract of land involved

**X. SIGNATURE OF ATTORNEY (OR PRO PER):**  Date June 12, 2012

**Notice to Counsel/Parties:** The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

**Key to Statistical codes relating to Social Security Cases:**

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

## Name &amp; Address:

Sara N. Kerrane (SBN 259239)  
 K&L Gates LLP  
 1900 Main Street, Suite 600, Irvine, CA 92614  
 Tel: 949/253-0900; Fax: 949/253-0902

UNITED STATES DISTRICT COURT  
 CENTRAL DISTRICT OF CALIFORNIA

PATIENT SAFETY TECHNOLOGIES, INC.,

CASE NUMBER

PLAINTIFF(S)

SACV12-00937 DOC (MLGx)

v.

CLEARCOUNT MEDICAL SOLUTIONS, INC.,

SUMMONS

DEFENDANT(S).

TO: DEFENDANT(S):

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it), you must serve on the plaintiff an answer to the attached ☒ complaint ☐ amended complaint ☐ counterclaim ☐ cross-claim or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff's attorney, Sara N. Kerrane, whose address is K&L Gates LLP, 1900 Main Street, Suite 600, Irvine, CA 92614. If you fail to do so, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

Clerk, U.S. District Court

Dated: June 12, 2012By: N. B.

Deputy Clerk

(Seal of the Court)



1191

[Use 60 days if the defendant is the United States or a United States agency, or is an officer or employee of the United States. Allowed 60 days by Rule 12(a)(3)].