US010046112B2

(12) **United States Patent**
Oruklu et al.

(10) **Patent No.: US 10,046,112 B2**
(45) **Date of Patent: Aug. 14, 2018**

(54) **MULTI-SENSOR INFUSION SYSTEM FOR DETECTING AIR OR AN OCCLUSION IN THE INFUSION SYSTEM**

(71) Applicant: **ICU Medical, Inc.**, San Clemente, CA (US)

(72) Inventors: **Meriyan Oruklu**, Chicago, IL (US); **Timothy L. Ruchti**, Gurnee, IL (US); **Paul T. Kotnik**, Commerce Township, MI (US); **Anatoly S. Belkin**, Glenview, IL (US); **Brian G. Markey**, Park Forest, IL (US)

(73) Assignee: **ICU Medical, Inc.**, San Clemente, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 899 days.

(21) Appl. No.: **14/285,797**

(22) Filed: **May 23, 2014**

(65) **Prior Publication Data**

US 2014/0350513 A1 Nov. 27, 2014

Related U.S. Application Data

(60) Provisional application No. 61/827,111, filed on May 24, 2013.

(51) **Int. Cl.**

A61M 5/168	(2006.01)
A61M 5/36	(2006.01)
A61M 5/50	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 5/16854*** (2013.01); ***A61M 5/365*** (2013.01); ***A61M 5/5086*** (2013.01);
(Continued)

(58) **Field of Classification Search**

CPC A61M 5/16854; A61M 2005/16854; A61M 5/365; A61M 5/5086; A61M 2205/332;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,401,337	A	9/1968	Beusman et al.
3,484,681	A	12/1969	Grady, Jr. et al.

(Continued)

FOREIGN PATENT DOCUMENTS

DE	31 12 762	1/1983
DE	34 35 647	7/1985

(Continued)

OTHER PUBLICATIONS

Alaedeen et al., "Total Parenteral Nutrition-Associated Hyperglycemia Correlates with Prolonged Mechanical Ventilation and Hospital Stay in Septic Infants", Journal of Pediatric Surgery, Jan. 2006, vol. 41, No. 1, pp. 239-244.

(Continued)

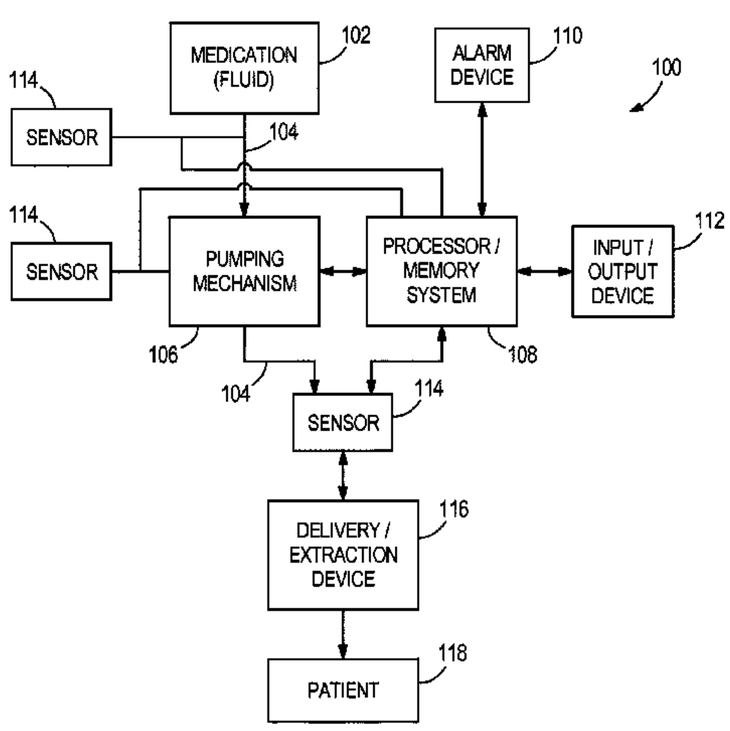
Primary Examiner — Lauren P Farrar

(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

An infusion system for being operatively connected to a fluid delivery line and to an infusion container includes a pump, a plurality of different types of sensors connected to the pump or the fluid delivery line, at least one processor, and a memory. The plurality of different types of sensors are configured to indicate whether air is in the fluid delivery line. The memory includes programming code for execution by the at least one processor. The programming code is configured to, based on measurements taken by the plurality of different types of sensors, determine: whether there is air in the fluid delivery line; whether there is a partial occlusion or a total occlusion in the fluid delivery line; or a percentage of the air present in the fluid delivery line or the probability of the air being in the fluid delivery line.

9 Claims, 13 Drawing Sheets



(52) **U.S. Cl.**
CPC *A61M 2005/16863* (2013.01); *A61M 2005/16868* (2013.01); *A61M 2005/16872* (2013.01); *A61M 2205/18* (2013.01); *A61M 2205/332* (2013.01); *A61M 2205/3317* (2013.01); *A61M 2205/3331* (2013.01); *A61M 2205/3351* (2013.01); *A61M 2205/3355* (2013.01); *A61M 2205/3576* (2013.01); *A61M 2205/52* (2013.01)

(58) **Field of Classification Search**
CPC A61M 2005/16872; A61M 2005/16868; A61M 2205/3355; A61M 2205/3351; A61M 2205/3331; A61M 2005/16863; A61M 2205/52; A61M 2205/3576; A61M 2205/3317; A61M 2205/18
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,699,320 A 10/1972 Zimmerman et al.
3,727,074 A 4/1973 Keller et al.
3,731,679 A 5/1973 Wilhelmson et al.
3,768,084 A 10/1973 Haynes
3,770,354 A 11/1973 Tsuruta et al.
3,778,702 A 12/1973 Finger
3,806,821 A 4/1974 Niemeyer et al.
3,854,038 A 12/1974 McKinley
3,886,459 A 5/1975 Hufford et al.
3,890,554 A 6/1975 Yoshitake et al.
3,898,637 A 8/1975 Wolstenholme
3,909,693 A 9/1975 Yoshitake et al.
3,910,701 A 10/1975 Henderson
3,911,343 A 10/1975 Oster
3,919,608 A 11/1975 Usami et al.
3,921,622 A 11/1975 Cole
3,933,431 A 1/1976 Trujillo et al.
3,935,876 A 2/1976 Massie et al.
3,966,358 A 6/1976 Heimes et al.
3,971,980 A 7/1976 Jungfer et al.
3,974,681 A 8/1976 Namery
3,990,444 A 11/1976 Vial
3,997,888 A 12/1976 Kremer
4,014,206 A 3/1977 Taylor
4,055,175 A 10/1977 Clemens et al.
4,068,521 A 1/1978 Cosentino et al.
4,114,144 A 9/1978 Hyman
4,151,845 A 5/1979 Clemens
4,155,362 A 5/1979 Jess
4,181,610 A 1/1980 Shintani et al.
4,210,138 A 7/1980 Jess et al.
4,213,454 A 7/1980 Shim
4,217,993 A 8/1980 Jess et al.
4,240,438 A 12/1980 Updike et al.
4,244,365 A 1/1981 McGill
4,256,437 A 3/1981 Brown
4,264,861 A 4/1981 Radu et al.
4,277,226 A 7/1981 Archibald et al.
4,278,085 A 7/1981 Shim
4,280,495 A 7/1981 Lampert
4,282,872 A 8/1981 Franetzki et al.
4,286,202 A 8/1981 Clancy et al.
4,290,346 A 9/1981 Bujan
4,291,692 A 9/1981 Bowman et al.
4,308,866 A 1/1982 Jeliffe
4,312,341 A 1/1982 Zissimopoulos
4,319,568 A 3/1982 Tregoning
4,322,201 A 3/1982 Archibald
4,323,849 A 4/1982 Smith
4,333,045 A 6/1982 Oltendorf
4,344,429 A 8/1982 Gupton et al.
4,346,707 A 8/1982 Whitney et al.
4,360,019 A 11/1982 Portner et al.
4,366,384 A 12/1982 Jensen
4,367,736 A 1/1983 Gupton
4,370,983 A 2/1983 Lichtenstein et al.
4,373,527 A 2/1983 Fischell
4,381,005 A 4/1983 Bujan
4,384,578 A 5/1983 Winkler
4,385,247 A 5/1983 Satomi
4,392,849 A 7/1983 Petre et al.
4,394,862 A 7/1983 Shim
4,395,259 A 7/1983 Prestele et al.
4,407,659 A 10/1983 Adam
4,411,651 A 10/1983 Schulman
4,418,565 A 12/1983 St. John
4,443,218 A 4/1984 Decant, Jr. et al.
4,444,546 A 4/1984 Pazemenas
4,447,191 A 5/1984 Bilstad et al.
4,447,224 A 5/1984 Decant, Jr. et al.
4,457,751 A 7/1984 Rodler
4,463,301 A 7/1984 Moriguchi et al.
4,464,170 A 8/1984 Clemens
4,468,222 A 8/1984 Lundquist
4,468,601 A 8/1984 Chamran et al.
4,469,481 A 9/1984 Kobayashi
4,475,666 A 10/1984 Bilbrey et al.
4,475,901 A 10/1984 Kraegen et al.
4,477,756 A 10/1984 Moriguchi
4,479,760 A 10/1984 Bilstad et al.
4,480,218 A 10/1984 Hair
4,487,601 A 12/1984 Lindemann
4,492,909 A 1/1985 Hartwig
4,496,346 A 1/1985 Mosteller
4,498,843 A 2/1985 Schneider et al.
4,501,531 A 2/1985 Bilstad et al.
4,510,266 A 4/1985 Eertink
4,515,584 A 5/1985 Abe et al.
4,519,792 A 5/1985 Dawe
4,525,163 A 6/1985 Slavik et al.
4,526,568 A 7/1985 Clemens et al.
4,529,401 A 7/1985 Leslie et al.
4,543,955 A 10/1985 Schroeppel
4,553,958 A 11/1985 LeCocq
4,559,036 A 12/1985 Wunsch
4,559,037 A 12/1985 Franetzki et al.
4,559,454 A 12/1985 Kramer
4,565,500 A 1/1986 Jeensalaute et al.
4,583,981 A 4/1986 Urquhart et al.
4,587,473 A 5/1986 Turvey
4,607,520 A 8/1986 Dam
4,624,661 A 11/1986 Arimond
4,627,835 A 12/1986 Fenton, Jr.
4,633,878 A 1/1987 Bombardieri
4,634,426 A 1/1987 Kamen
4,634,427 A 1/1987 Hannula et al.
4,636,144 A 1/1987 Abe et al.
4,648,869 A 3/1987 Bobo, Jr.
4,652,260 A 3/1987 Fenton, Jr. et al.
4,658,244 A 4/1987 Meijer
4,668,945 A 5/1987 Aldrovandi et al.
4,673,334 A 6/1987 Allington et al.
4,673,389 A 6/1987 Archibald et al.
4,676,776 A 6/1987 Howson et al.
4,677,359 A 6/1987 Enami et al.
4,678,979 A 7/1987 Hori
4,678,998 A 7/1987 Muramatsu
4,679,562 A 7/1987 Luksha
4,683,428 A 7/1987 Gete
4,685,903 A 8/1987 Cable et al.
4,690,673 A 9/1987 Bloomquist
4,691,153 A 9/1987 Nishimura
4,692,145 A 9/1987 Weyant
4,696,671 A 9/1987 Epstein et al.
4,697,129 A 9/1987 Enami et al.
4,705,506 A 11/1987 Archibald et al.
4,710,106 A 12/1987 Iwata et al.
4,714,462 A 12/1987 DiDomenico
4,714,463 A 12/1987 Archibald et al.
4,718,576 A 1/1988 Tamura et al.
4,722,734 A 2/1988 Kolin
4,731,051 A 3/1988 Fischell
4,731,057 A 3/1988 Tanaka et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,737,711 A 4/1988 O'Hare
4,739,346 A 4/1988 Buckley
4,741,732 A 5/1988 Crankshaw et al.
4,751,445 A 6/1988 Sakai
4,756,706 A 7/1988 Kerns et al.
4,764,166 A 8/1988 Spani et al.
4,764,697 A 8/1988 Christiaens
4,776,842 A 10/1988 Franetzki et al.
4,784,576 A 11/1988 Bloom et al.
4,785,184 A 11/1988 Bien et al.
4,785,799 A 11/1988 Schoon et al.
4,785,969 A 11/1988 McLaughlin
4,797,655 A 1/1989 Orndal et al.
4,803,389 A 2/1989 Ogawa et al.
4,803,625 A 2/1989 Fu et al.
4,818,186 A 4/1989 Pastrone et al.
4,821,558 A 4/1989 Pastrone et al.
4,828,545 A 5/1989 Epstein et al.
4,829,448 A 5/1989 Balding et al.
4,838,856 A 6/1989 Mulreany et al.
4,838,857 A 6/1989 Strowe et al.
4,840,542 A 6/1989 Abbott
4,842,584 A 6/1989 Pastrone et al.
4,845,487 A 7/1989 Frantz et al.
4,851,755 A 7/1989 Fincher
4,854,324 A 8/1989 Hirschman et al.
4,857,050 A 8/1989 Lentz et al.
4,858,154 A 8/1989 Anderson et al.
4,865,584 A 9/1989 Epstein et al.
4,874,359 A 10/1989 White et al.
4,882,575 A 11/1989 Kawahara
4,884,013 A 11/1989 Jackson et al.
4,884,065 A 11/1989 Crouse et al.
4,898,578 A 2/1990 Rubalcaba, Jr.
4,906,103 A 3/1990 Kao
4,908,017 A 3/1990 Howson et al.
4,910,475 A 3/1990 Lin
4,919,596 A 4/1990 Slate et al.
4,925,444 A 5/1990 Orkin et al.
4,927,411 A 5/1990 Laenen et al.
4,938,079 A 7/1990 Goldberg
4,943,279 A 7/1990 Samiotes et al.
4,946,439 A 8/1990 Eggers
4,950,235 A 8/1990 Slate et al.
4,966,579 A 10/1990 Polaschegg
4,968,941 A 11/1990 Rogers
4,976,687 A 12/1990 Martin
4,978,335 A 12/1990 Arthur, III
4,979,940 A 12/1990 Lapp et al.
4,981,467 A 1/1991 Bobo et al.
5,000,663 A 3/1991 Gorton
5,000,739 A 3/1991 Kulisz et al.
5,010,473 A 4/1991 Jacobs
5,018,945 A 5/1991 D'Silva
5,026,348 A 6/1991 Venegas
5,028,857 A 7/1991 Taghezout
5,032,112 A 7/1991 Fairchild et al.
5,034,004 A 7/1991 Crankshaw
5,041,086 A 8/1991 Koenig et al.
5,043,706 A 8/1991 Oliver
5,053,747 A 10/1991 Slate et al.
5,055,761 A 10/1991 Mills
5,058,161 A 10/1991 Weiss
5,059,171 A 10/1991 Bridge
5,064,412 A 11/1991 Henke et al.
5,078,683 A 1/1992 Sancoff et al.
5,084,663 A 1/1992 Olsson
5,084,828 A 1/1992 Kaufman et al.
5,088,981 A 2/1992 Howson et al.
5,097,505 A 3/1992 Weiss
5,100,380 A 3/1992 Epstein et al.
5,102,392 A 4/1992 Sakai et al.
5,104,374 A 4/1992 Bishko et al.
5,108,367 A 4/1992 Epstein et al.
5,109,850 A 5/1992 Blanco et al.
5,116,203 A 5/1992 Nartwick et al.
5,123,275 A 6/1992 Daoud et al.
5,124,627 A 6/1992 Okada
5,125,499 A 6/1992 Saathoff et al.
5,131,816 A 7/1992 Brown
5,132,603 A 7/1992 Yoshimoto
5,153,827 A 10/1992 Coutre et al.
5,161,222 A 11/1992 Montejo et al.
5,176,631 A 1/1993 Koenig
5,176,646 A 1/1993 Kuroda
5,179,340 A 1/1993 Rogers
5,180,287 A * 1/1993 Natwick A61M 5/142 340/606
5,181,910 A 1/1993 Scanlon
5,188,603 A 2/1993 Vaillancourt
5,190,522 A 3/1993 Wocicki et al.
5,194,796 A 3/1993 Domeki et al.
5,198,776 A 3/1993 Carr
5,205,819 A 4/1993 Ross et al.
5,206,522 A 4/1993 Danby et al.
5,211,626 A 5/1993 Frank et al.
5,213,573 A 5/1993 Sorich et al.
5,216,597 A 6/1993 Beckers
5,219,099 A 6/1993 Spence et al.
5,219,327 A 6/1993 Okada
5,221,268 A 6/1993 Barton et al.
5,229,713 A 7/1993 Bullock et al.
5,237,309 A 8/1993 Frantz et al.
5,243,982 A 9/1993 Möstl et al.
5,244,463 A 9/1993 Cordner, Jr. et al.
5,256,156 A 10/1993 Kern et al.
5,256,157 A 10/1993 Samiotes et al.
5,260,665 A 11/1993 Goldberg
5,257,206 A 12/1993 Hanson
5,274,316 A 12/1993 Evans et al.
5,283,510 A 2/1994 Tamaki et al.
5,287,851 A 2/1994 Beran et al.
5,292,306 A 3/1994 Wynkoop et al.
5,295,967 A 3/1994 Rondelet et al.
5,298,021 A 3/1994 Sherer
5,304,126 A 4/1994 Epstein et al.
5,317,506 A 5/1994 Coutre et al.
5,319,363 A 6/1994 Welch et al.
5,321,392 A 6/1994 Skakoon et al.
5,330,634 A 7/1994 Wong et al.
5,336,051 A 8/1994 Tamari
5,338,157 A 8/1994 Blomquist
5,342,298 A 8/1994 Michaels
5,343,734 A 9/1994 Maeda et al.
5,356,378 A 10/1994 Doan et al.
5,359,271 A 10/1994 Husher
5,364,346 A 11/1994 Schrezenmeir
5,366,346 A 11/1994 Danby
5,368,562 A 11/1994 Blomquist et al.
5,374,865 A 12/1994 Yoshimura et al.
5,376,070 A 12/1994 Purvis et al.
5,378,231 A 1/1995 Johnson et al.
5,389,071 A 2/1995 Kawahara et al.
5,389,078 A 2/1995 Zalesky et al.
5,394,732 A 3/1995 Johnson et al.
5,399,171 A 3/1995 Bowman et al.
5,408,326 A 4/1995 Priestley
5,415,528 A 5/1995 Ogden et al.
5,417,222 A 5/1995 Dempsey et al.
5,418,443 A 5/1995 Kikuchi
5,423,748 A 6/1995 Uhala
5,423,759 A 6/1995 Campbell
5,428,284 A 6/1995 Kaneda et al.
5,429,485 A 7/1995 Dodge
5,429,601 A 7/1995 Conley
5,429,602 A 7/1995 Hauser
5,431,627 A 7/1995 Pastrone et al.
5,434,508 A 7/1995 Ishida
5,437,624 A 8/1995 Langley et al.
5,444,316 A 8/1995 Ohya et al.
5,444,378 A 8/1995 Rogers
5,445,621 A 8/1995 Poli et al.
5,451,881 A 9/1995 Finger
5,455,423 A 10/1995 Mount et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,455,851 A 10/1995 Chaco et al.
5,464,392 A 11/1995 Epstein et al.
5,465,082 A 11/1995 Chaco
5,469,851 A 11/1995 Lipschutz
5,480,294 A 1/1996 Di Perna et al.
5,485,408 A 1/1996 Blomquist
5,486,286 A 1/1996 Peterson et al.
5,489,265 A 2/1996 Montalvo et al.
5,496,273 A 3/1996 Pastrone et al.
5,505,696 A 4/1996 Miki
5,505,828 A 4/1996 Wong et al.
5,507,288 A 4/1996 Bocker et al.
5,520,637 A 5/1996 Pager et al.
5,522,798 A 6/1996 Johnson et al.
5,527,630 A 6/1996 Nagata
5,533,389 A 7/1996 Kamen et al.
5,537,853 A 7/1996 Finburgh et al.
5,542,040 A 7/1996 Chang et al.
5,545,140 A 8/1996 Conero et al.
5,547,470 A 8/1996 Johnson et al.
5,554,115 A 9/1996 Thomas et al.
5,562,615 A 10/1996 Nassif
5,563,486 A 10/1996 Yamamoto et al.
5,572,105 A 11/1996 Nojima et al.
5,584,667 A 12/1996 Davis
5,586,868 A 12/1996 Lawless et al.
5,590,653 A 1/1997 Aida et al.
5,594,786 A 1/1997 Chaco et al.
5,601,420 A 2/1997 Warner et al.
5,616,124 A 4/1997 Hague et al.
5,620,312 A 4/1997 Hyman et al.
5,620,608 A 4/1997 Rosa et al.
5,626,140 A 5/1997 Feldman et al.
5,626,563 A 5/1997 Dodge et al.
5,627,443 A 5/1997 Kimura et al.
5,628,731 A 5/1997 Dodge et al.
5,630,710 A 5/1997 Tune et al.
5,634,896 A 6/1997 Bryant et al.
5,637,095 A 6/1997 Nason et al.
5,640,075 A 6/1997 Brasseur et al.
5,640,150 A 6/1997 Atwater
5,643,212 A 7/1997 Coutre et al.
5,648,710 A 7/1997 Ikeda
5,658,133 A 8/1997 Anderson et al.
5,658,250 A 8/1997 Blomquist et al.
5,659,234 A 8/1997 Cresens
5,662,612 A 9/1997 Niehoff
5,665,065 A 9/1997 Colman et al.
5,669,877 A 9/1997 Blomquist
5,672,154 A 9/1997 Sillén et al.
5,681,285 A 10/1997 Ford et al.
5,681,286 A 10/1997 Niehoff
5,685,844 A 11/1997 Marttila
5,687,717 A 11/1997 Halpern et al.
5,689,229 A 11/1997 Chaco et al.
5,691,613 A 11/1997 Gutwillinger
5,695,464 A 12/1997 Viallet
5,695,473 A 12/1997 Olsen
5,697,899 A 12/1997 Hillman et al.
5,712,795 A 1/1998 Layman et al.
5,713,856 A 2/1998 Eggers et al.
5,718,562 A 2/1998 Lawless et al.
5,718,569 A 2/1998 Holst
5,720,721 A 2/1998 Dumas et al.
5,733,259 A 3/1998 Valcke et al.
5,738,659 A 4/1998 Neer et al.
5,744,027 A 4/1998 Connell et al.
5,744,929 A 4/1998 Miyazaki
5,752,813 A 5/1998 Tyner et al.
5,755,691 A 5/1998 Hilborne
5,761,072 A 6/1998 Bardsley, Jr. et al.
5,764,034 A 6/1998 Bowman et al.
5,772,635 A 6/1998 Dastur et al.
5,778,256 A 7/1998 Darbee
5,781,442 A 7/1998 Engleson et al.
5,782,805 A 7/1998 Meinzer et al.
5,788,669 A 8/1998 Peterson
5,789,923 A 8/1998 Shimoyama et al.
5,793,211 A 8/1998 Shimoyama et al.
5,795,327 A 8/1998 Wilson et al.
5,798,934 A 8/1998 Saigo et al.
5,800,387 A * 9/1998 Duffy A61M 5/142 604/505
5,807,322 A 9/1998 Lindsey et al.
5,810,770 A 9/1998 Chin et al.
5,813,972 A 9/1998 Nazarian et al.
5,814,004 A 9/1998 Tamari
5,814,015 A 9/1998 Gargano et al.
5,816,779 A 10/1998 Lawless et al.
5,822,715 A 10/1998 Worthington et al.
5,827,179 A 10/1998 Lichter et al.
5,832,448 A 11/1998 Brown
5,836,910 A 11/1998 Duffy et al.
5,841,261 A 11/1998 Nojima et al.
5,841,284 A 11/1998 Takahashi
5,843,035 A 12/1998 Bowman
5,850,344 A 12/1998 Conkright
5,857,843 A 1/1999 Leason et al.
5,865,805 A 2/1999 Ziemba
5,867,821 A 2/1999 Ballantyne et al.
5,871,465 A 2/1999 Vasko
5,872,453 A 2/1999 Shimoyama et al.
5,875,195 A 2/1999 Dixon
5,882,300 A 3/1999 Malinouskas et al.
5,882,339 A 3/1999 Beiser et al.
5,885,245 A 3/1999 Lynch et al.
5,889,379 A 3/1999 Yanagi et al.
5,894,209 A 4/1999 Takagi et al.
5,897,493 A 4/1999 Brown
5,897,498 A 4/1999 Canfield, II et al.
5,898,292 A 4/1999 Takemoto et al.
5,901,150 A 5/1999 Jhuboo et al.
5,910,252 A 6/1999 Truitt et al.
5,915,240 A 6/1999 Karpf
5,920,263 A 7/1999 Huttenhoff et al.
5,923,159 A 7/1999 Ezell
5,924,074 A 7/1999 Evans
5,932,987 A 8/1999 McLoughlin
5,935,099 A 8/1999 Peterson et al.
5,941,846 A 8/1999 Duffy et al.
5,954,527 A 9/1999 Jhuboo et al.
5,956,501 A 9/1999 Brown
5,957,885 A 9/1999 Bollish et al.
5,971,594 A 10/1999 Sahai et al.
5,973,497 A 10/1999 Bergk et al.
5,975,081 A 11/1999 Hood et al.
5,989,222 A 11/1999 Cole et al.
5,991,525 A 11/1999 Shah et al.
5,993,393 A 11/1999 Ryan et al.
5,994,876 A 11/1999 Canny et al.
5,997,476 A 12/1999 Brown
6,000,828 A 12/1999 Leet
6,003,006 A 12/1999 Colella et al.
6,012,034 A 1/2000 Hamparian et al.
6,017,318 A 1/2000 Gauthier et al.
6,021,392 A 2/2000 Lester et al.
6,023,977 A 2/2000 Langdon et al.
6,024,539 A 2/2000 Blomquist
6,032,676 A 3/2000 Moore
6,068,612 A 5/2000 Bowman
6,073,106 A 6/2000 Rozen et al.
6,077,246 A 6/2000 Kullas et al.
6,104,295 A 8/2000 Gaisser et al.
6,110,152 A 8/2000 Kovelman
RE36,871 E 9/2000 Epstein et al.
6,122,536 A 9/2000 Sun et al.
6,142,008 A 11/2000 Cole et al.
6,150,942 A 11/2000 O'Brien
6,157,914 A 12/2000 Seto et al.
6,159,147 A 12/2000 Lichter et al.
6,182,667 B1 2/2001 Hanks et al.
6,186,141 B1 2/2001 Pike et al.
6,189,105 B1 2/2001 Lopes
6,195,589 B1 2/2001 Ketcham

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,208,107 B1 3/2001 Maske et al.
6,212,936 B1 4/2001 Meisberger
6,231,320 B1 5/2001 Lawless et al.
6,234,176 B1 5/2001 Domae et al.
6,236,326 B1 5/2001 Murphy et al.
6,241,704 B1 6/2001 Peterson et al.
6,248,067 B1 6/2001 Causey, III et al.
6,259,355 B1 7/2001 Chaco et al.
6,267,725 B1 7/2001 Dubberstein et al.
6,269,340 B1 7/2001 Ford et al.
6,270,455 B1 8/2001 Brown
6,271,813 B1 8/2001 Palalau
6,277,072 B1 8/2001 Bardy
6,280,380 B1 8/2001 Bardy
6,280,408 B1 8/2001 Sipin
6,283,761 B1 9/2001 Joao
6,285,155 B1 9/2001 Maske et al.
6,312,378 B1 11/2001 Bardy
6,347,553 B1 2/2002 Morris et al.
6,349,740 B1 2/2002 Cho et al.
6,396,583 B1 5/2002 Clare
6,408,679 B1 6/2002 Kline-Schoder et al.
6,413,238 B1 7/2002 Maget
6,418,334 B1 7/2002 Unger et al.
6,445,053 B1 9/2002 Cho
6,463,785 B1 10/2002 Kline-Schoder et al.
6,467,331 B1 10/2002 Kline-Schoder et al.
6,468,242 B1 10/2002 Wilson et al.
6,475,178 B1 11/2002 Krajewski
6,482,158 B2 11/2002 Mault
6,485,263 B1 11/2002 Bryant et al.
6,485,418 B2 11/2002 Yasushi et al.
6,494,831 B1 12/2002 Koritzinsky
6,497,680 B1 12/2002 Holst et al.
6,503,221 B1 1/2003 Briggs
6,516,667 B1 2/2003 Broad et al.
6,517,482 B1 2/2003 Eiden et al.
6,519,569 B1 2/2003 White et al.
6,529,751 B1 3/2003 Van Driel et al.
6,539,315 B1 3/2003 Adams et al.
6,540,672 B1 4/2003 Simonsen et al.
6,544,212 B2 4/2003 Galley et al.
6,544,228 B1 4/2003 Heitmeier
6,558,351 B1 5/2003 Steil et al.
6,564,825 B2 5/2003 Lowery et al.
6,565,509 B1 5/2003 Say et al.
6,572,542 B1 6/2003 Houben et al.
6,572,545 B2 6/2003 Knobbe et al.
6,572,576 B2 6/2003 Brugger et al.
6,581,117 B1 6/2003 Klein et al.
6,589,229 B1 7/2003 Connelly et al.
6,599,281 B1 7/2003 Struys et al.
6,602,191 B2 8/2003 Quy
6,605,072 B2 8/2003 Struys et al.
6,616,633 B1 9/2003 Butterfield et al.
6,622,542 B2 9/2003 Derek
6,629,449 B1 10/2003 Kline-Schoder et al.
6,640,246 B1 10/2003 Gardy, Jr. et al.
6,641,533 B2 11/2003 Causey, III et al.
6,652,455 B1 11/2003 Kocher
6,653,937 B2 11/2003 Nelson et al.
6,685,668 B1 2/2004 Cho et al.
6,689,091 B2 2/2004 Bui et al.
6,692,241 B2 2/2004 Watanabe et al.
6,721,582 B2 4/2004 Trepagnier et al.
6,725,200 B1 4/2004 Rost
6,740,072 B2 5/2004 Starkweather et al.
6,749,403 B2 6/2004 Bryant et al.
6,752,787 B1 6/2004 Causey, III et al.
6,780,156 B2 8/2004 Haueter et al.
6,783,328 B2 8/2004 Lucke et al.
6,790,198 B1 9/2004 White et al.
6,807,965 B1 10/2004 Hickle
6,809,653 B1 10/2004 Mann et al.
6,813,964 B1 11/2004 Clark et al.
6,830,558 B2 12/2004 Flaherty et al.
6,840,113 B2 1/2005 Fukumura et al.
6,852,104 B2 2/2005 Blomquist
6,869,425 B2 3/2005 Briggs et al.
6,873,268 B2 3/2005 Lebel et al.
6,885,881 B2 4/2005 Leonhardt
6,915,170 B2 7/2005 Engleson et al.
6,923,763 B1 8/2005 Kovatchev et al.
6,936,029 B2 8/2005 Mann et al.
6,942,636 B2 9/2005 Holst et al.
6,945,954 B2 9/2005 Hochman et al.
6,958,705 B2 10/2005 Lebel et al.
6,964,204 B2 11/2005 Clark et al.
6,973,374 B2 12/2005 Ader
6,974,437 B2 12/2005 Lebel et al.
6,978,779 B2 12/2005 Haveri et al.
6,979,326 B2 12/2005 Mann et al.
6,981,960 B2 1/2006 Cho et al.
6,985,870 B2 1/2006 Martucci et al.
6,986,347 B2 1/2006 Hickle
6,997,920 B2 2/2006 Mann et al.
7,006,005 B2 2/2006 Nazarian et al.
7,025,743 B2 4/2006 Mann et al.
7,029,455 B2 4/2006 Flaherty
7,029,456 B2 4/2006 Ware et al.
7,060,059 B2 6/2006 Keith et al.
7,082,843 B2 8/2006 Clark et al.
7,092,796 B2 8/2006 Vanderveen
7,104,763 B2 9/2006 Bouton et al.
7,108,680 B2 9/2006 Rohr et al.
7,109,878 B2 9/2006 Mann et al.
7,137,964 B2 11/2006 Flaherty
7,141,037 B2 11/2006 Butterfield et al.
7,154,397 B2 12/2006 Zerhusen et al.
7,171,277 B2 1/2007 Engleson et al.
7,185,288 B2 2/2007 McKeever
7,201,734 B2 4/2007 Hickle
7,204,823 B2 4/2007 Estes et al.
7,206,715 B2 4/2007 Vanderveen et al.
7,213,009 B2 5/2007 Pestotnik
7,220,240 B2 5/2007 Struys et al.
7,229,430 B2 6/2007 Hickle et al.
7,230,529 B2 6/2007 Ketcherside
7,232,430 B2 6/2007 Carlisle
7,238,164 B2 7/2007 Childers et al.
7,247,154 B2 7/2007 Hickle
7,267,664 B2 9/2007 Rizzo
7,267,665 B2 9/2007 Steil et al.
7,278,983 B2 10/2007 Ireland et al.
7,300,418 B2 11/2007 Zaleski
7,327,273 B2 2/2008 Hung et al.
7,338,470 B2 3/2008 Katz
7,347,836 B2 3/2008 Peterson et al.
7,354,420 B2 4/2008 Steil et al.
7,356,382 B2 4/2008 Vanderveen
7,360,999 B2 4/2008 Nelson et al.
7,369,948 B1 5/2008 Ferenczi et al.
7,384,410 B2 6/2008 Eggers et al.
7,398,183 B2 7/2008 Holland et al.
7,399,277 B2 7/2008 Saidara et al.
7,402,153 B2 7/2008 Steil et al.
7,402,154 B2 7/2008 Mendez
7,407,489 B2 8/2008 Mendez
7,414,534 B1 8/2008 Kroll et al.
7,430,675 B2 9/2008 Lee et al.
7,447,643 B1 11/2008 Olson
7,452,190 B2 11/2008 Bouton et al.
7,454,314 B2 11/2008 Holland et al.
7,471,994 B2 12/2008 Ford et al.
7,482,818 B2 1/2009 Greenwald et al.
7,483,756 B2 1/2009 Engleson et al.
7,490,021 B2 2/2009 Holland et al.
7,491,187 B2 2/2009 Van Den Berghe et al.
7,517,332 B2 4/2009 Tonelli et al.
7,523,401 B1 4/2009 Aldridge
7,561,986 B2 7/2009 Vanderveen et al.
7,645,258 B2 1/2010 White et al.
7,654,127 B2 2/2010 Krulevitch et al.
7,657,443 B2 2/2010 Crass

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,678,048 B1 3/2010 Urbano et al.
7,699,806 B2 4/2010 Ware et al.
7,705,727 B2 4/2010 Pestotnik
7,766,873 B2 * 8/2010 Moberg A61M 5/145 604/131
7,785,313 B2 8/2010 Mastrototaro
7,786,909 B2 8/2010 Udupa et al.
7,806,886 B2 10/2010 Kanderian, Jr. et al.
7,826,981 B2 11/2010 Goode, Jr. et al.
7,847,276 B2 12/2010 Carlisle
7,860,583 B2 12/2010 Condurso et al.
7,871,394 B2 1/2011 Halbert et al.
7,876,443 B2 1/2011 Bernacki
7,895,053 B2 2/2011 Holland et al.
7,895,882 B2 3/2011 Carlisle
7,896,834 B2 3/2011 Smisson, III
7,896,842 B2 3/2011 Palmroos et al.
7,905,710 B2 3/2011 Wang et al.
7,933,780 B2 4/2011 De La Huerga
7,945,452 B2 5/2011 Fathallah et al.
7,981,073 B2 7/2011 Mollstam
7,981,082 B2 7/2011 Wang et al.
8,034,020 B2 10/2011 Dewey
8,038,593 B2 10/2011 Friedman et al.
8,065,161 B2 11/2011 Howard et al.
8,067,760 B2 11/2011 Carlisle
8,075,546 B2 12/2011 Carlisle et al.
8,078,983 B2 12/2011 Davis et al.
8,149,131 B2 4/2012 Blornquist
8,175,668 B1 5/2012 Nabutovsky et al.
8,177,739 B2 5/2012 Cartledge et al.
8,185,322 B2 5/2012 Schroeder et al.
8,219,413 B2 7/2012 Martinez et al.
8,231,578 B2 7/2012 Fathallah et al.
8,234,128 B2 7/2012 Martucci et al.
8,271,106 B2 9/2012 Wehba et al.
8,287,514 B2 10/2012 Miller et al.
8,291,337 B2 10/2012 Gannin et al.
8,313,308 B2 11/2012 Lawless et al.
8,317,750 B2 11/2012 Ware et al.
8,317,752 B2 11/2012 Cozmi et al.
8,340,792 B2 12/2012 Condurso et al.
8,359,338 B2 1/2013 Butterfield et al.
8,361,021 B2 1/2013 Wang et al.
8,388,598 B2 3/2013 Steinkogler
8,398,616 B2 3/2013 Budiman
8,403,908 B2 3/2013 Jacobson et al.
8,449,524 B2 5/2013 Braig et al.
8,494,879 B2 7/2013 Davis et al.
8,504,179 B2 8/2013 Blomquist
8,517,990 B2 8/2013 Teel et al.
8,518,021 B2 8/2013 Stewart et al.
8,539,812 B2 9/2013 Stringham et al.
8,543,416 B2 9/2013 Palmroos et al.
8,577,692 B2 11/2013 Silkaitis et al.
8,622,990 B2 1/2014 Estes et al.
8,630,722 B2 1/2014 Condurso et al.
8,665,214 B2 3/2014 Forutanpour et al.
8,666,769 B2 3/2014 Butler et al.
8,700,421 B2 4/2014 Feng et al.
8,706,233 B2 4/2014 Su et al.
8,721,584 B2 5/2014 Braithwaite et al.
8,761,906 B2 6/2014 Condurso et al.
8,768,719 B2 7/2014 Wehba et al.
8,771,251 B2 7/2014 Ruchti et al.
8,792,981 B2 7/2014 Yudovsky et al.
8,821,432 B2 9/2014 Unverdorben
8,823,382 B2 9/2014 Rondoni et al.
8,964,185 B1 2/2015 Luo et al.
9,005,150 B2 4/2015 Ware et al.
9,026,370 B2 5/2015 Rubalcaba et al.
9,084,855 B2 7/2015 Ware et al.
9,114,217 B2 8/2015 Sur et al.
9,134,735 B2 9/2015 Lowery et al.
9,134,736 B2 9/2015 Lowery et al.
9,138,526 B2 9/2015 Ware et al.
9,240,002 B2 1/2016 Hume et al.
9,333,291 B2 5/2016 Jacobson et al.
9,381,296 B2 7/2016 Arrizza et al.
9,393,362 B2 7/2016 Cozmi et al.
9,707,341 B2 7/2017 Dumas, III et al.
2001/0016056 A1 8/2001 Westphal et al.
2001/0032099 A1 10/2001 Joao
2001/0037060 A1 11/2001 Thompson et al.
2001/0044731 A1 11/2001 Coffman et al.
2002/0015018 A1 2/2002 Shimazu et al.
2002/0032583 A1 3/2002 Joao
2002/0040208 A1 4/2002 Flaherty et al.
2002/0045806 A1 4/2002 Baker, Jr. et al.
2002/0082728 A1 6/2002 Mueller et al.
2002/0087115 A1 7/2002 Hartlaub
2002/0095486 A1 7/2002 Bahl
2002/0099282 A1 7/2002 Knobbe et al.
2002/0152239 A1 10/2002 Bautista-Lloyd et al.
2003/0009244 A1 1/2003 Engleson
2003/0013959 A1 1/2003 Grunwald et al.
2003/0025602 A1 2/2003 Medema et al.
2003/0028082 A1 2/2003 Thompson
2003/0030001 A1 2/2003 Cooper et al.
2003/0050621 A1 3/2003 Lebel et al.
2003/0060688 A1 3/2003 Ciarniello et al.
2003/0060765 A1 3/2003 Campbell et al.
2003/0079746 A1 5/2003 Hickle
2003/0104982 A1 6/2003 Wittmann et al.
2003/0106553 A1 6/2003 Vanderveen
2003/0125662 A1 7/2003 Bui
2003/0130616 A1 7/2003 Steil
2003/0139701 A1 7/2003 White et al.
2003/0140928 A1 7/2003 Bui et al.
2003/0141981 A1 7/2003 Bui
2003/0143746 A1 7/2003 Sage, Jr.
2003/0160683 A1 8/2003 Blomquist
2003/0187338 A1 10/2003 Say et al.
2003/0200116 A1 10/2003 Forrester
2003/0204274 A1 10/2003 Ullestad et al.
2003/0204416 A1 10/2003 Acharya
2003/0212364 A1 11/2003 Mann et al.
2003/0212379 A1 11/2003 Bylund et al.
2003/0217962 A1 11/2003 Childers et al.
2004/0057226 A1 3/2004 Berthou et al.
2004/0064342 A1 4/2004 Browne et al.
2004/0077996 A1 4/2004 Jasperson et al.
2004/0120825 A1 6/2004 Bouton et al.
2004/0147034 A1 7/2004 Gore et al.
2004/0167464 A1 8/2004 Ireland et al.
2004/0167465 A1 8/2004 Kohler
2004/0167804 A1 8/2004 Simpson
2004/0172222 A1 9/2004 Simpson et al.
2004/0172283 A1 9/2004 Vanderveen
2004/0172302 A1 9/2004 Martucci et al.
2004/0181314 A1 9/2004 Zaleski
2004/0193325 A1 9/2004 Bonderud
2004/0193453 A1 9/2004 Butterfield et al.
2004/0204638 A1 10/2004 Diab et al.
2004/0204673 A1 10/2004 Flaherty et al.
2004/0220517 A1 11/2004 Starkweather et al.
2004/0247445 A1 * 12/2004 Nelson A61M 5/14224 417/1
2004/0254434 A1 12/2004 Goodnow et al.
2005/0021006 A1 1/2005 Tonnies
2005/0038680 A1 2/2005 McMahon
2005/0055242 A1 3/2005 Bello et al.
2005/0055244 A1 3/2005 Mullan et al.
2005/0065465 A1 3/2005 Lebel et al.
2005/0075544 A1 4/2005 Shapiro et al.
2005/0096593 A1 5/2005 Pope et al.
2005/0099624 A1 5/2005 Staehr
2005/0107923 A1 5/2005 Vanderveen
2005/0119914 A1 6/2005 Batch
2005/0131739 A1 6/2005 Rabinowitz et al.
2005/0137522 A1 6/2005 Aoki
2005/0171503 A1 8/2005 Van Den Berghe et al.
2005/0171815 A1 8/2005 Vanderveen
2005/0177096 A1 8/2005 Bollish et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2005/0182306 A1 8/2005 Sloan
2005/0182355 A1 8/2005 Bui
2005/0192529 A1 9/2005 Butterfield et al.
2005/0192557 A1 9/2005 Brauker et al.
2005/0197554 A1 9/2005 Polcha
2005/0197621 A1 9/2005 Poulsen et al.
2005/0224083 A1 10/2005 Crass
2005/0240305 A1 10/2005 Bogash et al.
2005/0273059 A1 12/2005 Mernoe et al.
2005/0277890 A1 12/2005 Stewart et al.
2006/0009727 A1 1/2006 O'Mahony et al.
2006/0009734 A1 1/2006 Martin
2006/0047270 A1 3/2006 Shelton
2006/0053036 A1 3/2006 Coffman et al.
2006/0064020 A1 3/2006 Burnes et al.
2006/0064053 A1 3/2006 Bollish et al.
2006/0079831 A1 4/2006 Gilbert
2006/0100746 A1 5/2006 Leibner-Druska
2006/0100907 A1 5/2006 Holland et al.
2006/0106649 A1 5/2006 Eggers et al.
2006/0116639 A1 6/2006 Russell
2006/0173260 A1 8/2006 Gaoni et al.
2006/0173406 A1 8/2006 Hayes et al.
2006/0190302 A1 8/2006 Eggers et al.
2006/0195022 A1 8/2006 Trepagnier et al.
2006/0200007 A1 9/2006 Brockway et al.
2006/0211404 A1 9/2006 Cromp et al.
2006/0224141 A1 10/2006 Rush et al.
2006/0226088 A1 10/2006 Robinson et al.
2006/0226089 A1 10/2006 Robinson et al.
2006/0226090 A1 10/2006 Robinson et al.
2006/0229557 A1 10/2006 Fathallah et al.
2006/0229918 A1 10/2006 Fotsch et al.
2006/0264895 A1 11/2006 Flanders
2006/0265246 A1 11/2006 Hoag
2006/0266128 A1 11/2006 Clark et al.
2006/0270971 A1 11/2006 Gelfand et al.
2006/0272421 A1 12/2006 Frinak et al.
2006/0275142 A1 12/2006 Bouton et al.
2007/0015972 A1 1/2007 Wang et al.
2007/0060796 A1 3/2007 Kim
2007/0060871 A1 3/2007 Istoc
2007/0060874 A1 3/2007 Nesbitt et al.
2007/0062250 A1 3/2007 Krulevitch et al.
2007/0065363 A1 3/2007 Dalal et al.
2007/0078314 A1 4/2007 Grounsell
2007/0084288 A1 4/2007 Thomas et al.
2007/0088333 A1 4/2007 Levin et al.
2007/0100665 A1 5/2007 Brown
2007/0112298 A1 5/2007 Mueller et al.
2007/0118405 A1 5/2007 Campbell et al.
2007/0142822 A1 6/2007 Remde
2007/0156452 A1 7/2007 Batch
2007/0191817 A1 8/2007 Martin
2007/0214003 A1 9/2007 Holland et al.
2007/0215545 A1 9/2007 Bissler et al.
2007/0233035 A1 10/2007 Wehba et al.
2007/0233049 A1 10/2007 Wehba et al.
2007/0257788 A1 11/2007 Carlson
2008/0009684 A1 1/2008 Corsetti et al.
2008/0033361 A1 2/2008 Evans et al.
2008/0039777 A1 2/2008 Katz et al.
2008/0058773 A1 3/2008 John
2008/0071210 A1 3/2008 Moubayed et al.
2008/0091466 A1 4/2008 Butler et al.
2008/0097289 A1 4/2008 Steil et al.
2008/0097317 A1 4/2008 Alholm et al.
2008/0098798 A1 5/2008 Riley et al.
2008/0119822 A1 5/2008 Knauper
2008/0125701 A1 5/2008 Moberg et al.
2008/0139907 A1 6/2008 Rao et al.
2008/0145249 A1 6/2008 Smisson
2008/0177254 A1 7/2008 Shelton et al.
2008/0188796 A1 8/2008 Steil et al.
2008/0200870 A1 8/2008 Palmroos et al.
2008/0208484 A1 8/2008 Butterfield et al.
2008/0214919 A1 9/2008 Harmon et al.
2008/0243055 A1 10/2008 Fathallah et al.
2008/0262469 A1 10/2008 Bristol et al.
2008/0269663 A1 10/2008 Arnold et al.
2008/0269714 A1 10/2008 Mastrototaro et al.
2008/0269723 A1 10/2008 Mastrototaro et al.
2008/0275384 A1 11/2008 Mastrototaro et al.
2008/0300572 A1 12/2008 Rankers et al.
2009/0001908 A1 1/2009 Shubinsky et al.
2009/0005703 A1 1/2009 Fasciano
2009/0006061 A1 1/2009 Thukral et al.
2009/0006129 A1 1/2009 Thukral
2009/0006133 A1 1/2009 Weinert
2009/0015824 A1 1/2009 Shubinsky et al.
2009/0043171 A1 2/2009 Rule
2009/0054743 A1 2/2009 Stewart
2009/0054754 A1 2/2009 McMahon et al.
2009/0082676 A1 3/2009 Bennison
2009/0097029 A1 4/2009 Tokhtuev et al.
2009/0112155 A1 4/2009 Zhao
2009/0124963 A1 5/2009 Hogard et al.
2009/0124964 A1 5/2009 Leach et al.
2009/0143726 A1 6/2009 Bouton et al.
2009/0144025 A1 6/2009 Bouton et al.
2009/0144026 A1 6/2009 Bouton et al.
2009/0149743 A1 6/2009 Barron et al.
2009/0157040 A1* 6/2009 Jacobson A61M 5/16804 604/505
2009/0177146 A1 7/2009 Nesbitt et al.
2009/0177769 A1 7/2009 Roberts
2009/0177992 A1 7/2009 Rubalcaba et al.
2009/0178485 A1 7/2009 Thomas et al.
2009/0183147 A1 7/2009 Davis et al.
2009/0205426 A1 8/2009 Balschat et al.
2009/0209938 A1 8/2009 Aalto-Setala
2009/0209945 A1 8/2009 Lobl et al.
2009/0212966 A1 8/2009 Panduro
2009/0221890 A1 9/2009 Saffer et al.
2009/0223294 A1 9/2009 Thomas et al.
2009/0270810 A1 10/2009 DeBelser
2009/0270833 A1 10/2009 DeBelser
2010/0022988 A1 1/2010 Wochner
2010/0280430 A1 1/2010 Caleffi et al.
2010/0036310 A1 2/2010 Hillman
2010/0056992 A1 3/2010 Hayter
2010/0079760 A1 4/2010 Bernacki
2010/0094251 A1 4/2010 Estes et al.
2010/0121170 A1 5/2010 Rule
2010/0121415 A1 5/2010 Skelton et al.
2010/0131434 A1 5/2010 Magent et al.
2010/0141460 A1 6/2010 Tokhtuev et al.
2010/0147081 A1 6/2010 Thomas et al.
2010/0152554 A1 6/2010 Steine et al.
2010/0160854 A1 6/2010 Gauthier
2010/0185142 A1 7/2010 Kamen et al.
2010/0198034 A1 8/2010 Thomas et al.
2010/0198182 A1 8/2010 Lanigan et al.
2010/0198183 A1 8/2010 Lanigan et al.
2010/0212407 A1 8/2010 Stringham et al.
2010/0212675 A1 8/2010 Walling et al.
2010/0214110 A1 8/2010 Wang et al.
2010/0217621 A1 8/2010 Schoenberg
2010/0271479 A1 10/2010 Heydlauf
2010/0273738 A1 10/2010 Valcke et al.
2010/0292634 A1 11/2010 Kircher
2010/0295686 A1 11/2010 Sloan et al.
2010/0298765 A1 11/2010 Budiman et al.
2010/0317093 A1 12/2010 Turewicz et al.
2010/0318025 A1 12/2010 John
2011/0001605 A1 1/2011 Kiani et al.
2011/0004186 A1 1/2011 Butterfield
2011/0009797 A1 1/2011 Kelly et al.
2011/0040247 A1 2/2011 Mandro et al.
2011/0046558 A1 2/2011 Gravesen et al.
2011/0062703 A1 3/2011 Lopez et al.
2011/0064612 A1 3/2011 Franzoni et al.
2011/0071464 A1 3/2011 Palerm
2011/0072379 A1 3/2011 Gannon

(56) **References Cited**

U.S. PATENT DOCUMENTS

2011/0078608	A1	3/2011	Gannon et al.	
2011/0099313	A1	4/2011	Bolanowski	
2011/0105983	A1	5/2011	Kelly et al.	
2011/0137241	A1	6/2011	DelCastilio et al.	
2011/0162647	A1	7/2011	Huby et al.	
2011/0175728	A1	7/2011	Baker, Jr.	
2011/0190598	A1	8/2011	Shusterman	
2011/0190694	A1	8/2011	Lanier et al.	
2011/0238013	A1*	9/2011	Wang	A61M 5/16831 604/123
2011/0264006	A1	10/2011	Ali et al.	
2011/0264043	A1	10/2011	Kotnick et al.	
2011/0282321	A1	11/2011	Steil et al.	
2011/0320049	A1	12/2011	Chossat et al.	
2012/0025995	A1	2/2012	Moberg et al.	
2012/0035535	A1	2/2012	Johnson et al.	
2012/0059234	A1	3/2012	Barrett et al.	
2012/0095433	A1	4/2012	Hungerford et al.	
2012/0123322	A1	5/2012	Scarpaci et al.	
2012/0143116	A1	6/2012	Ware et al.	
2012/0180790	A1	7/2012	Montgomery	
2012/0185267	A1	7/2012	Kamen et al.	
2012/0191059	A1	7/2012	Cummings et al.	
2012/0194341	A1	8/2012	Peichel et al.	
2012/0203177	A1	8/2012	Lanier	
2012/0226350	A1	9/2012	Rudser et al.	
2012/0245525	A1	9/2012	Pope et al.	
2012/0259278	A1	10/2012	Hayes et al.	
2013/0006666	A1	1/2013	Schneider	
2013/0009551	A1	1/2013	Knapp	
2013/0012917	A1	1/2013	Miller et al.	
2013/0041342	A1	2/2013	Bernini et al.	
2013/0083191	A1	4/2013	Lowery et al.	
2013/0085443	A1	4/2013	Lowery et al.	
2013/0085689	A1	4/2013	Sur et al.	
2013/0110538	A1	5/2013	Butterfield et al.	
2013/0150766	A1	6/2013	Olde et al.	
2013/0150821	A1	6/2013	Bollish et al.	
2013/0158504	A1	6/2013	Ruchti et al.	
2013/0201482	A1	8/2013	Munro	
2013/0116649	A1	9/2013	Kouyoumjian et al.	
2013/0253430	A1	9/2013	Kouyoumjian et al.	
2013/0261993	A1	10/2013	Ruchti et al.	
2013/0291116	A1	10/2013	Homer	
2013/0296823	A1	11/2013	Melker et al.	
2013/0296984	A1	11/2013	Burnett et al.	
2013/0345658	A1	12/2013	Browne et al.	
2013/0345666	A1	12/2013	Panduro et al.	
2014/0039446	A1	2/2014	Day	
2014/0224829	A1	8/2014	Capone et al.	
2014/0358077	A1	12/2014	Oruklu et al.	
2015/0025453	A1	1/2015	Ledford et al.	
2015/0246175	A1	9/2015	Shubinsky et al.	
2015/0343141	A1	12/2015	Lindo et al.	
2016/0103960	A1	4/2016	Hume et al.	
2016/0175517	A1	6/2016	Sileika et al.	
2016/0256622	A1	9/2016	Day et al.	

FOREIGN PATENT DOCUMENTS

DE	35 30 747	3/1987
DE	38 27 444	2/1990
DE	197 34 002	9/1998
DE	199 01 078	2/2000
DE	198 44 252	3/2000
DE	199 32 147	1/2001
DE	103 52 456	7/2005
EP	0 291 727	11/1988
EP	0 319 275	6/1989
EP	0 341 582	11/1989
EP	0 370 162	5/1990
EP	0 387 724	9/1990
EP	0 453 211	10/1991
EP	0 462 405	12/1991
EP	0 516 130	12/1992
EP	0 519 765	12/1992
EP	0 643 301	3/1995
EP	0 683 465	11/1995
EP	0 880 936	12/1998
EP	0 954 090	11/1999
EP	1 174 817	1/2002
EP	1 197 178	4/2002
EP	1 500 025	4/2003
EP	1 813 188	8/2007
EP	2 228 004	9/2010
EP	2 243 506	10/2010
FR	2 717 919	9/1995
GB	2 121 971	1/1984
GB	2 312 022	10/1997
GB	2 312 046	10/1997
JP	04-231966	8/1992
JP	2005-021463	1/2005
JP	2006-517423	7/2006
WO	WO 84/000690	3/1984
WO	WO 90/007942	7/1990
WO	WO 91/016087	10/1991
WO	WO 91/016416	10/1991
WO	WO 93/004284	3/1993
WO	WO 95/016200	6/1995
WO	WO 95/031233	11/1995
WO	WO 96/008755	3/1996
WO	WO 96/025186	8/1996
WO	WO 96/041156	12/1996
WO	WO 97/010013	3/1997
WO	WO 98/012670	3/1998
WO	WO 98/014234	4/1998
WO	WO 98/019263	5/1998
WO	WO 98/044320	10/1998
WO	WO 98/056441	12/1998
WO	WO 99/015216	4/1999
WO	WO 99/051003	10/1999
WO	WO 00/013580	3/2000
WO	WO 00/041621	7/2000
WO	WO 01/014974	3/2001
WO	WO 01/033484	5/2001
WO	WO 02/005702	1/2002
WO	WO 03/006091	1/2003
WO	WO 03/053498	7/2003
WO	WO 2004/060455	7/2004
WO	WO 2005/050526	6/2005
WO	WO 2005/057175	6/2005
WO	WO 2005/065749	7/2005
WO	WO 2007/087443	8/2007
WO	063429	5/2008
WO	WO 2008/067245	6/2008
WO	WO 2008/088490	7/2008
WO	WO 2008/134146	11/2008
WO	2009/026420 A1	2/2009
WO	WO 2009/016504	2/2009
WO	WO 2009/023406	2/2009
WO	WO 2009/023407	2/2009
WO	WO 2009/023634	2/2009
WO	WO 2009/049252	4/2009
WO	WO 2009/127683	10/2009
WO	WO 2010/017279	2/2010
WO	WO 2010/075371	7/2010
WO	WO 2010/099313	9/2010
WO	WO 2010/114929	10/2010
WO	WO 2010/119409	10/2010
WO	WO 2010/124127	10/2010
WO	WO 2010/135646	11/2010
WO	WO 2010/135654	11/2010
WO	WO 2010/135670	11/2010
WO	WO 2010/135686	11/2010
WO	WO 2010/148205	12/2010
WO	WO 2011/017778	2/2011
WO	WO 2011/080188	7/2011
WO	WO 2011/109774	9/2011
WO	WO 2012/042763	4/2012
WO	2013/028524 A1	2/2013

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

WO	WO 2013/096769	6/2013
WO	WO 2015/134478	9/2015

OTHER PUBLICATIONS

Allegro, "3955—Full-Bridge PWM Microstepping Motor Drive", Datasheet, 1997, pp. 16.
Aragon, Daleen RN, Ph.D., CCRN, "Evaluation of Nursing Work Effort and Perceptions About Blood Glucose Testing in Tight Glycemic Control", American Journal of Critical Care, Jul. 2006, vol. 15, No. 4, pp. 370-377.
Baxter, "Baxter Receives 510(k) Clearance for Next-Generation SIGMA Spectrum Infusion Pump with Master Drug Library" Press Release, May 8, 2014, pp. 2. http://web.archive.org/web/20160403140025/http://www.baxter.com/news-media/newsroom/press-releases/2014/05_08_14_sigma.page.
Bequette, Ph.D., "A Critical Assessment of Algorithms and Challenges in the Development of a Closed-Loop Artificial Pancreas", Diabetes Technology & Therapeutics, Feb. 28, 2005, vol. 7, No. 1, pp. 28-47.
Bequette, B. Wayne, Ph.D., "Analysis of Algorithms for Intensive Care Unit Blood Glucose Control", Journal of Diabetes Science and Technology, Nov. 2007, vol. 1, No. 6, pp. 813-824.
Binder et al., "Insulin Infusion with Parenteral Nutrition in Extremely Low Birth Weight Infants with Hyperglycemia", Journal of Pediatrics, Feb. 1989, vol. 114, No. 2, pp. 273-280.
Bode et al., "Intravenous Insulin Infusion Therapy: Indications, Methods, and Transition to Subcutaneous Insulin Therapy", Endocrine Practice, Mar./Apr. 2004, vol. 10, Supplement 2, pp. 71-80.
Cannon, MD et al., "Automated Heparin-Delivery System to Control Activated Partial Thromboplastin Time", Circulation, Feb. 16, 1999, vol. 99, pp. 751-756.
"CareAware® Infusion Management", Cerner Store, as printed May 12, 2011, pp. 3, https://store.cerner.com/items/7.
Chen et al., "Enabling Location-Based Services on Wireless LANs", The 11th IEEE International Conference on Networks, ICON 2003, Sep. 28-Oct. 1, 2003, pp. 567-572.
Cheung et al., "Hyperglycemia is Associated with Adverse Outcomes in Patients Receiving Total Parenteral Nutrition", Diabetes Care, Oct. 2005, vol. 28, No. 10, pp. 2367-2371.
Davidson et al., "A Computer-Directed Intravenous Insulin System Shown to be Safe, Simple, and Effective in 120,618 h of Operation", Diabetes Care, Oct. 2005, vol. 28, No. 10, pp. 2418-2423.
Diabetes Close Up, Close Concerns AACE Inpatient Management Conference Report, Consensus Development Conference on Inpatient Diabetes and Metabolic Control, Washington, D.C., Dec. 14-16, 2003, pp. 1-32.
Fogt et al., Development and Evaluation of a Glucose Analyzer for a Glucose-Controlled Insulin Infusion System (Biostator®), Clinical Chemistry, 1978, vol. 24, No. 8, pp. 1366-1372.
Goldberg et al., "Clinical Results of an Updated Insulin Infusion Protocol in Critically Ill Patients", Diabetes Spectrum, 2005, vol. 18, No. 3, pp. 188-191.
Halpern et al., "Changes in Critical Care Beds and Occupancy in the United States 1985-2000: Differences Attributable to Hospital Size", Critical Care Medical, Aug. 2006, vol. 34, No. 8, pp. 2105-2112.
Hospira, "Plum A+™ Infusion System" as archived Dec. 1, 2012, pp. 2. www.hospira.com/products_and_services/infusion_pumps/plum/index.
Hospira, "Plum XL™ Series Infusion System" Technical Service Manual, Feb. 2005, Lake Forest, Illinois, USA, pp. i-vii, 5-14, 8-3.
International Search Report and Written Opinion received in PCT Application No. PCT/US2014/039347, dated Oct. 16, 2014 in 9 pages.
International Preliminary Report on Patentability and Written Opinion received in PCT Application No. PCT/US2014/039347, dated Dec. 3, 2015 in 8 pages.
Lamsdale et al., "A Usability Evaluation of an Infusion Pump by Nurses Using a Patient Simulator", Proceedings of the Human Factors and Ergonomics Society 49th Annual Meeting, Sep. 2005, pp. 1024-1028.
Magaji et al., "Inpatient Management of Hyperglycemia and Diabetes", Clinical Diabetes, 2011, vol. 29, No. 1, pp. 3-9.
Mauseth et al., "Proposed Clinical Application for Tuning Fuzzy Logic Controller of Artificial Pancreas Utilizing a Personalization Factor", Journal of Diabetes Science and Technology, Jul. 2010, vol. 4, No. 4, pp. 913-922.
Maynard et al., "Subcutaneous Insulin Order Sets and Protocols: Effective Design and Implementation Strategies", Journal of Hospital Medicine, Sep./Oct. 2008, vol. 3, Issue 5, Supplement 5, pp. S29-S41.
Microchip Technology Inc., "MTA11200B; TrueGauge™ Intelligent Battery Management I.C.", https://www.elektronic.ropia.eu/pdf/stock/mcp/mta11200b.pdf, 1995, pp. 44.
Moghissi, Etie, MD, FACP, FACE, "Hyperglycemia in Hospitalized Patients", A Supplement to ACP Hospitalist, Jun. 15, 2008, pp. 32.
Nuckols et al., "Programmable Infusion Pumps in ICUs: An Analysis of Corresponding Adverse Drug Events", Journal of General Internal Medicine, 2007, vol. 23, Supp. 1, pp. 41-45.
Pretty et al., "Hypoglycemia Detection in Critical Care Using Continuous Glucose Monitors: An in Silico Proof of Concept Analysis", Journal of Diabetes Science and Technology, Jan. 2010, vol. 4, No. 1, pp. 15-24.
Saager et al., "Computer-Guided Versus Standard Protocol for Insulin Administration in Diabetic Patients Undergoing Cardiac Surgery", Annual Meeting of the American Society of Critical Care Anesthesiologists, Oct. 13, 2006.
Sebald et al., "Numerical Analysis of a Comprehensive in Silico Subcutaneous Insulin Absorption Compartmental Model", 31st Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Sep. 2-6, 2009, pp. 3901-3904.
SGS—Thomson Microelectronics, "L6219—Stepper Motor Drive", Datasheet, Dec. 1996, pp. 10.
SGS—Thomson Microelectronics, "PBL3717A—Stepper Motor Drive", Datasheet, Apr. 1993, pp. 11.
Simonsen, Michael Ph.D., POC Testing, New Monitoring Strategies on Fast Growth Paths in European Healthcare Arenas, Biomedical Business & Technology, Jan. 2007, vol. 30, No. 1, pp. 1-36.
Smith, Joe, "Infusion Pump Informatics", CatalyzeCare: Transforming Healthcare, as printed May 12, 2011, pp. 2.
Tang et al., "Linear Dimensionality Reduction Using Relevance Weighted LDA", Pattern Recognition, 2005, vol. 38, pp. 485-493, <http://staff.ustc.edu.cn/~ketang/papers/TangSuganYaoQin_PR04.pdf>.
Thomas et al., "Implementation of a Tight Glycaemic Control Protocol Using a Web-Based Insulin Dose Calculator", Anaesthesia, 2005, vol. 60, pp. 1093-1100.
Van Den Berghe, M.D., Ph.D., et al., "Intensive Insulin Therapy in Critically Ill Patients", The New England Journal of Medicine, Nov. 8, 2001, vol. 345, No. 19, pp. 1359-1367.
Van Den Berghe, M.D., Ph.D., et al., "Intensive Insulin Therapy in the Medical ICU", The New England Journal of Medicine, Feb. 2, 2006, vol. 354, No. 5, pp. 449-461.
Westbrook et al., "Errors in the Administration of Intravenous Medications in Hospital and the Role of Correct Procedures and Nurse Experience", BMJ Quality & Safety, 2011, vol. 20, pp. 1027-1034.
Zakariah et al., "Combination of Biphasic Transmittance Waveform with Blood Procalcitonin Levels for Diagnosis of Sepsis in Acutely Ill Patients", Critical Care Medicine, 2008, vol. 36, No. 5, pp. 1507-1512.

* cited by examiner

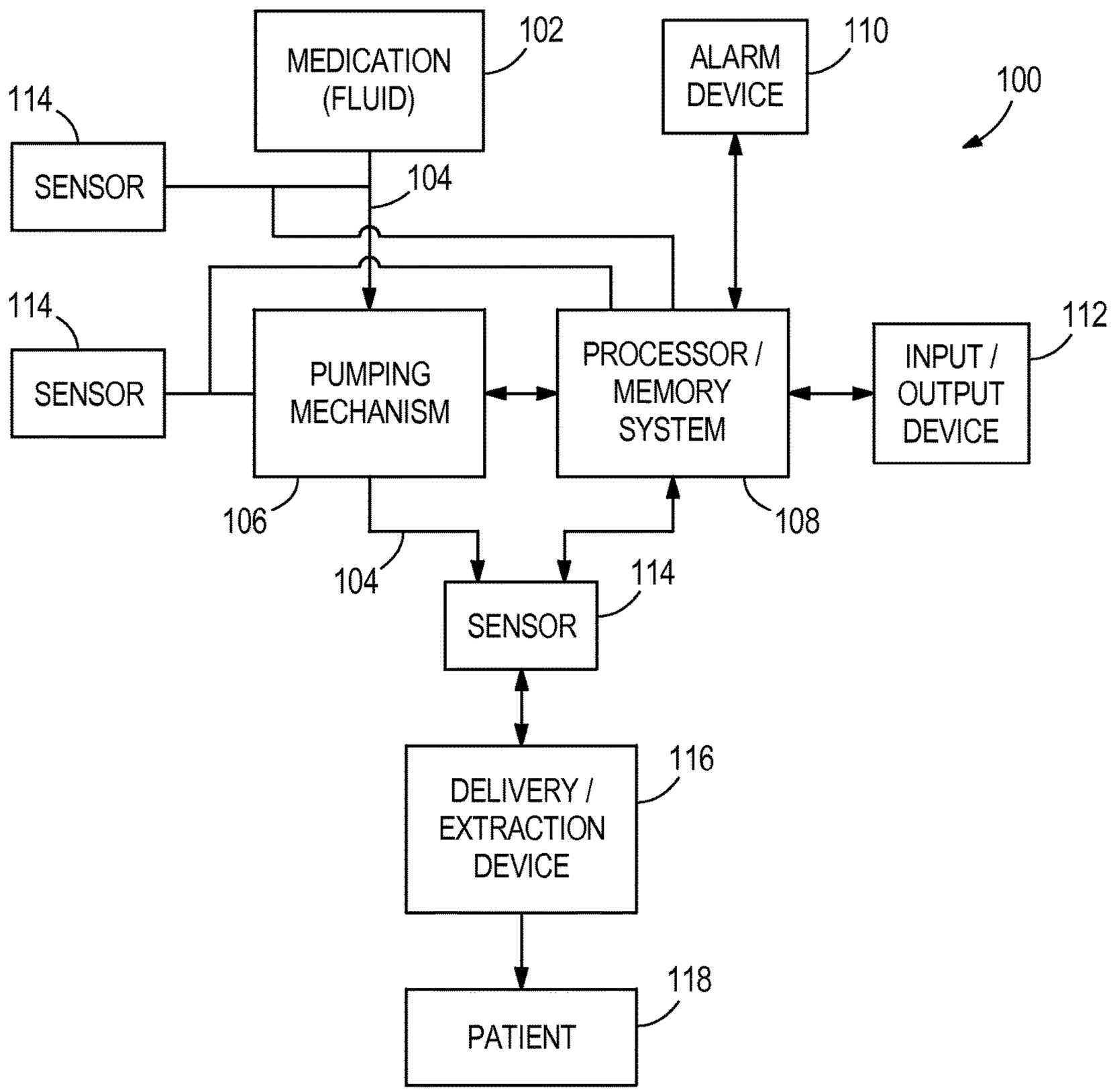

MEDICATION (FLUID)
102
ALARM DEVICE
110
100
114
SENSOR
104
114
SENSOR
PUMPING MECHANISM
PROCESSOR / MEMORY SYSTEM
INPUT / OUTPUT DEVICE
112
106
108
104
SENSOR
114
DELIVERY / EXTRACTION DEVICE
116
PATIENT
118

FIG. 1

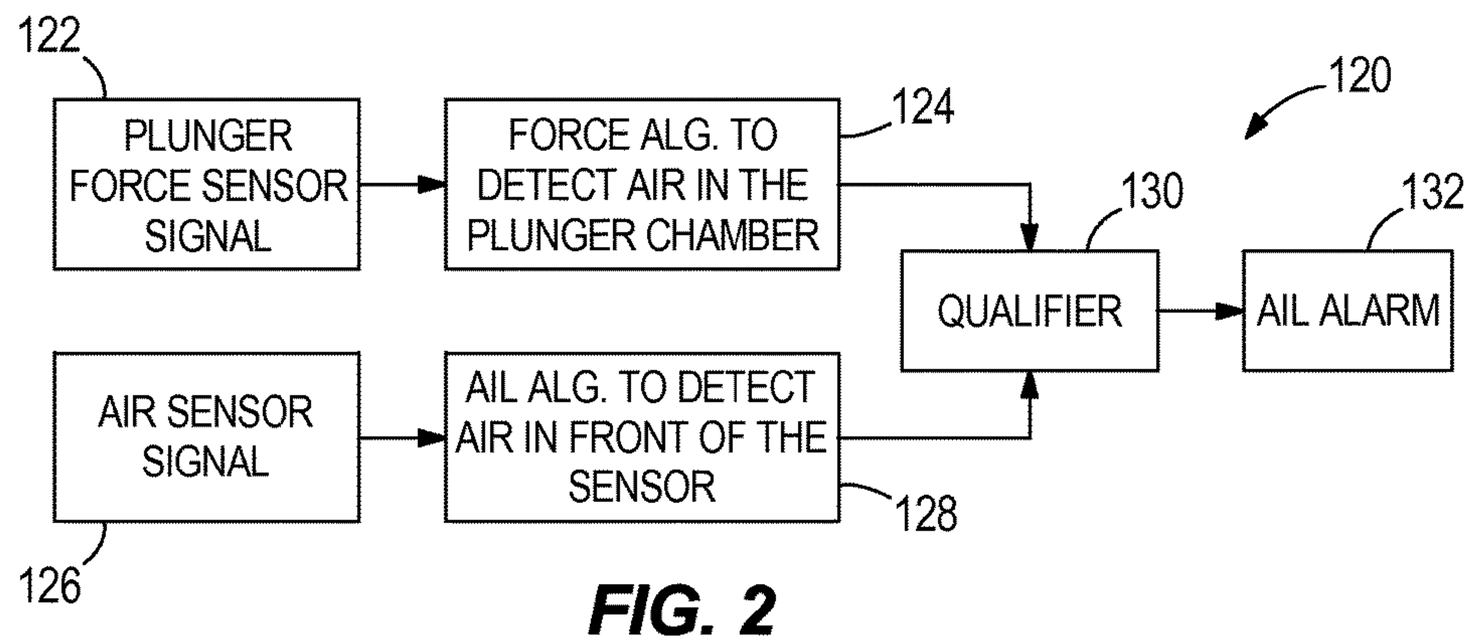


FIG. 2

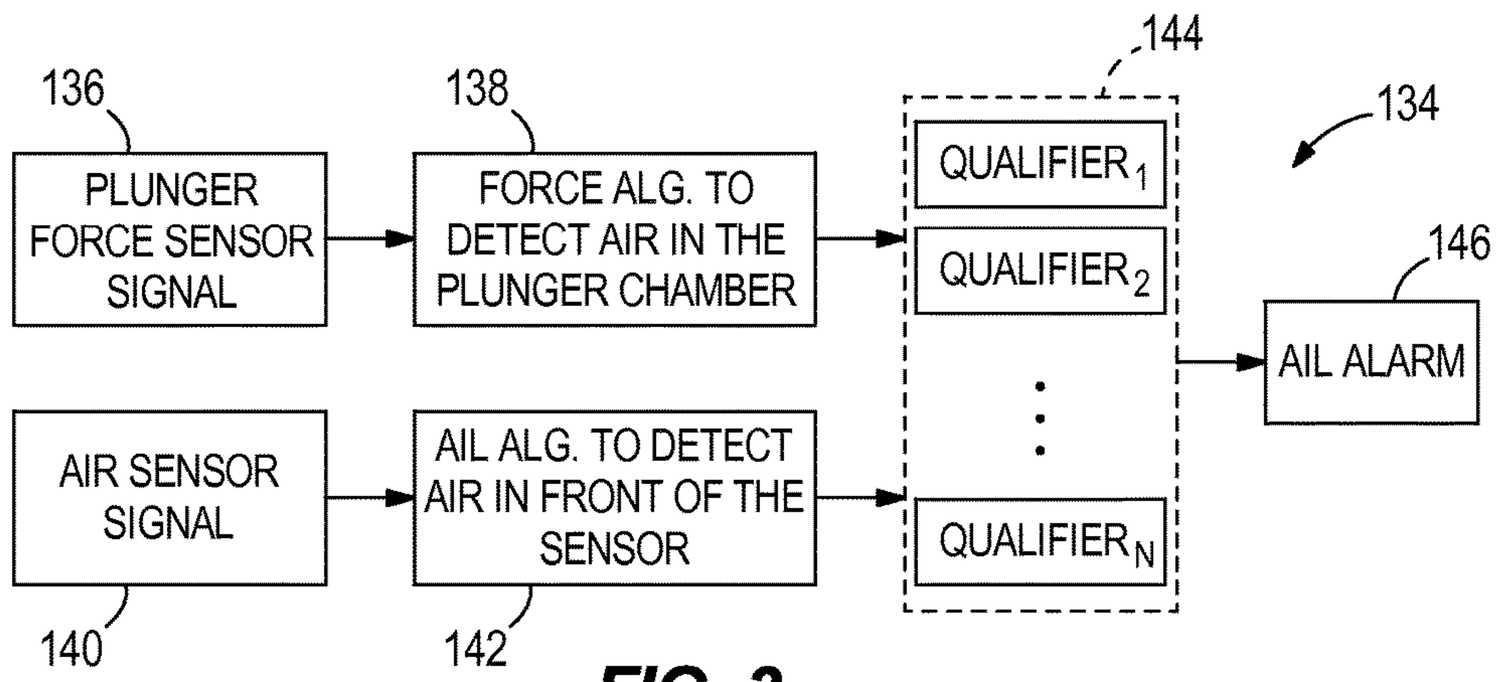


FIG. 3

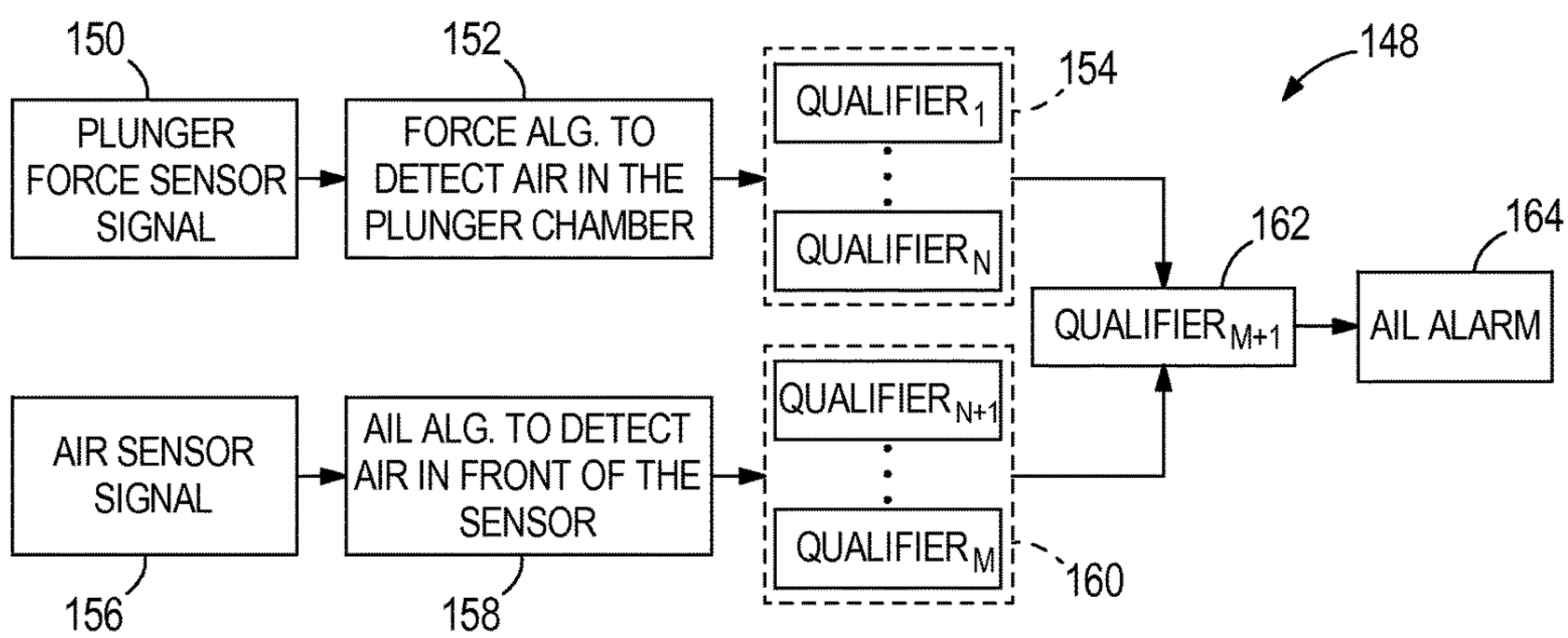


FIG. 4

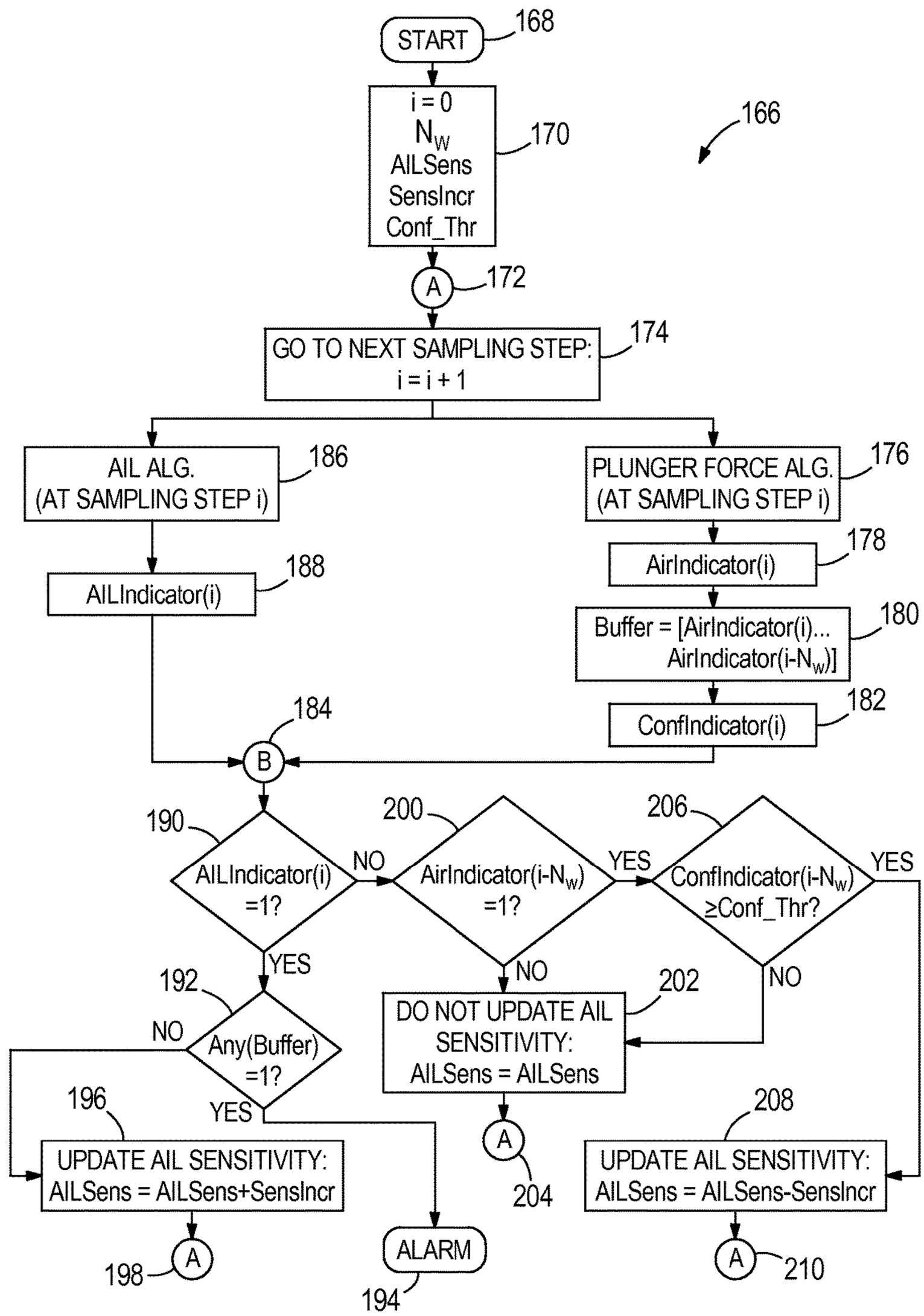

START
168
i = 0
N_W
AILSens
SensIncr
Conf_Thr
170
166
A
172
GO TO NEXT SAMPLING STEP:
i = i + 1
174
AIL ALG.
(AT SAMPLING STEP i)
186
PLUNGER FORCE ALG.
(AT SAMPLING STEP i)
176
AILIndicator(i)
188
AirIndicator(i)
178
Buffer = [AirIndicator(i)...
AirIndicator(i-N_W)]
180
ConfIndicator(i)
182
184
B
190
AILIndicator(i)
=1?
NO
200
AirIndicator(i-N_W)
=1?
YES
206
ConfIndicator(i-N_W)
≥Conf_Thr?
YES
YES
192
Any(Buffer)
=1?
NO
YES
NO
202
DO NOT UPDATE AIL
SENSITIVITY:
AILSens = AILSens
NO
196
UPDATE AIL SENSITIVITY:
AILSens = AILSens+SensIncr
A
204
208
UPDATE AIL SENSITIVITY:
AILSens = AILSens-SensIncr
198
A
ALARM
194
A
210

FIG. 5

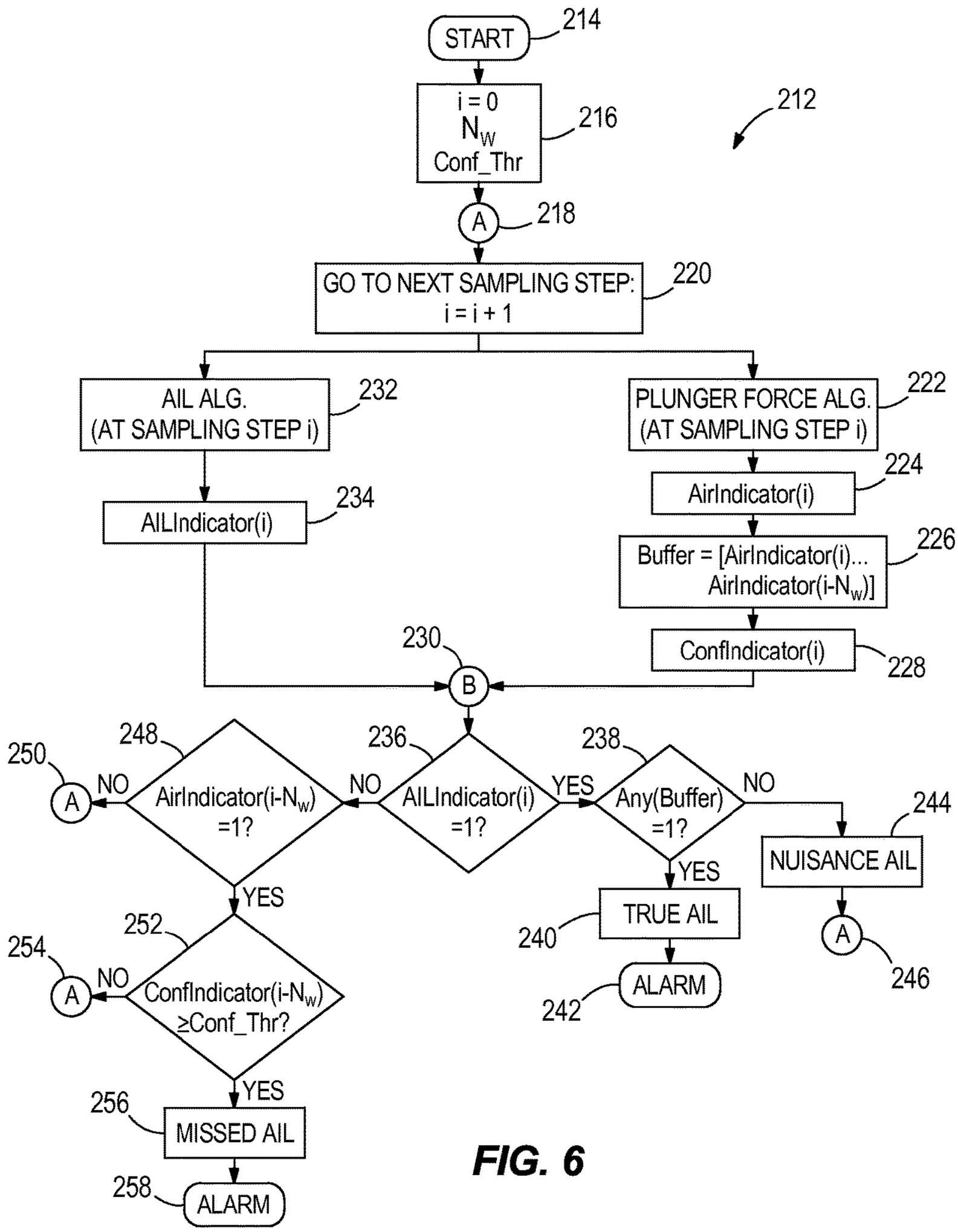

START
214
i = 0
N_W
Conf_Thr
216
212
A
218
GO TO NEXT SAMPLING STEP:
i = i + 1
220
AIL ALG.
(AT SAMPLING STEP i)
232
PLUNGER FORCE ALG.
(AT SAMPLING STEP i)
222
AIL Indicator(i)
234
AirIndicator(i)
224
Buffer = [AirIndicator(i)...
AirIndicator(i-N_W)]
226
ConfIndicator(i)
228
230
B
248
250
A
NO
AirIndicator(i-N_W)
=1?
236
NO
AIL Indicator(i)
=1?
YES
238
Any(Buffer)
=1?
NO
244
NUISANCE AIL
YES
TRUE AIL
240
ALARM
242
A
246
YES
252
254
A
NO
ConfIndicator(i-N_W)
≥Conf_Thr?
YES
256
MISSED AIL
258
ALARM

FIG. 6

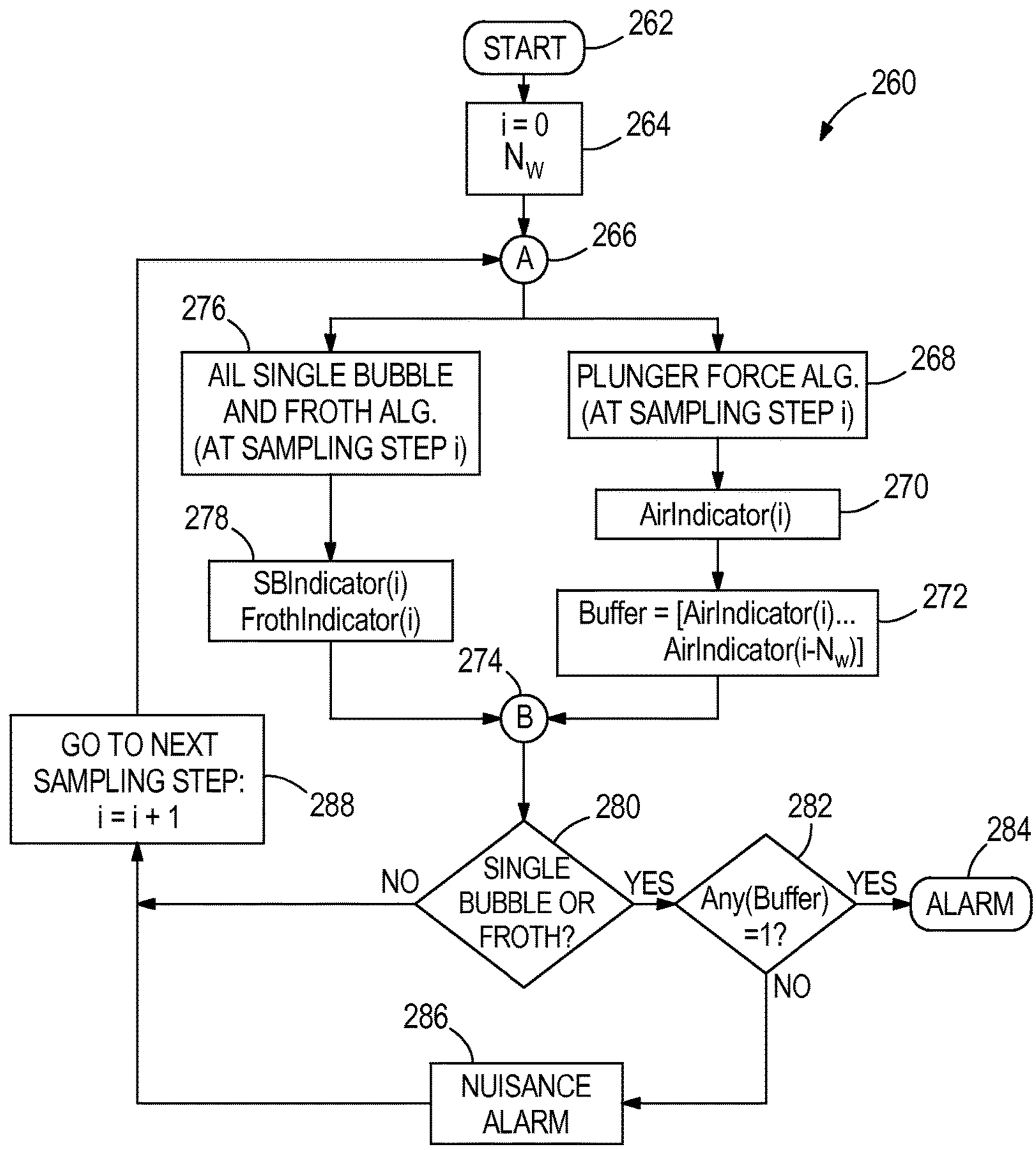

START
262
260
i = 0
N_W
264
A
266
276
AIL SINGLE BUBBLE AND FROTH ALG. (AT SAMPLING STEP i)
PLUNGER FORCE ALG. (AT SAMPLING STEP i)
268
AirIndicator(i)
270
278
SBIndicator(i)
FrothIndicator(i)
Buffer = [AirIndicator(i)... AirIndicator(i-N_w)]
272
274
B
GO TO NEXT SAMPLING STEP: i = i + 1
288
280
282
284
NO
SINGLE BUBBLE OR FROTH?
YES
Any(Buffer) =1?
YES
ALARM
NO
286
NUISANCE ALARM

FIG. 7

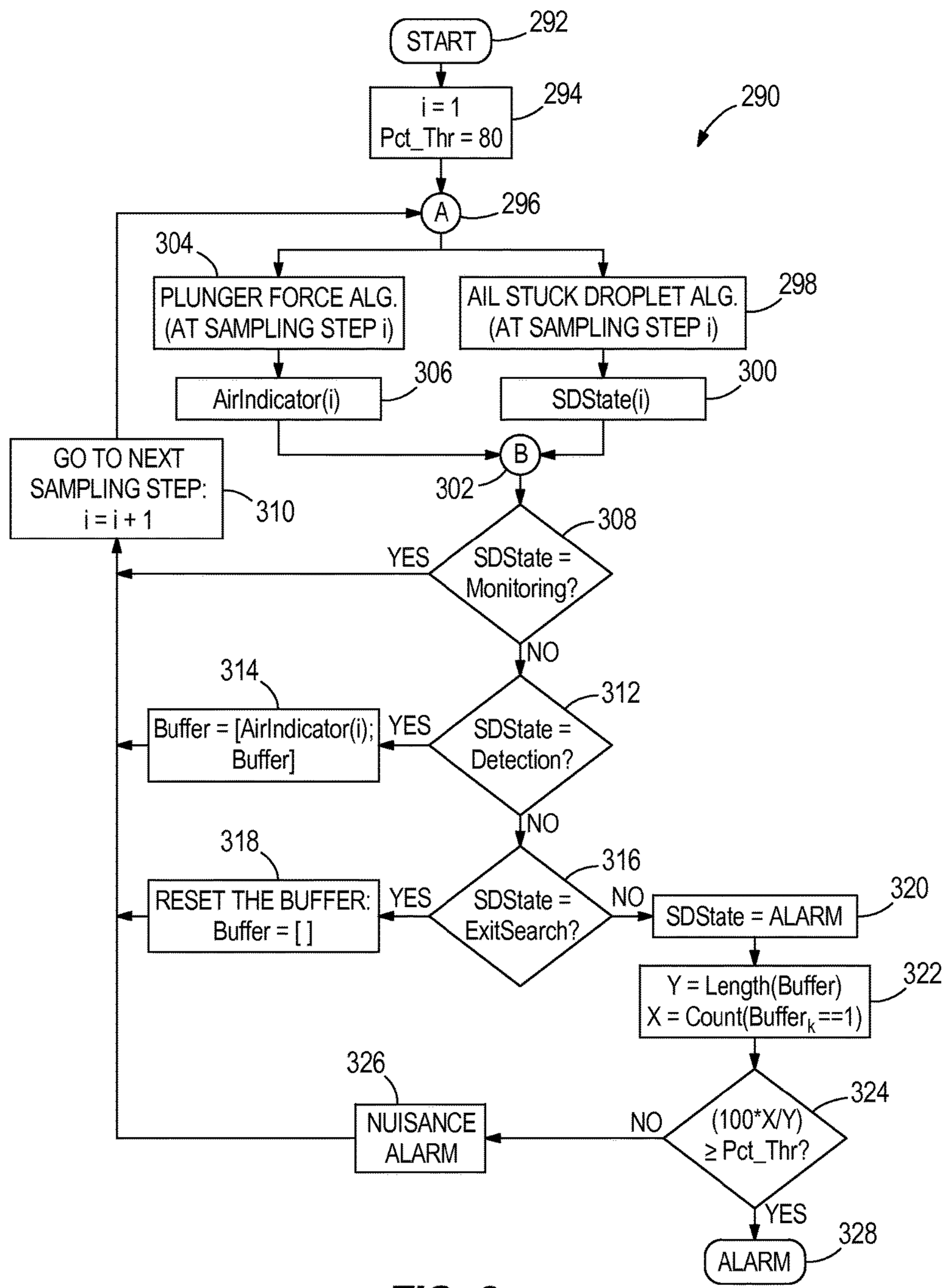

START
292
i = 1
Pct_Thr = 80
294
290
A
296
304
PLUNGER FORCE ALG.
(AT SAMPLING STEP i)
AIL STUCK DROPLET ALG.
(AT SAMPLING STEP i)
298
AirIndicator(i)
306
SDState(i)
300
GO TO NEXT
SAMPLING STEP:
i = i + 1
310
B
302
308
YES
SDState =
Monitoring?
NO
314
Buffer = [AirIndicator(i);
Buffer]
YES
312
SDState =
Detection?
NO
318
RESET THE BUFFER:
Buffer = [ ]
YES
316
SDState =
ExitSearch?
NO
SDState = ALARM
320
Y = Length(Buffer)
X = Count(Buffer$_k$==1)
322
326
NUISANCE
ALARM
NO
(100*X/Y)
≥ Pct_Thr?
324
YES
ALARM
328

FIG. 8

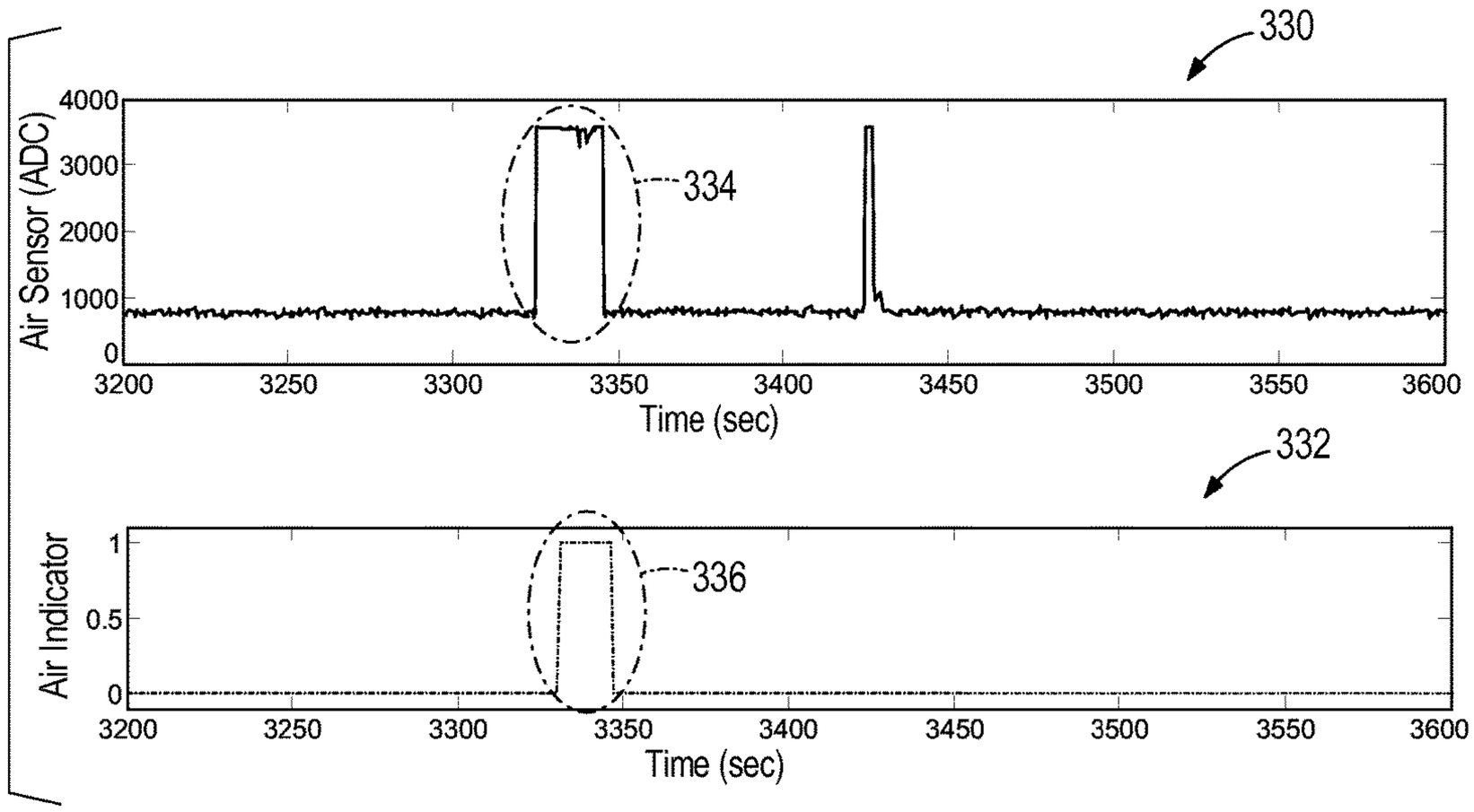

330
Air Sensor (ADC)
4000
3000
2000
1000
0
334
3200
3250
3300
3350
3400
3450
3500
3550
3600
Time (sec)
332
Air Indicator
1
0.5
0
336
Time (sec)

FIG. 9

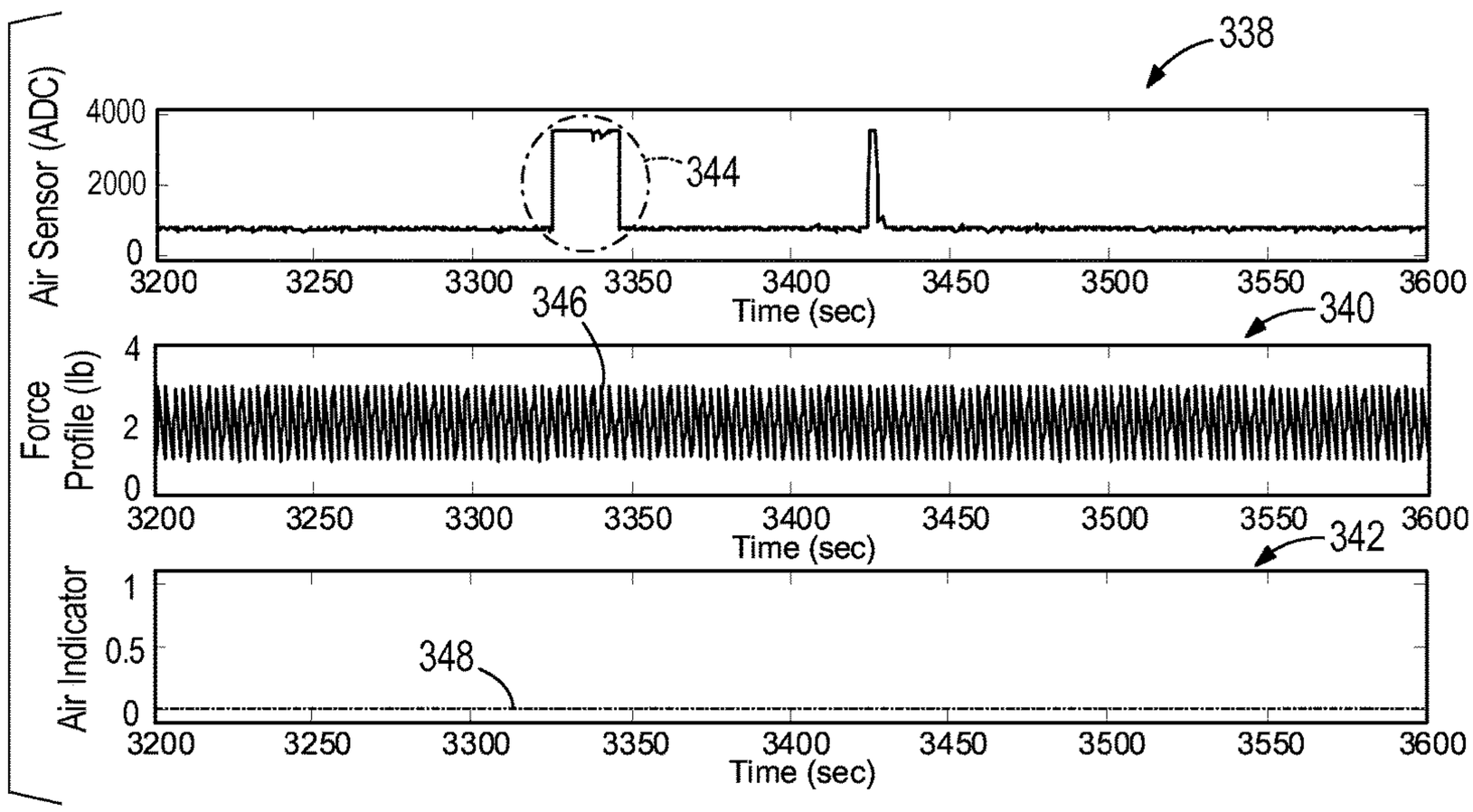

338
Air Sensor (ADC)
4000
2000
0
344
3200
3250
3300
3350
3400
3450
3500
3550
3600
Time (sec)
346
340
Force Profile (lb)
4
2
0
Time (sec)
342
Air Indicator
1
0.5
0
348
Time (sec)

FIG. 10

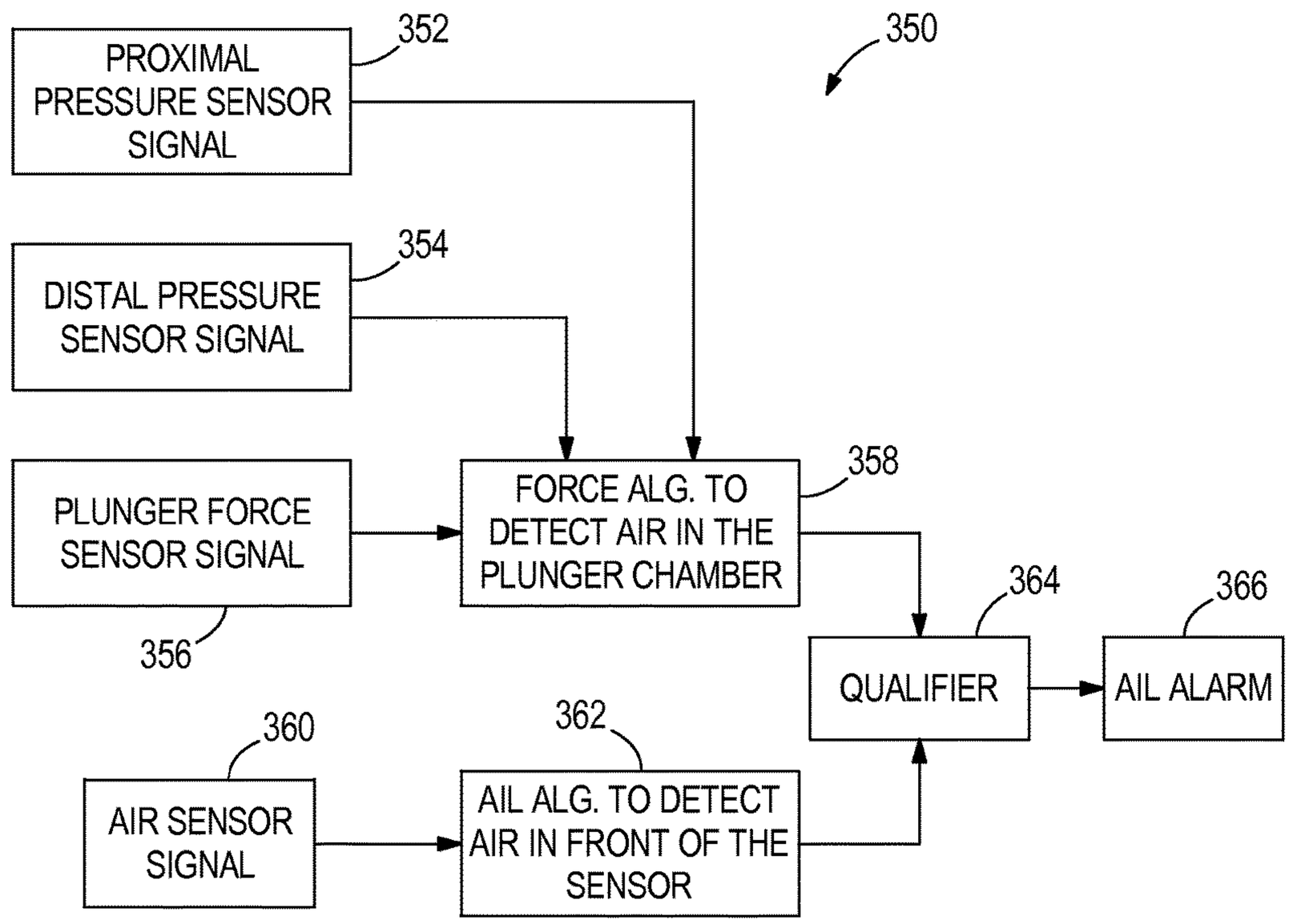

350
PROXIMAL PRESSURE SENSOR SIGNAL
352
DISTAL PRESSURE SENSOR SIGNAL
354
PLUNGER FORCE SENSOR SIGNAL
356
FORCE ALG. TO DETECT AIR IN THE PLUNGER CHAMBER
358
QUALIFIER
364
AIL ALARM
366
AIR SENSOR SIGNAL
360
AIL ALG. TO DETECT AIR IN FRONT OF THE SENSOR
362

FIG. 11

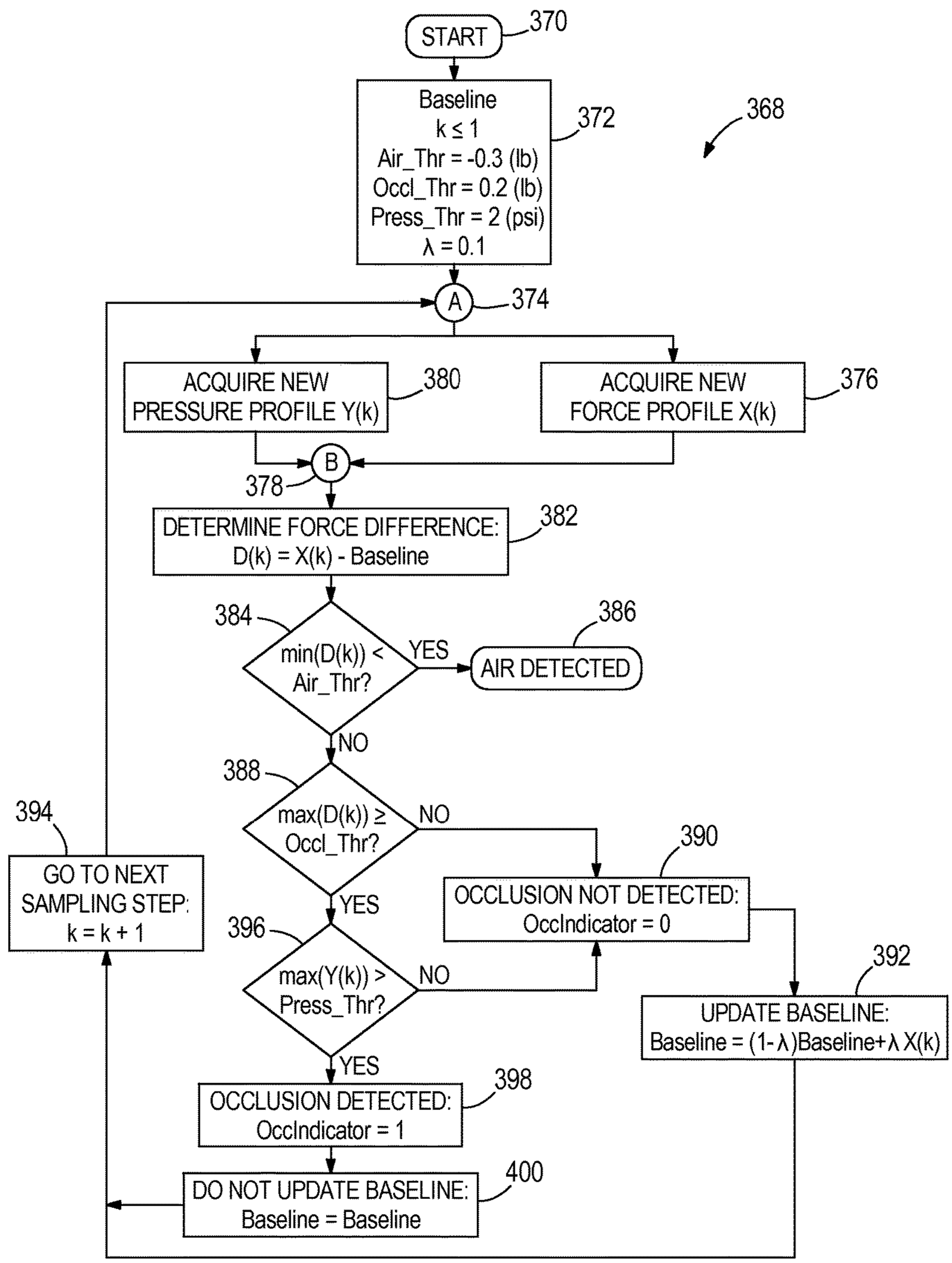

START
370
Baseline
k ≤ 1
Air_Thr = -0.3 (lb)
Occl_Thr = 0.2 (lb)
Press_Thr = 2 (psi)
λ = 0.1
372
368
A
374
ACQUIRE NEW PRESSURE PROFILE Y(k)
380
ACQUIRE NEW FORCE PROFILE X(k)
376
B
378
DETERMINE FORCE DIFFERENCE: D(k) = X(k) - Baseline
382
384
min(D(k)) < Air_Thr?
YES
386
AIR DETECTED
NO
388
max(D(k)) ≥ Occl_Thr?
NO
390
OCCLUSION NOT DETECTED: OccIndicator = 0
YES
396
max(Y(k)) > Press_Thr?
NO
392
UPDATE BASELINE: Baseline = (1-λ)Baseline+λ X(k)
YES
398
OCCLUSION DETECTED: OccIndicator = 1
400
DO NOT UPDATE BASELINE: Baseline = Baseline
394
GO TO NEXT SAMPLING STEP: k = k + 1

FIG. 12

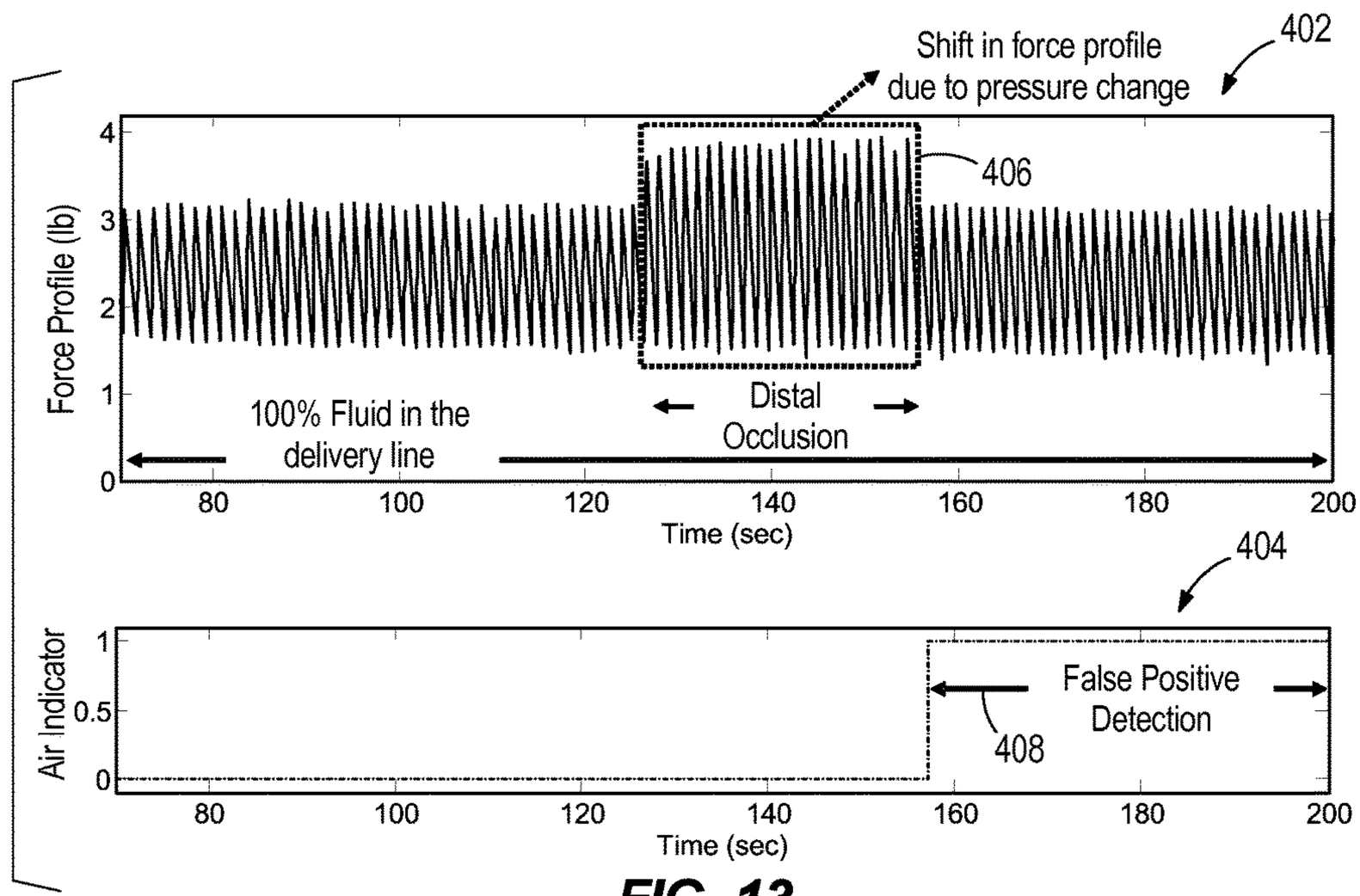

402
Shift in force profile
due to pressure change
406
Force Profile (lb)
100% Fluid in the
delivery line
Distal
Occlusion
Time (sec)
404
Air Indicator
False Positive
Detection
408
Time (sec)

FIG. 13

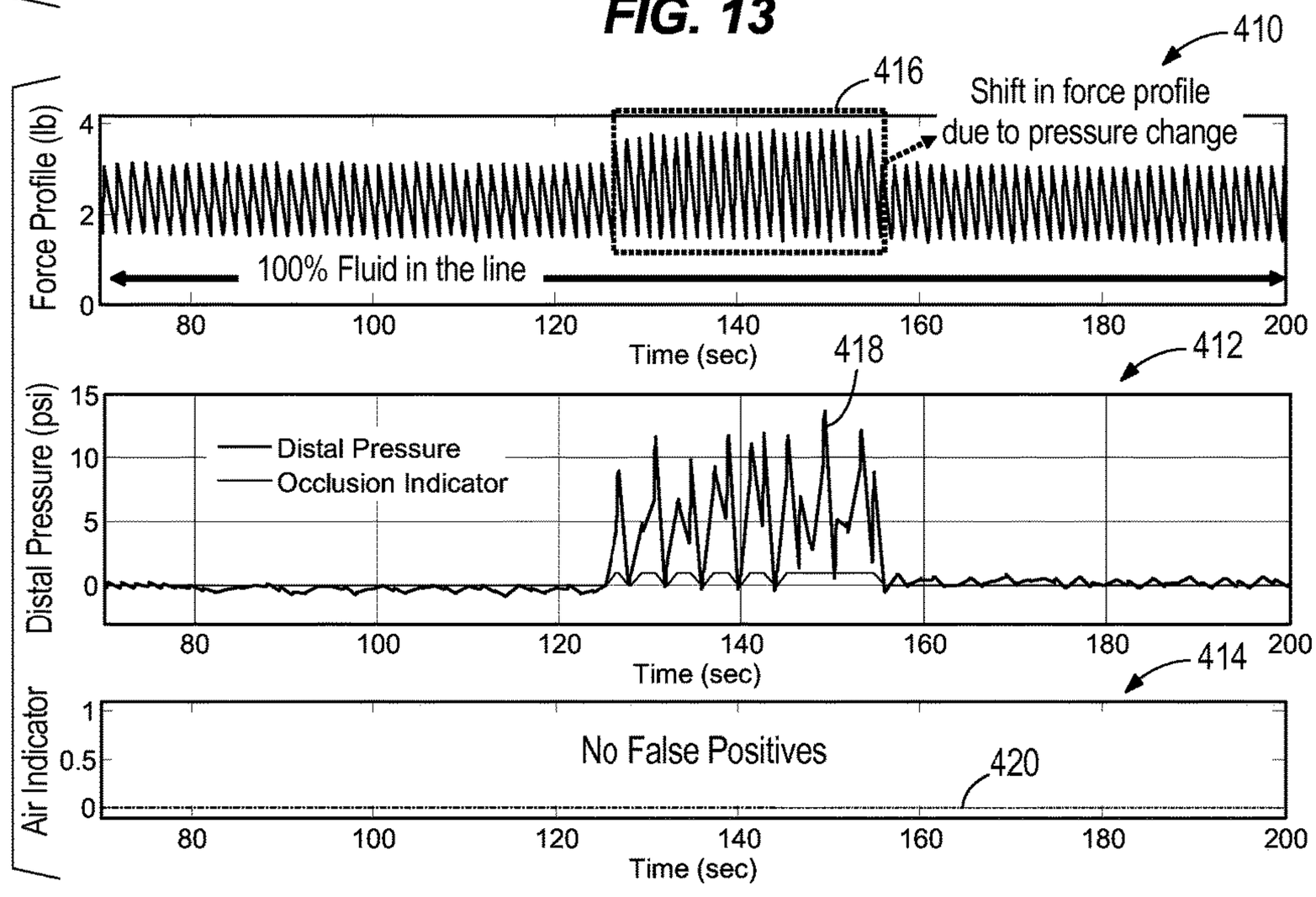

410
416
Shift in force profile
due to pressure change
Force Profile (lb)
100% Fluid in the line
Time (sec)
418
412
Distal Pressure (psi)
Distal Pressure
Occlusion Indicator
Time (sec)
414
Air Indicator
No False Positives
420
Time (sec)

FIG. 14

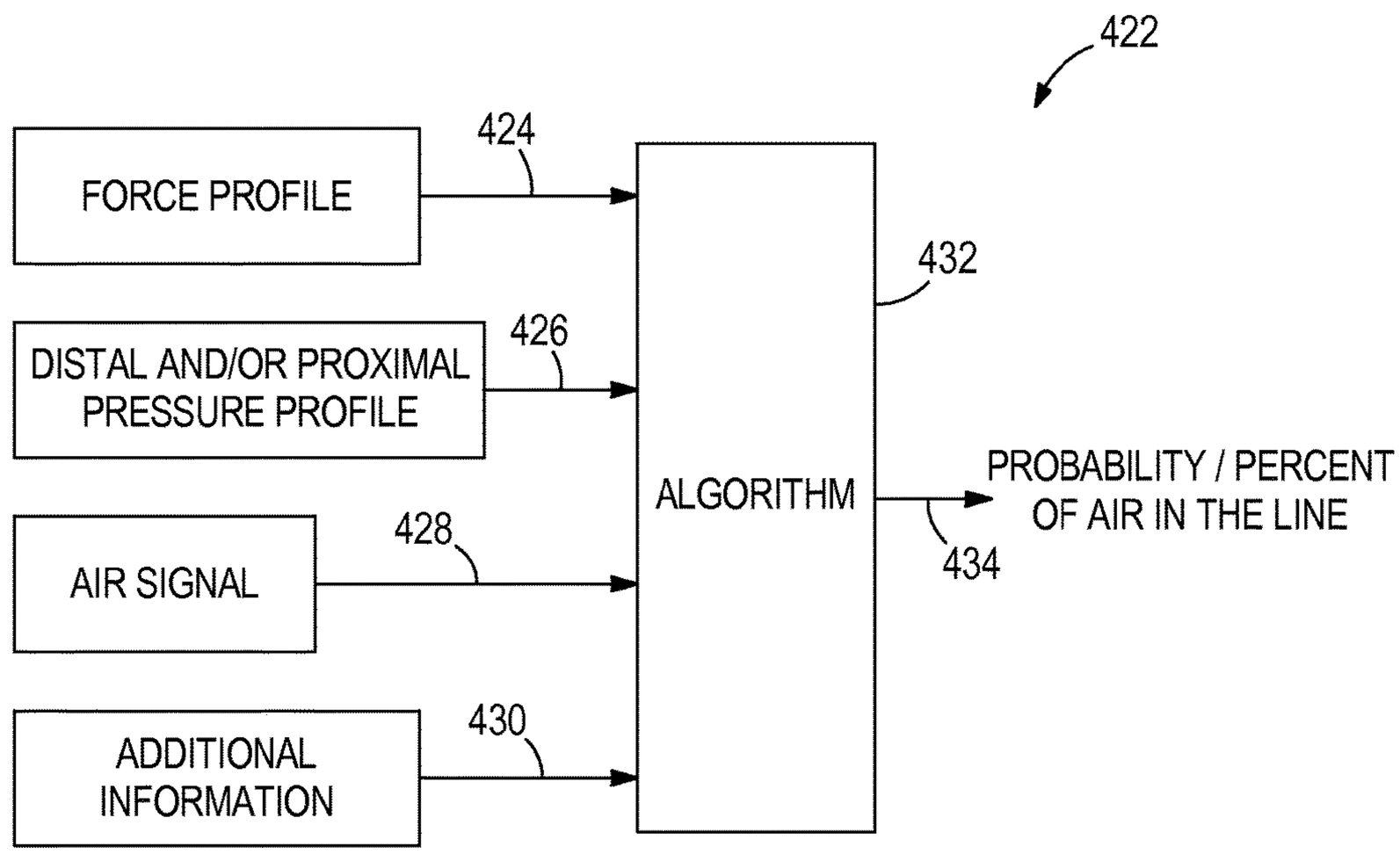

422
FORCE PROFILE
424
DISTAL AND/OR PROXIMAL PRESSURE PROFILE
426
AIR SIGNAL
428
ADDITIONAL INFORMATION
430
ALGORITHM
432
PROBABILITY / PERCENT OF AIR IN THE LINE
434

FIG. 15

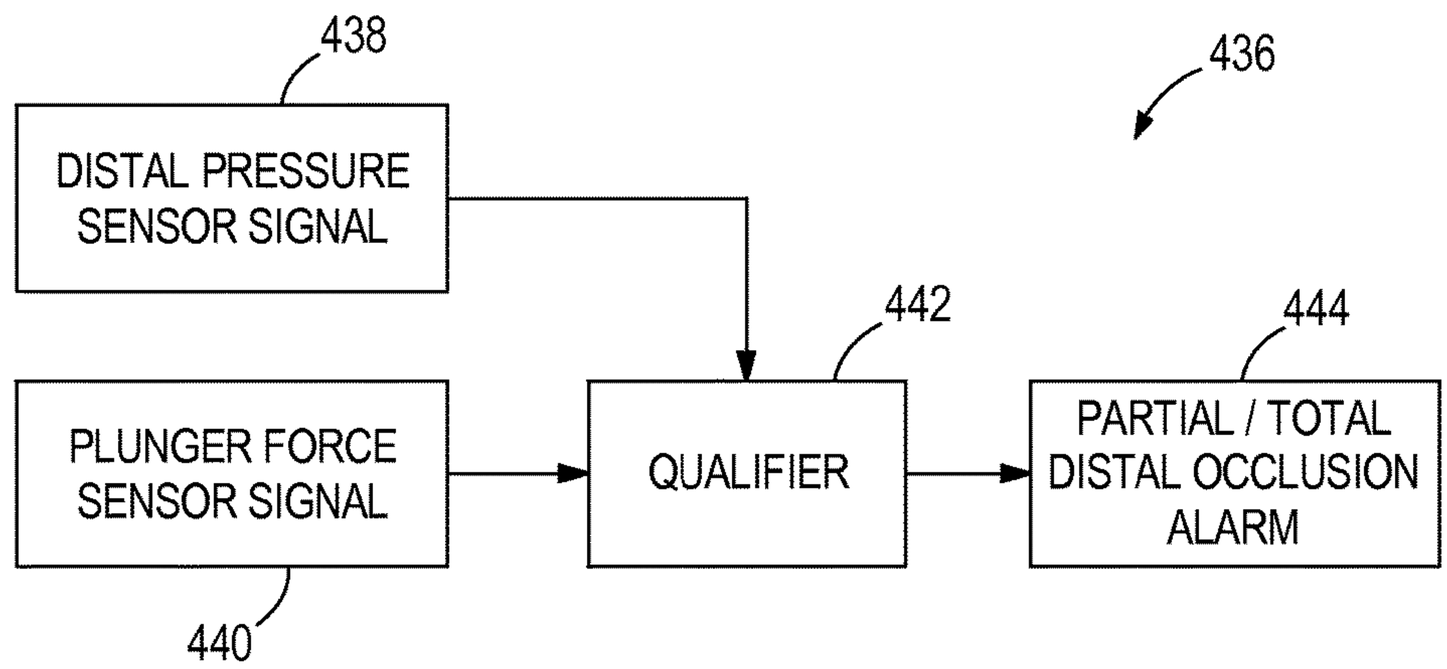

438
436
DISTAL PRESSURE SENSOR SIGNAL
442
444
PLUNGER FORCE SENSOR SIGNAL
QUALIFIER
PARTIAL / TOTAL DISTAL OCCLUSION ALARM
440

FIG. 16

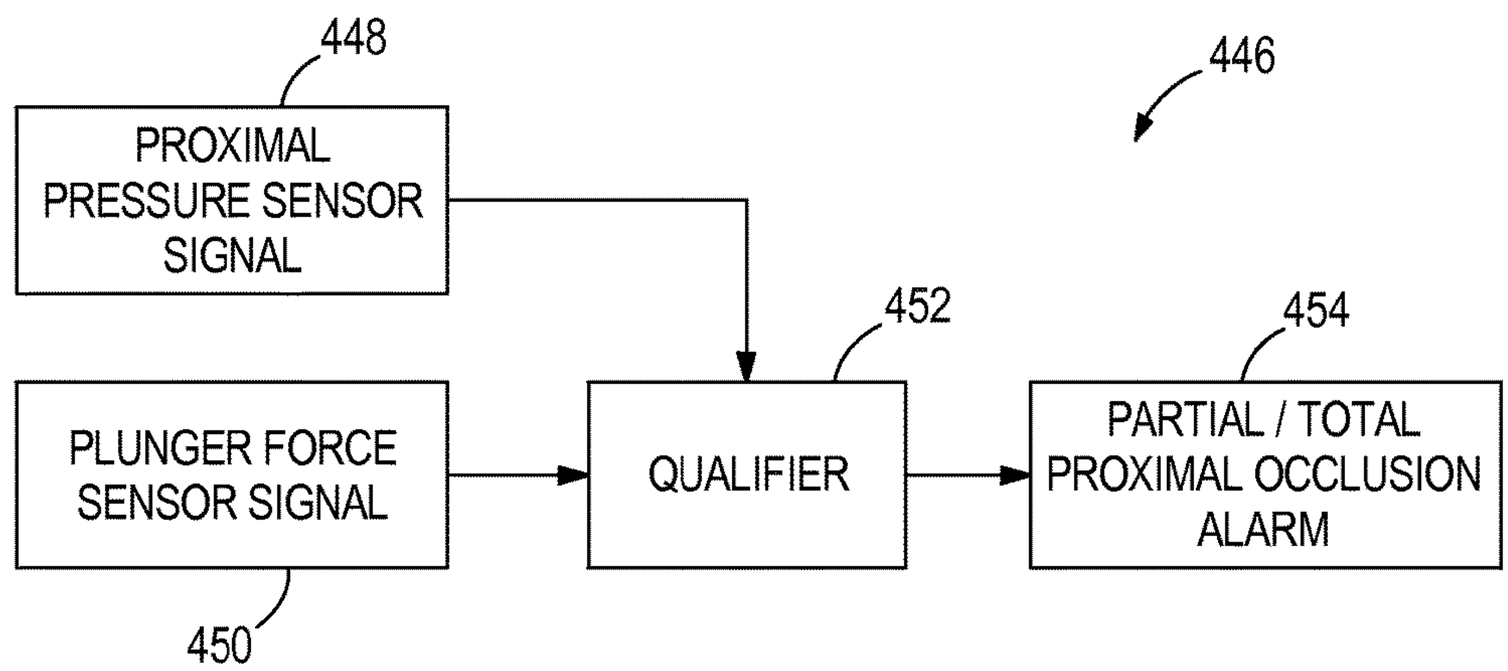

448
446
PROXIMAL PRESSURE SENSOR SIGNAL
452
454
PLUNGER FORCE SENSOR SIGNAL
QUALIFIER
PARTIAL / TOTAL PROXIMAL OCCLUSION ALARM
450

FIG. 17

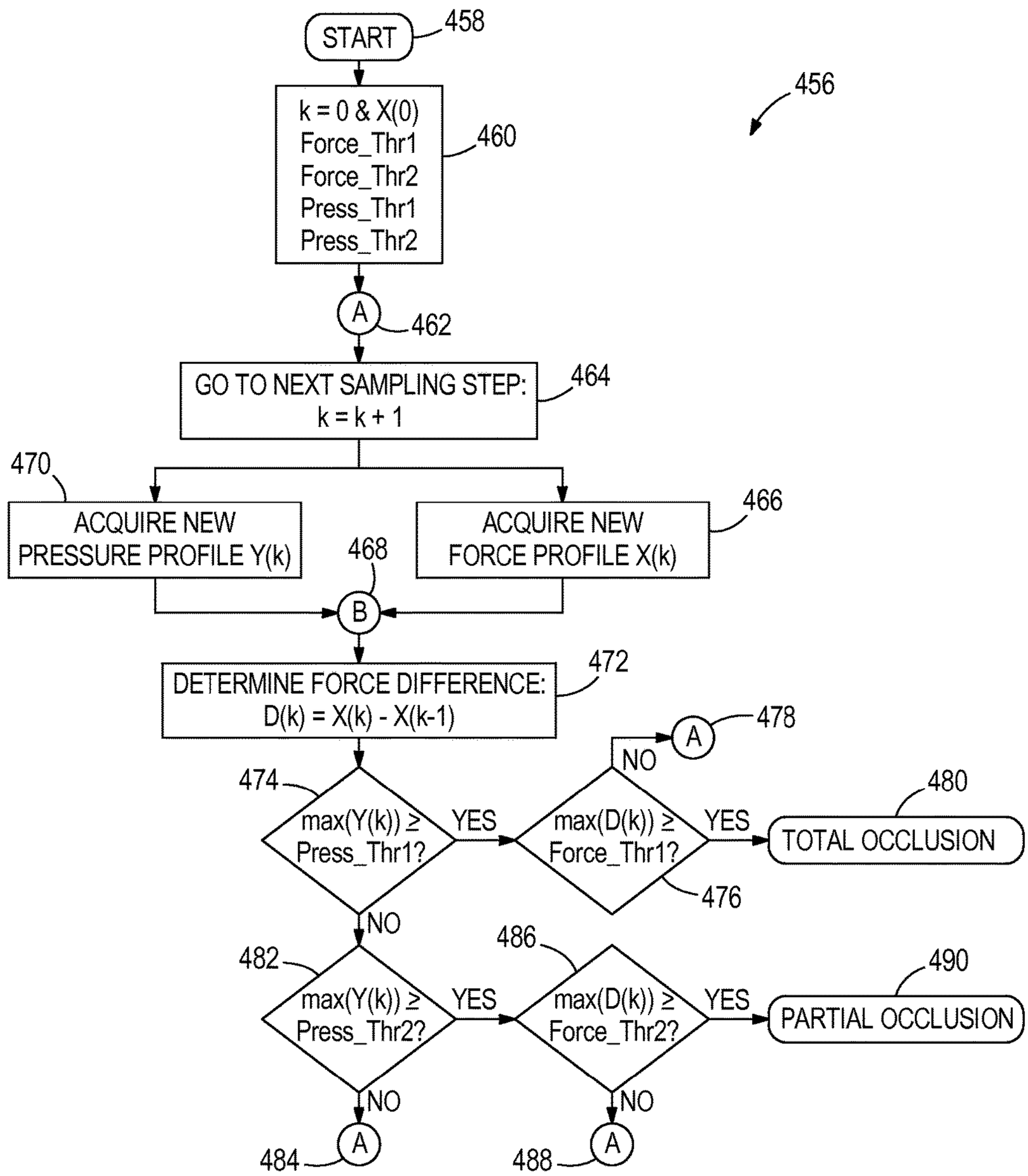

START
458
456
k = 0 & X(0)
Force_Thr1
Force_Thr2
Press_Thr1
Press_Thr2
460
A
462
GO TO NEXT SAMPLING STEP:
k = k + 1
464
470
ACQUIRE NEW
PRESSURE PROFILE Y(k)
ACQUIRE NEW
FORCE PROFILE X(k)
466
468
B
DETERMINE FORCE DIFFERENCE:
D(k) = X(k) - X(k-1)
472
A
478
NO
474
max(Y(k)) ≥
Press_Thr1?
YES
max(D(k)) ≥
Force_Thr1?
YES
480
TOTAL OCCLUSION
476
NO
486
482
max(Y(k)) ≥
Press_Thr2?
YES
max(D(k)) ≥
Force_Thr2?
YES
490
PARTIAL OCCLUSION
NO
NO
A
484
A
488

FIG. 18

MULTI-SENSOR INFUSION SYSTEM FOR DETECTING AIR OR AN OCCLUSION IN THE INFUSION SYSTEM

FIELD OF THE DISCLOSURE

This disclosure relates to detection systems and methods for detecting air or occlusions in an infusion system.

BACKGROUND

Existing strategies for detecting air in the line of an infusion device often involve the use of ultrasonic sensors that are physically located on opposite sides of a tubing segment. When fluid is present in the tube, propagation of the acoustic signal is efficient and produces a large electrical signal via the receiver circuit. On the other hand, the presence of air in the tube causes an acoustical open circuit which substantially attenuates the detected signal. In current practice, detection of air in the tubing segment is performed on the basis of a simple (static) air-fluid boundary or threshold that is applied to the sensor voltage signal. When the air sensor signal moves beyond the pre-defined air/fluid threshold, an alarm condition occurs and the IV infusion is paused.

Additionally, in current practice, there exist methods/algorithms that utilize the plunger force sensor readings to detect the presence of air in the plunger chamber. Several Hospira™ pumps involve the use of a cassette with a chamber that is compressed by an actuated plunger to pump fluid at a controlled rate from the drug container to the patient. The measured force during a pumping cycle is directly related to the type of fluid in the chamber. For instance, fluids are relatively incompressible and generate a higher and different force profile than air. Similarly, a combination of fluid and air in the chamber results in a hybrid force profile that is indicative of the mixture percentages.

Both methods described above rely on observations from a single sensor (i.e., air sensor or force sensor). Faulty sensor observations are the major drawback of such single-sensor based systems/algorithms. For instance, for air sensor based algorithms, a variety of situations (e.g., dancing micro air bubbles, stuck fluid droplet at the end-of-bag, etc.) exist which generate false alarms or mask the presence of air in front of the air-sensor leading to false negatives. Similarly, force sensor based algorithms can be fooled by variable distal/proximal pressure during delivery (e.g., kinked tubing due to patient movement). The measured force during a pumping cycle is affected by the pressure applied to both distal and proximal sides of the tubing. For instance, drop in a distal pressure will cause drop in the plunger force readings, which will be perceived as a transition from fluid to air in the chamber by the existing force algorithms and cause a false positive detection of air. Single-sensor based air-in-line detection systems may fail to detect an end-of-bag situation that can result in air in the line, or may incorrectly determine that the fluid in the line is air (i.e., causing nuisance alarms).

A system and method is needed to overcome one or more issues of one or more of the existing infusion systems or methods.

SUMMARY

In one embodiment, an infusion system is disclosed for being operatively connected to a fluid delivery line and to an infusion container containing an infusion fluid. The infusion system includes a pump, a plurality of different types of sensors connected to the pump or the fluid delivery line, at least one processor, and a memory. The plurality of different types of sensors are configured to indicate whether air is in the fluid delivery line. The at least one processor is in electronic communication with the pump and the plurality of different types of sensors. The memory is in electronic communication with the at least one processor. The memory includes programming code for execution by the at least one processor. The programming code is configured to, based on measurements taken by the plurality of different types of sensors, determine the following: (1) whether there is air in the fluid delivery line; (2) whether there is a partial occlusion or a total occlusion in the fluid delivery line; or (3) a percentage of the air present in the fluid delivery line or the probability of the air being in the fluid delivery line.

In another embodiment, a method for infusing an infusion fluid is disclosed. In one step, infusion fluid is pumped through a fluid delivery line of an infusion system. In another step, measurements are taken with a plurality of different types of sensors connected to the infusion system. In an additional step, at least one processor determines, based on the measurements taken by the plurality of the different types of the sensors, the following: (1) whether there is air in the fluid delivery line; (2) whether there is a partial occlusion or a total occlusion in the fluid delivery line; or (3) a percentage of the air present in the fluid delivery line or the probability of the air being in the fluid delivery line.

The scope of the present disclosure is defined solely by the appended claims and is not affected by the statements within this summary.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure can be better understood with reference to the following drawings and description. The components in the figures are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the disclosure.

FIG. **1** illustrates a block diagram of one embodiment of an infusion system;

FIG. **2** illustrates a flowchart of one embodiment of a method for determining whether air is present in an infusion system;

FIG. **3** illustrates a flowchart of another embodiment of a method for determining whether air is in an infusion system;

FIG. **4** illustrates a flowchart of still another embodiment of a method for determining whether air is in an infusion system;

FIG. **5** illustrates a flowchart of another embodiment of a method for determining whether air is in an infusion system using both plunger force sensor readings and air-in-line sensor readings;

FIG. **6** illustrates a flowchart of another embodiment of a method for determining whether air is in an infusion system using both plunger force sensor readings and air-in-line sensor readings;

FIG. **7** illustrates a flowchart of another embodiment of a method for determining whether air is in an infusion system using both plunger force sensor readings and air-in-line sensor readings;

FIG. **8** illustrates a flowchart of another embodiment of a method for determining whether air is in an infusion system using both plunger force sensor readings and air-in-line sensor readings;

FIG. **9** illustrates two related graphs illustrating how the use of a single-sensor based algorithm for detecting the presence of air within an infusion system can lead to a false positive detection of air in the infusion system;

FIG. **10** illustrates three related graphs illustrating how the use of a multi-sensor based algorithm for detecting the presence of air within the infusion system tested in FIG. **9** eliminates the false positive detection of air in the in the infusion system;

FIG. **11** illustrates a flowchart of one embodiment of a method for determining whether air is in an infusion system;

FIG. **12** illustrates a flowchart of another embodiment of a method for determining whether air is in an infusion system using plunger force sensor readings and pressure sensor readings;

FIG. **13** illustrates two related graphs illustrating how the use of a single-sensor based algorithm for detecting the presence of air within an infusion system can lead to a false positive detection of air in the infusion system;

FIG. **14** illustrates three related graphs illustrating how the use of a multi-sensor based algorithm for detecting the presence of air within the infusion system tested in FIG. **13** eliminates the false positive detection of air in the in the infusion system;

FIG. **15** illustrates a flowchart of an embodiment of a method for determining a probability of air being in an infusion system;

FIG. **16** illustrates a flowchart of an embodiment of a method for determining whether a partial or total distal occlusion is present in an infusion system;

FIG. **17** illustrates a flowchart of another embodiment of a method for determining whether a partial or total proximal occlusion is present in an infusion system; and

FIG. **18** illustrates a flowchart of another embodiment of a method of detecting a partial or total occlusion in an infusion system.

DETAILED DESCRIPTION

The following detailed description is of the best currently contemplated modes of carrying out the disclosure. The description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the disclosure, since the scope of the disclosure is best defined by the appended claims. It is noted that the Figures are purely for illustrative purposes and are not to scale.

In this disclosure, multi-sensor algorithms that utilize signals from at least two different sensors, such as air, force, and pressure sensors, are utilized. Further, methods are disclosed of combining and qualifying the signals from multi-sensors to improve the robustness and reliability (i.e., true negative and false positive performance) of air detection systems.

The disclosure is a software based solution for detecting the presence of air within a fluid delivery line. The target application is an air-in-line and end-of-bag detection system for IV medication infusion pumps (e.g., Symbig™, Gemstar™, or Plum™).

In the disclosure signals from multiple-sensors (i.e., acoustic air sensor, force sensor, distal and proximal pressure sensors) are integrated in order to improve the robustness, and the true negative and false positive performance of IV infusion air-in-line detection systems. Disclosed herein are methods of combining and qualifying the signals from multi-sensors to improve the reliability of air detection systems.

In an alternate embodiment, the disclosure can be used to fully characterize the type of fluid-air mixture present in the infusion line by using multiple-sensor signals to determine the percent of air present or the probability of the presence of air. In another alternate embodiment, the disclosure can be used to improve the robustness and reliability of occlusion detection systems by combining and qualifying the signals from multi-sensors.

The following is a summary of some distinguishing elements of this disclosure. An event detection and qualifier algorithm is disclosed which determines the presence of air in the line during delivery on the basis of air sensor and plunger force sensor observations. An event detection and qualifier algorithm is disclosed that determines the presence of air in the line during delivery on the basis of air sensor, plunger force sensor, and distal and proximal pressure sensor observations. An event detection and qualifier algorithm is disclosed that determines the presence of a partial or total distal/proximal occlusion in the fluid delivery line on the basis of plunger force and pressure sensor signals. A multivariate pattern recognition system is disclosed which determines the percent of air present or the probability of the presence of air in the line.

One problem addressed in this disclosure is to integrate signals from multi-sensors in order to improve the robustness, and the true negative and false positive performance of IV infusion air-in-line detection systems. Disclosed herein are methods of combining and qualifying the signals from multi-sensors to improve the reliability of air detection systems.

Another problem addressed in this disclosure is to fully characterize the type of fluid/air mixture present in the infusion line. Disclosed herein are methods that integrate signals from multi-sensors in order to determine the probability or the percent of air present in the line.

Still another problem addressed in this disclosure is the detection of partial and total distal/proximal occlusion in the fluid delivery line. Disclosed herein are methods of combining and qualifying the signals from multi-sensors to improve the robustness and reliability of occlusion detection systems. In current practice, distal/proximal occlusion algorithms are typically based on pressure readings only.

The disclosure improves the air detection capability of existing infusion pump systems that rely on sensors to make a real-time assessment. In doing so, the disclosed methods do not require additional hardware modifications but instead leverage the acquired multi-sensor signals. Additionally, the disclosure does not necessarily replace existing software modules for air detection but adds an additional safety layer.

The disclosure provides a method for improving the robustness of air detection systems by reducing the likelihood of a false positive air detection. This reduces the chances of an interruption of therapy due to a false alarm. The disclosure further provides a means to improve the sensitivity and specificity of air detection by fusing data collected by multiple sensors.

In current practice, air-in-line algorithms are typically based on air sensor signals only and are used to signify the presence of a single bubble, froth, stuck droplet, or cumulative air in the fluid delivery line. Similarly, plunger force algorithms that are based on plunger force signal only, are typically used to signify the presence of air in the plunger chamber. In this disclosure, plunger force algorithms are integrated with air-in-line algorithms to provide a more robust air-in-line detection system with improved true negative and false positive performance.

There is a delay between force and air sensor readings due to the physical location of the two sensors. For instance, for a Symbiq™ pump, the force sensor is located on the plunger and the air sensor is located distal to the plunger, and the fluid volume between the two sensors is approximately 150 μL (or 2 full plunger strokes). The integrated system disclosed herein utilizes both force and air sensor signals to account for such delays.

FIG. **1** illustrates a block diagram of an infusion system **100** under one embodiment of the disclosure. The infusion system **100** comprises: an infusion container **102**; a fluid delivery line **104**; a pump device **106**; a processing device **108**; an alarm device **110** that generates an audio, visual, or other sensory signal or the like to a user; an input/output device **112**; a plurality of different types of sensors **114**; and a delivery/extraction device **116**. The infusion system **100** may comprise an infusion system such as the Plum™, Gemstar™, Symbiq™, or other type of infusion system.

The infusion container **102** comprises a container for delivering an infusion fluid such as IV fluid or a drug to a patient **118**. The fluid delivery line **104** comprises one or more tubes, connected between the infusion container **102**, the pump device **106**, the plurality of different types of sensors **114**, and the delivery/extraction device **116**, for transporting infusion fluid from the infusion container **102**, through the pump device **106**, through the plurality of different types of sensors **114**, through the delivery/extraction device **116** to the patient **118**. The fluid delivery line **104** may also be used to transport blood, delivered to or extracted from the patient **118** using the delivery/extraction device **116**, through the plurality of different types of sensors **114** as a result of a pumping action of the pump device **106**. The pump device **106** comprises a pump for pumping infusion fluid from the infusion container **102** or for pumping blood to or from the patient **118**. The pump device **106** may comprise a plunger based pump, a peristaltic pump, or another type of pump.

The processing device **108** comprises at least one processor for processing information received from the plurality of different types of sensors **114** and for executing one or more algorithms to determine: (1) whether there is air in the fluid delivery line **104**; (2) whether there is a partial or total occlusion in the fluid delivery line **104**; (3) or a percentage of air present in the fluid delivery line **104** or the probability of the air being in the fluid delivery line **104**. The processing device **108** includes or is in electronic communication with a computer readable memory, containing programming code containing the one or more algorithms for execution by the processor, and a clock. The alarm device **110** comprises an alarm, triggered by the processing device **108**, for notifying the clinician (also referred to as 'user' herein) of: (1) whether there is air in the fluid delivery line **104**; (2) whether there is a partial or total occlusion in the fluid delivery line **104**; (3) or a percentage of air present in the fluid delivery line **104** or the probability of the air being in the fluid delivery line **104**. The alarm device **110** may be configured to stop the pump device **106** prior to a significant amount of air being delivered through the fluid delivery line **104** and the delivery/extraction device **116** to the patient **118**.

The input/output device **112** comprises a device which allows a clinician to input or receive information. The input/output device **112** allows a clinician to input information such as: medication information regarding the infusion fluid being delivered from the infusion container **102**; infusion information regarding the infusion of the infusion fluid being delivered from the infusion container **102**; distance information regarding the distance(s) between the plurality of different type of sensors; delay information regarding the delay(s) in measurements between the plurality of different types of sensors **114**; the selection of settings for the processing device **108** to apply in using the programming code containing the algorithm(s); or other information that is pertinent to the infusion. The medication information regarding the infusion fluid delivered from the infusion container **102** may comprise a formulation of the infusion fluid, a rate of the infusion fluid, a duration of the infusion fluid, a viscosity of the infusion fluid, a therapy of the infusion fluid, or a property of the infusion fluid. The infusion information regarding the infusion fluid delivered from the infusion container **102** may comprise a volume of the infusion fluid in the infusion container or another parameter regarding the infusion of the infusion fluid. The input/output device **112** may allow a clinician to select and/or confirm a user-inputted medication infusion program to be applied by the processing device **108**. The input/output device **112** may further output information to the clinician. In other embodiments, any of the information inputted into the input/output device **112** may be pre-installed into the programming code or the processing device **108**.

The plurality of different types of sensors **114** may comprise any number, combination, or configuration of pressure sensors, force sensors, air sensors, or other type of sensors. The pressure sensors may comprise one or more proximal or distal pressure sensors for detecting the amount of pressure in the fluid delivery line **104** proximal or distal to the pump device **106**. The amount of pressure detected by the one or more pressure sensors is indicative of whether air, fluid, or some combination thereof is present in the fluid delivery line **104**. For instance, U.S. Pat. No. 8,403,908 to Jacobson et al., which is commonly owned and hereby incorporated by reference, discloses the use of pressure sensors to determine whether air, fluid, or some combination thereof is present in the fluid delivery line **104**. The one or more force sensors may comprise one or more force sensors for detecting the amount of force on a plunger of the pump device **106**. The amount of force detected by the one or more force sensors is indicative of whether air, fluid, or some combination thereof is present in the fluid delivery line **104**. For instance, U.S. Ser. No. 13/851,207 filed 27 Mar. 2013, which is commonly owned and hereby incorporated by reference, discloses the use of force sensors to determine whether air, fluid, or some combination thereof is present in the fluid delivery line **104**. The one or more air sensors may comprise one or more air sensors for detecting whether air, fluid, or a combination thereof is present in the fluid delivery line **104**. The strength of the signal that propagates from the one or more air sensors through the fluid delivery line **104** is indicative of whether air, fluid, or some combination thereof is present in the fluid delivery line **104**. For instance, U.S. Pat. No. 7,981,082 to Wang et al., which is commonly owned and hereby incorporated by reference, discloses the use of air sensors to determine whether air, fluid, or some combination thereof is present in the fluid delivery line **104**. In other embodiments, any number, types, combinations, or configurations of sensors **114** may be used to determine whether air, fluid, or some combination thereof is present in the fluid delivery line **104**.

The delivery/extraction device **116** comprises a patient vascular access point device for delivering infusion fluid from the infusion container **102** to the patient **118**, or for extracting blood from the patient **118**. The delivery/extraction device **116** may comprise a needle, a catheter, a cannula, or another type of delivery/extraction device. In other embodiments, the infusion system **100** of FIG. **1** may be

altered to vary the components, to take away one or more components, or to add one or more components.

FIG. **2** illustrates a flowchart of one embodiment of a method **120** for determining whether air is in an infusion system. The method **120** may utilize the system of FIG. **1**. In other embodiments, the method **120** may utilize varying systems. In step **122**, a force sensor determines how much force is acting upon a plunger or pumping member of a pump. In step **124**, a force algorithm is applied using the force sensor measurements of step **122** in order to detect whether air is in a chamber of the pump based on the force sensor measurements. In step **126**, an air sensor determines how much of a signal propagates through a fluid delivery line of the infusion system. In step **128**, an air-in-line algorithm is applied using the air sensor measurements of step **126** in order to detect whether air is located in the fluid delivery line at the air sensor based on the air sensor measurements. In step **130**, a single qualifier algorithm is applied which uses both the results of the application of the force algorithm in step **124** and the results of the application of the air-in-line algorithm of step **128** in order to determine whether air is in the infusion system. The qualifier algorithm of step **130** integrates the decisions of steps **124** and **128** which were based on the measurements of the force sensor and the air sensor and in doing so considers the delay between the force sensor and the air sensor which results due to the distance between them. In such manner, by considering the air results of different types of sensors at different locations a more accurate determination is made as to whether air is contained in the infusion system. In step **132**, the alarm device turns on or generates an alarm if step **130** determines that air is in the infusion system. In other embodiments, the method **120** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **3** illustrates a flowchart of another embodiment of a method **134** for determining whether air is in an infusion system. The method **134** may utilize the system of FIG. **1**. In other embodiments, the method **134** may utilize varying systems. In step **136**, a force sensor determines how much force is acting upon a plunger or pumping member of a pump. In step **138**, a force algorithm is applied using the force sensor measurements of step **136** in order to detect whether air is in a chamber of the pump based on the force sensor measurements. In step **140**, an air sensor determines how much of a signal propagates through a fluid delivery line of the infusion system. In step **142**, an air-in-line algorithm is applied using the air sensor measurements of step **140** in order to detect whether air is located in the fluid delivery line at the air sensor based on the air sensor measurements. In step **144**, multiple qualifier algorithms are applied which use both the results of the application of the force algorithm in step **138** and the results of the application of the air-in-line algorithm of step **142** in order to determine whether air is in the infusion system. The multiple qualifier algorithms of step **144** integrate the decisions of steps **138** and **142** which were based on the measurements of the force sensor and the air sensor and in doing so consider the delay between the force sensor and the air sensor which results due to the distance between them. In such manner, by considering the air results of different types of sensors at different locations a more accurate determination is made as to whether air is contained in the infusion system. In step **146**, the alarm device generates or turns on an alarm if step **144** determines that air is in the infusion system. In other embodiments, the method **134** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **4** illustrates a flowchart of still another embodiment of a method **148** for determining whether air is in an infusion system. The method **148** may utilize the system of FIG. **1**. In other embodiments, the method **148** may utilize varying systems. In step **150**, a force sensor determines how much force is acting upon a plunger or pumping member of a pump. In step **152**, a force algorithm is applied using the force sensor measurements of step **150** in order to detect whether air is in a chamber of the pump based on the force sensor measurements. In step **154**, multiple qualifier algorithms are applied which use the results of the application of the force algorithm in step **152** in order to determine whether air is in the infusion system. In step **156**, an air sensor determines how much of a signal propagates through a fluid delivery line of the infusion system. In step **158**, an air-in-line algorithm is applied using the air sensor measurements of step **156** in order to detect whether air is located in the fluid delivery line at the air sensor based on the air sensor measurements. In step **160**, multiple qualifier algorithms are applied which use the results of the application of the air-in-line algorithm in step **158** in order to determine whether air is in the infusion system. In step **162**, a single qualifier algorithm is applied which uses both the results of the multiple qualifier algorithms of step **154** and the results of the multiple qualifier algorithms of step **160** in order to determine whether air is in the infusion system. The qualifier algorithm of step **162** integrates the decisions of steps **154** and **160** which were based on the measurements of the force sensor and the air sensor and in doing so considers the delay between the force sensor and the air sensor which results due to the distance between them. In such manner, by considering the air results of different types of sensors at different locations a more accurate determination is made as to whether air is contained in the infusion system. In step **164**, the alarm device turns on or generates an alarm if step **162** determines that air is in the infusion system. In other embodiments, the method **148** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **5** illustrates a flowchart of another embodiment of a method **166** for determining whether air is in an infusion system using both plunger force sensor readings and air-in-line sensor readings. It can be applied to any air-in-line algorithm as long as it outputs an air-in-line indicator at each sampling step indicating whether air was detected in the line by the air-in-line sensor. Similarly, it can be applied to any force algorithm as long as it outputs an air indicator and a confidence indicator at each sampling step indicating whether air was detected in the line by the plunger force sensor and to what confidence level the air indicator based on the plunger force sensor determined that the air was present. The method **166** uses the force algorithm to adjust the sensitivity of the air-in-line algorithm during infusion (i.e. the sensitivity of the air-in-line algorithm is increased when the force algorithm detects air with high confidence and the air-in-line algorithm fails to detect the air; and the sensitivity of the air-in-line algorithm is decreased when the force algorithm does not detect air anywhere in a buffer and the air-in-line algorithm mistakenly detects the air). The method **166** takes into account delays between the air-in-line indicator and the air indicator which result from differences in locations of the air-in-line sensor and the plunger force sensor by utilizing a buffer that stores previous air indicators based on the plunger force sensor measurements. The

method **166** may utilize the system of FIG. **1**. In other embodiments, the method **166** may utilize varying systems.

In step **168**, the method starts. The method proceeds from step **168** to step **170**. In step **170**, the variables are set including setting sampling step i=0, setting the number Nw of pumping strokes of delay between a plunger force sensor and an air-in-line sensor, setting the air-in-line sensitivity AILSens of the air-in-line sensor to an initial setting, setting the air-in-line sensitivity increment SensIncr of the air-in-line sensor to an initial setting, and setting the percent confidence threshold Conf_Thr to an initial setting. It is noted that throughout this disclosure that sampling step i represents one stroke of the pump of the infusion system. The method proceeds from step **170** through location step **172** to step **174**. In step **174**, sampling step i is reset to i=i+1. The method proceeds from step **174** to step **176**.

In step **176**, a plunger force algorithm is used to determine at sampling step i whether air is detected in a pumping chamber based on measurements of a plunger force sensor. The method proceeds from step **176** to step **178**. In step **178**, if air is detected in step **176** then an air indicator Airindicator (i) is set to 1 and if air is not detected in step **176** then the air indicator Airindicator(i) is set to 0. The method proceeds from step **178** to step **180**. In step **180**, a Buffer is saved as [AirIndicator(i) . . . AirIndicator(i−Nw)] saving the 1 or 0 setting made in step **178**. For instance, if it takes 2 pumping strokes of the pump for the infusion fluid to travel from the plunger force sensor to the air-in-line sensor, then Nw is set to 2 to accommodate for this delay and the Buffer saves the Airindicator(i) for the current sample i, the AirIndicator(i−1) for the previous sample i−1, and the Airindicator(i−2) for two samples before. In step **182**, a confidence indicator ConfIndicator(i) is set for the current sample i as to the percent confidence in the presence of air being present in the pumping chamber. The method proceeds from step **182** through location step **184** to step **190**.

While the method proceeds from step **174** to **176**, the method also simultaneously proceeds from step **174** to step **186**. In step **186**, an air-in-line algorithm is used to determine at sampling step i whether air is detected in a fluid-delivery-line of the infusion system based on measurements from the air-in-line sensor. The method proceeds from step **186** to step **188**. In step **188**, if air is detected in step **186** then an air-in-line AILIndicator(i) is set to 1 and if air is not detected in step **186** then the air-in-line AILIndicator(i) is set to 0. The method proceeds from step **188** through location step **184** to step **190**.

In step **190**, a determination is made as to whether the air-in-line indicator AILIndicator(i) equals 1. If a determination is made that the air-in-line indicator AILIndicator(i) does equal 1, then the method proceeds from step **190** to step **192**. In step **192**, if any of the buffer saved in step **180** is set to 1 (i.e. if any of AirIndicator(i) . . . AirIndicator(i−Nw) is set to 1), then the method proceeds from step **192** to step **194** and turns on the alarm indicating that air is disposed in the infusion system since both the air-in-line indicator (AILIndicator) and the plunger force indicator (AirIndicator) indicated that air was in the infusion system (i.e. AILIndicator(i)=1 and one or more of the entries saved in the AirIndicator buffer=1). When the alarm is turned on in step **194**, the infusion system is turned off automatically or manually by the clinician to stop the infusion of the infusion fluid.

In step **192**, if any of the buffer saved in step **180** is not set to 1 (i.e. if any of AirIndicator(i) . . . AirIndicator(i−Nw) is not set to 1), then the method proceeds from step **192** to step **196**. In step **196**, the air-in-line sensitivity AILSens is updated to decrease the sensitivity using the equation AILSens=AILSens+SensIncr. The air-in-line sensitivity is decreased in step **196** because air was detected by the air-in-line indicator AILIndicator (i.e. AILIndicator(i)=1) but air was not detected by the plunger force indicator AIRIndicator (i.e. none of the entries in the AirIndicator buffer=1) which demonstrates that the air-in-line indicator AILIndicator caused a false positive. To increase the robustness of the air-detection system in step **196** the sensitivity of the air-in-line indicator is decreased to reduce the occurrence of false positives. It is noted that to decrease the air-in-line sensitivity in step **196** the AILSens is actually increased because the larger the AILSens is the less sensitive the algorithm will be causing it to only detect larger air-slugs. The method proceeds from step **196** through location step **198** though location step **172** to step **174** and repeats the process steps.

In step **190**, if the air-in-line indicator AILIndicator(i) is not set to 1 the method proceeds from step **190** to step **200**. In step **200**, a determination is made whether Airindicator (i−Nw) is set to 1 (i.e. whether the plunger force indicator Nw cycles ahead of the air-in-line detector determined that air was in the infusion system to accommodate for the delay between the plunger force sensor and the air-in-line sensor). If the determination is made in step **200** that the Airindicator (i−Nw) is not set to 1 the method proceeds from step **200** to step **202**. In step **202**, the AIL Sensitivity is not updated (i.e. AILSens remains equal to AILSens since neither the air-in-line indicator (AILIndicator) nor the plunger force indicator (AirIndicator) indicated that air was in the infusion system). The method proceeds from step **202** through location step **204** through location step **172** to step **174** and repeats the process steps.

If the determination is made in step **200** that the Airindicator(i−Nw) is set to 1 the method proceeds from step **200** to step **206**. In step **206**, a determination is made whether the confidence indicator ConfIndicator(i−Nw) of the force algorithm (indicating the confidence level that air has been detected in the infusion system by the plunger force sensor by applying the force algorithm Nw cycles ahead of the air-in-line sensor) is greater than or equal to the confidence threshold (Conf_Thr). If the determination is made in step **206** that the confidence indicator of the force algorithm is not greater than or equal to the confidence threshold, the method proceeds from step **206** to step **202**. In step **202**, the air-in-line sensitivity AILSens is not updated (i.e. AILSens remains equal to AILSens since the air-in-line indicator (AILIndicator) did not indicate that air was in the infusion system and the plunger force indicator (AirIndicator) only indicated with low confidence that air was in the infusion system). The method proceeds from step **202** through location step **204** through location step **172** to step **174** and repeats the process steps.

If the determination is made in step **206** that the confidence indicator ConfIndicator(i−Nw) of the force algorithm is greater than or equal to the confidence threshold Conf_Thr, the method proceeds from step **206** to step **208**. In step **208**, the air-in-line sensitivity is updated to increase the sensitivity using the equation AILSens=AILSens−SensIncr. The air-in-line sensitivity is increased in step **208** because air was not detected by the air-in-line indicator AILIndicator (i.e. AILIndicator(i) was not set to 1) but air was detected by the plunger force indicator AIRIndicator with a high confidence level (Airindicator(i−Nw) was set to 1 and the ConfIndicator(i−Nw) was greater than or equal to Conf_Thr) which demonstrates that the air-in-line indicator AILIndicator was not sensitive enough and caused a missed air-in-line

AILIndicator detection of air. To increase the robustness of the air-detection system in step **208** the sensitivity of the air-in-line indicator is increased to reduce the occurrence of missed positive detections of air in the infusion system. It is noted that to increase the air-in-line sensitivity in step **208** the AILSens is actually decreased because the smaller the AILSens is the more sensitive the algorithm will be causing it to detect smaller air-slugs. The method proceeds from step **208** through location step **210** through location step **172** to step **174** and repeats the process steps. In other embodiments, the method **166** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **6** illustrates a flowchart of another embodiment of a method **212** for determining whether air is in an infusion system using both plunger force sensor readings and air-in-line sensor readings. It can be applied to any air-in-line algorithm as long as it outputs an air-in-line indicator at each sampling step indicating whether air was detected in the line by the air-in-line sensor. Similarly, it can be applied to any force algorithm as long as it outputs an air indicator and a confidence indicator at each sampling step indicating whether air was detected in the line by the plunger force sensor and to what confidence level the air indicator based on the plunger force sensor determined that the air was present. The method **212** uses the force algorithm to declare true, missed, or nuisance/false air-in-line alarms. The method **212** takes into account delays between the air-in-line indicator and the air indicator which result from differences in locations of the air-in-line sensor and the plunger force sensor by utilizing a buffer that stores previous air indicators based on the plunger force sensor measurements. The method **212** may utilize the system of FIG. **1**. In other embodiments, the method **212** may utilize varying systems.

In step **214**, the method starts. The method proceeds from step **214** to step **216**. In step **216**, the variables are set including setting sampling step i=0, setting the number Nw of pumping strokes of delay between the plunger force sensor and an air-in-line sensor, and setting the percent confidence threshold Conf_Thr to an initial setting. The method proceeds from step **216** through location step **218** to step **220**. In step **220**, sampling step i is reset to i=i+1. The method proceeds from step **220** to step **222**.

In step **222**, a plunger force algorithm is used to determine at sampling step i whether air is detected in a pumping chamber based on measurements of a plunger force sensor. The method proceeds from step **222** to step **224**. In step **224**, if air is detected in step **222** then an air indicator Airindicator (i) is set to 1 and if air is not detected in step **222** then the air indicator Airindicator(i) is set to 0. The method proceeds from step **224** to step **226**. In step **226**, a Buffer is saved as [AirIndicator(i) . . . AirIndicator(i−Nw)] saving the 1 or 0 setting made in step **224**. For instance, if it takes 2 pumping strokes of the pump for the infusion fluid to travel from the plunger force sensor to the air-in-line sensor, then Nw is set to 2 to accommodate for this delay and the Buffer saves the Airindicator(i) for the current sample i, the Airindicator(i−1) for the previous sample i−1, and the Airindicator(i−2) for two samples before. In step **228**, a confidence indicator ConfIndicator(i) is set for the current sample i as to the percent confidence in the presence of air being present in the pumping chamber. The method proceeds from step **228** through location step **230** to step **236**.

While the method proceeds from step **220** to **222**, the method also simultaneously proceeds from step **220** to step **232**. In step **232**, an air-in-line algorithm is used to determine at sampling step i whether air is detected in a fluid-delivery-line of the infusion system based on measurements from the air-in-line sensor. The method proceeds from step **232** to step **234**. In step **234**, if air is detected in step **232** then an air-in-line AILIndicator(i) is set to 1 and if air is not detected in step **232** then the air-in-line AILIndicator(i) is set to 0. The method proceeds from step **234** through location step **230** to step **236**.

In step **236**, a determination is made as to whether the air-in-line indicator AILIndicator(i) equals 1. If it is determined in step **236** that the air-in-line indicator AILIndicator (i) equals 1, the method proceeds from step **236** to step **238**. In step **238**, if any of the buffer saved in step **226** is set to 1 (i.e. if any of AirIndicator(i) . . . AirIndicator(i−Nw) is set to 1), the method proceeds from step **238** to step **240** and determines that there is air in the infusion system. The method proceeds from step **240** to step **242** and turns on the alarm indicating that air is disposed in the infusion system since both the air-in-line indicator (AILIndicator) and the plunger force indicator (AirIndicator) indicated that air was in the infusion system (i.e. AILIndicator(i)=1 and one or more of the entries saved in the AirIndicator buffer=1). When the alarm is turned on in step **242**, the infusion system is turned off automatically or manually by the clinician to stop the infusion of the infusion fluid.

In step **238**, if any of the buffer saved in step **226** is not set to 1 (i.e. if any of AirIndicator(i) . . . AirIndicator(i−Nw) is not set to 1), the method proceeds from step **238** to step **244**. In step **244**, a determination is made that the air-in-line indicator AILIndicator resulted in a nuisance air-in-line determination since although the air-in-line indicator indicated that air was present no AirIndicator in the buffer indicated that air was present. The method proceeds from step **244** through location step **246** through location step **218** to step **220** and repeats the process steps.

If it is determined in step **236** that the air-in-line indicator AILIndicator(i) does not equal 1, the method proceeds from step **236** to step **248**. In step **248**, a determination is made whether Airindicator(i−Nw) is set to 1 (i.e. whether the plunger force indicator Nw cycles ahead of the air-in-line detector determined that air was in the infusion system to accommodate for the delay between the plunger force sensor and the air-in-line sensor). If the determination is made in step **248** that the Airindicator(i−Nw) is not set to 1 the method proceeds from step **248** through location step **250** through location step **218** to step **220** and repeats the process steps (since neither the air-in-line indicator AILIndicator nor the air indicator AirIndicator indicated that air was in the infusion system).

If the determination is made in step **248** that the Airindicator(i−Nw) is set to 1 the method proceeds from step **248** to step **252**. In step **252**, a determination is made whether the confidence indicator ConfIndicator(i−Nw) of the force algorithm (indicating the confidence level that air has been detected in the infusion system by the plunger force sensor by applying the force algorithm Nw cycles ahead of the air-in-line sensor) is greater than or equal to the confidence threshold (Conf_Thr). If the determination is made in step **252** that the confidence indicator of the force algorithm is not greater than or equal to the confidence threshold, the method proceeds from step **252** through location step **254** through location step **218** to step **220** and repeats the process steps (since the air-in-line indicator AILIndicator did not indicate that air was in the infusion system and the air indicator AirIndicator did not confidently predict that air was in the infusion system).

If the determination is made in step **252** that the confidence indicator of the force algorithm is greater than or

equal to the confidence threshold, the method proceeds from step **252** to step **256**. In step **256**, a determination is made that the air-in-line indicator AILIndicator wrongly determined that air was not present in the infusion system (since the air-in-line indicator AILIndicator did not indicate that air was in the infusion system but the air indicator AirIndicator confidently determined that air was in the infusion system). The method proceeds from step **256** to step **258**. In step **258**, the alarm is turned on indicating that air is disposed in the infusion system. When the alarm is turned on in step **258**, the infusion system is turned off automatically or manually by the clinician to stop the infusion of the infusion fluid. In other embodiments, the method **212** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **7** illustrates a flowchart of another embodiment of a method **260** for determining whether air is in an infusion system using both plunger force sensor readings and air-in-line sensor readings. It can be applied to any air-in-line single bubble algorithm or froth algorithm as long as it outputs an air-in-line single bubble indicator and a froth indicator at each sampling step indicating whether a single bubble or froth was detected in the line by the air-in-line sensor. Similarly, it can be applied to any force algorithm as long as it outputs an air indicator at each sampling step indicating whether air was detected in the line by the plunger force sensor. The method **260** uses the force algorithm to declare true air alarms, or nuisance/false air-in-line single bubble or froth alarms. The method **260** takes into account delays between the air-in-line indicator and the air indicator which result from differences in locations of the air-in-line sensor and the plunger force sensor by utilizing a buffer that stores previous air indicators based on the plunger force sensor measurements. The method **260** may utilize the system of FIG. **1**. In other embodiments, the method **260** may utilize varying systems.

In step **262**, the method starts. The method proceeds from step **262** to step **264**. In step **264**, the variables are set including setting sampling step i=1 and setting the number Nw of pumping strokes of delay between a plunger force sensor and an air-in-line sensor. The method proceeds from step **264** through location step **266** to step **268**. In step **268**, a plunger force algorithm is used to determine at sampling step i whether air is detected in a pumping chamber based on measurements of a plunger force sensor. The method proceeds from step **268** to step **270**. In step **270**, if air is detected in step **268** then an air indicator Airindicator(i) is set to 1 and if air is not detected in step **268** then the air indicator Airindicator(i) is set to 0. The method proceeds from step **270** to step **272**. In step **272**, a Buffer is saved as [AirIndicator(i) . . . AirIndicator(i−Nw)] saving the 1 or 0 setting made in step **270**. For instance, if it takes 2 pumping strokes of the pump for the infusion fluid to travel from the plunger force sensor to the air-in-line sensor, then Nw is set to 2 to accommodate for this delay and the Buffer saves the Airindicator(i) for the current sample i, the Airindicator(i−1) for the previous sample i−1, and the Airindicator(i−2) for two samples before. The method proceeds from step **272** through location step **274** to step **280**.

While the method proceeds from step **266** to **268**, the method also simultaneously proceeds from step **266** to step **276**. In step **276**, an air-in-line single bubble algorithm and an air-in-line froth algorithm is used to determine at sampling step i whether a single bubble or forth is detected in a fluid-delivery-line of the infusion system based on measurements from the air-in-line sensor. The method proceeds from step **276** to step **278**. In step **278**, if a single bubble is detected in step **276** then a single bubble indicator SBIndicator(i) is set to 1 and if the single bubble is not detected in step **276** then the SBIndicator(i) is set to 0. Similarly, in step **278**, if froth is detected in step **276** then a froth indicator FrothIndicator(i) is set to 1 and if the froth is not detected in step **276** then the froth indicator FrothIndicator(i) is set to 0. The method proceeds from step **278** through location step **274** to step **280**.

In step **280**, a determination is made as to whether either the single bubble indicator SBIndicator(i) is set to 1 or the froth indicator FrothIndicator(i) is set to 1. If step **280** determines that either the single bubble indicator SBIndicator(i) is set to 1 or the froth indicator FrothIndicator(i) is set to 1, then the method proceeds from step **280** to step **282**. In step **282**, a determination is made as to whether any of the buffer saved in step **272** is set to 1 (i.e. if any of AirIndicator (i) . . . AirIndicator(i−Nw) is set to 1). If step **282** determines that any of the buffer saved in step **272** is set to 1, then the method proceeds from step **282** to step **284** and turns on the alarm indicating that air is disposed in the infusion system since the plunger force indicator (AirIndicator) indicated that air was in the infusion system and either the single bubble indicator (SBIndicator) or the froth indicator (FrothIndicator) indicated that a single bubble or froth was in the infusion system. When the alarm was turned on in step **284**, the infusion system is turned off automatically or manually by the clinician to stop the infusion of the infusion fluid.

If step **282** determines that none of the buffer saved in step **272** is set to 1, then the method proceeds from step **282** to step **286**. In step **286**, a nuisance alarm is turned on because the plunger force indicator AirIndicator found that no air was in the infusion system but the single bubble indicator SBIndicator or the froth indicator FrothIndicator detected that a single bubble or froth was present in the infusion system. The method proceeds from step **286** to step **288**. In step **288**, sampling step i is incremented to i=i+1. The method proceeds from step **288** through location step **266** to steps **268** and **276** and repeats the process steps.

If step **280** determines that neither the single bubble indicator SBIndicator(i) is set to 1 nor the froth indicator FrothIndicator(i) is set to 1, then the method proceeds from step **280** to step **288**. In step **288**, sampling step i is incremented to i=i+1. The method proceeds from step **288** through location step **266** to steps **268** and **276** and repeats the process steps. In another embodiment, if step **280** determines that neither the single bubble indicator SBIndicator(i) is set to 1 nor the froth indicator FrothIndicator(i) is set to 1, then the method can determine whether the plunger force indicator AirIndicator found that air was in the infusion system and if it did then a missed alarm can be turned on. In other embodiments, the method **260** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **8** illustrates a flowchart of another embodiment of a method **290** for determining whether air is in an infusion system using both plunger force sensor readings and air-in-line sensor readings. It can be applied to any force algorithm as long as it outputs an air indicator at each sampling step indicating whether air was detected in the line by the plunger force sensor. It can be applied to air-in-line stuck droplet algorithms which determine at each sampling step or pumping stroke whether it is in a monitoring state, a detection state, an exit state, or an alarm state. The method **290** uses the force algorithm and the various states of the air-in-line stuck droplet algorithm to declare true air alarms, or nui-

sance/false air alarms. The method **290** may utilize the system of FIG. **1**. In other embodiments, the method **290** may utilize varying systems.

In step **292**, the method starts. The method proceeds from step **292** to step **294**. In step **294**, the variables are set including setting sampling step i=1, and setting the percent threshold Pct_Thr=80. The method proceeds from step **294** through location step **296** to step **298**. In step **298**, an air-in-line stuck droplet algorithm is used to determine at sampling step i whether a stuck droplet is detected in the infusion system based on measurements of an air-in-line sensor. The method proceeds from step **298** to step **300**. In step **300**, the stuck droplet state at sampling step i SDState(i) is determined as being either in a monitoring state, in a detection state, in an exit search state, or in an alarm state. The method proceeds from step **300** through location step **302** to step **308**.

While the method proceeds from location step **296** to step **298**, the method also simultaneously proceeds from location step **296** to step **304**. In step **304**, a plunger force algorithm is used to determine at sampling step i whether air is detected in a pumping chamber based on measurements of a plunger force sensor. The method proceeds from step **304** to step **306**. In step **306**, if air is detected in step **304** then an air indicator Airindicator(i) is set to 1 and if air is not detected in step **304** then the air indicator Airindicator(i) is set to 0. The method proceeds from step **306** through location step **302** to step **308**.

In step **308**, a determination is made based on the determination of step **300** whether the stuck droplet state at sampling step i SDState(i) is in a monitoring state. In the monitoring state, the algorithm will search for a stuck droplet pattern. If in step **308** the determination is made that the stuck droplet state at sampling step i SDState(i) is in a monitoring state, then the method proceeds to step **310**. In step **310**, the sampling step i is set to i=i+1 in order to advance to the next sampling step in order to monitor the next sample (i.e. the next pumping stroke). The method proceeds from step **310** to location step **296** and repeats the process steps.

If in step **308** the determination is made that the stuck droplet state at sampling step i SDState(i) is not in a monitoring state then the method proceeds to step **312**. In step **312**, a determination is made based on the determination of step **300** whether the stuck droplet state at sampling step i SDState(i) is in a detection state. In the detection state, the algorithm detects a possible stuck droplet pattern and has to decide if it is a match or not. If in step **312** the determination is made that the stuck droplet state at sampling step i SDState(i) is in a detection state, then the method proceeds to step **314**. In step **314**, a Buffer is saved as [AirIndicator(i) . . .] saving the AirIndicator(i) determination made in step **306** for the current sample i as being 1 or 0. The Buffer will continue to save all AirIndicator(i) determinations made in step **306** for all samples i until the Buffer is reset. It is noted that the values in the Buffer will later be used to determine in the alarm state whether the air-in-line algorithm decision as to whether air is in the infusion system is a nuisance or a true alarm. The method then proceeds from step **314** to step **310**. In step **310**, the sampling step i is set to i=i+1 in order to advance to the next sampling step in order to monitor the next sample (i.e. the next pumping stroke). The method proceeds from step **310** to location step **296** and repeats the process steps.

If in step **312** the determination is made that the stuck droplet state at sampling step i SDState(i) is not in a detection state, then the method proceeds to step **316**. In step **316**, a determination is made based on the determination of step **300** whether the stuck droplet state at sampling step i SDState(i) is in an exit search state. In the exit search state, the algorithm decides that the suspected stuck droplet pattern is not a match and therefore is not a stuck droplet. If in step **316** the determination is made that the stuck droplet state at sampling step i SDState(i) is in an exit search state, then the method proceeds to step **318**. In step **318**, the Buffer saved in **314** is reset/cleared so that all previously stored values are deleted. The method proceeds from step **318** to step **310**. In step **310**, the sampling step i is set to i=i+1 in order to advance to the next sampling step in order to monitor the next sample (i.e. the next pumping stroke). The method proceeds from step **310** to location step **296** and repeats the process steps.

If in step **316** the determination is made that the stuck droplet state at sampling step i SDState(i) is not in an exit search state, then the method proceeds to step **320**. In step **320**, a determination is made based on the determination of step **300** that the stuck droplet state at sampling step i SDState(i) is in an alarm state. The method proceeds from step **320** to step **322**. In step **322**, an X value is saved and a Y value is saved. The X value comprises the number of 1 values saved in the Buffer of step **314**. The Y value comprises the overall number of values saved in the Buffer of step **314**. For instance, if the Buffer of step **314** is saved as [1 0 0 1 0] then X=2 because there are two 1 values saved and Y=5 because there are five overall 1's and 0's saved. The method proceeds from step **322** to step **324**. In step **324**, a determination is made as to whether 100 multiplied by X/Y is greater than or equal to the percent threshold Pct_Thr of 80 set in step **294** (whether 100*X/Y is greater than or equal to Pct_Thr). If in step **324** the determination is made that 100 multiplied by X/Y is not greater than or equal to the percent threshold Pct_Thr of 80 set in step **294** then the method proceeds to step **326**. For instance, if X=2 and Y=5 then 100*2/5=40 which is not greater than or equal to Pct_Thr of 80 so the method would proceed to step **326**. In step **326**, a nuisance alarm is turned on and the infusion is not stopped because less than the threshold number of the buffer determinations, made by the plunger force algorithm, determined that air was in the infusion system leading to the determination that the stuck droplet alarm state set in step **320** was a nuisance alarm. The method proceeds from step **326** to step **310**. In step **310**, the sampling step i is set to i=i+1 in order to advance to the next sampling step in order to monitor the next sample (i.e. the next pumping stroke). The method proceeds from step **310** to location step **296** and repeats the process steps.

If in step **324** the determination is made that 100 multiplied by X/Y is greater than or equal to the percent threshold Pct_Thr of 80 set in step **294** then the method proceeds to step **328**. For instance, if the Buffer set in step **314** is [1 1 1 0 1] then X=4 and Y=5 and 100*4/5=80 which is greater than or equal to Pct_Thr of 80 so the method would proceed to step **328**. In step **328**, an alarm is turned on indicating that air is contained in the infusion system because greater than or equal to the threshold number of the buffer determinations, made by the plunger force algorithm, determined that air was in the infusion system leading to the determination that the stuck droplet alarm state set in step **320** was a true air alarm. When the alarm is turned on in step **328**, the infusion system is turned off automatically or manually by the clinician to stop the infusion of the infusion fluid. In other embodiments, the method **290** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **9** illustrates two related graphs **330** and **332** illustrating how the use of a single-sensor based algorithm for detecting the presence of air within an infusion system can lead to a false positive detection of air in the infusion system. The graphs **330** and **332** were taken from an infusion system which did not contain a significant amount of air to warrant stopping the infusion system. The X-axis of graph **330** represents time in seconds during the infusion of infusion fluid delivered by the infusion system. The Y-axis of graph **330** represents air sensor readings of the single air-in-line sensor in analog-to-digital counts (ADC) for the infusion system during the infusion of the infusion fluid. The portion **334** of the plotted air-sensor readings shows that the air-sensor readings substantially increase and then decrease around 3,325 seconds to 3,350 seconds.

Similarly, the X-axis of graph **332** represents the corresponding time in seconds during the infusion of infusion fluid delivered by the infusion system. The Y-axis of graph **332** represents air indicator determinations made based on the air-in-line sensor readings of the corresponding graph **330**. The portion **336** of the plotted air indicator readings shows that the air indicator readings substantially increase and then decrease around 3,325 seconds to 3,350 seconds based on the air-sensor readings of the corresponding graph **330**. This portion **336** would result in a false positive detection of air when using a typical single-sensor based air-in-line algorithm. This false positive is caused by dancing micro bubbles of air in the infusion system. This is problematic as the infusion system would be shut down due to this false positive creating an improper delay in therapy to the patient.

FIG. **10** illustrates three related graphs **338**, **340**, and **342** illustrating how the use of a multi-sensor based algorithm for detecting the presence of air within the infusion system tested in FIG. **9** eliminates the false positive detection of air in the in the infusion system. The graphs **338**, **340**, and **342** were taken from the infusion system tested in FIG. **9** which did not contain a significant amount of air to warrant stopping the infusion system. The X-axis of graph **338** represents time in seconds during the infusion of infusion fluid delivered by the infusion system. The Y-axis of graph **338** represents air sensor readings of an air-in-line sensor in analog-to-digital counts (ADC) for the infusion system during the infusion of the infusion fluid. The portion **344** of the plotted air-sensor readings shows that the air-sensor readings substantially increase and then decrease around 3,325 seconds to 3,350 seconds.

Similarly, the X-axis of graph **340** represents the corresponding time in seconds during the infusion of infusion fluid delivered by the infusion system. The Y-axis of graph **340** represents force profile readings in pounds taken by a plunger force sensor connected to the infusion system. The plotted portion **346** of the force profile readings shows that the plot is substantially uniform during the entire time plotted from 3,200 seconds to 3,600 seconds which does not indicate that air is in the infusion system.

Similarly, the X-axis of graph **342** represents the corresponding time in seconds during the infusion of infusion fluid delivered by the infusion system. The Y-axis of graph **342** represents air indicator determinations made by integrating the air-sensor readings and the force profile readings of the corresponding graphs **338** and **340**. The plotted portion **348** of the air indicator readings shows that the air indicator readings stayed at 0 during the entire time plotted from 3,200 seconds to 3,600 seconds based on the integrated air-sensor readings and force profile readings of the corresponding graphs **338** and **340**. As a result, the use of multiple different types of sensors to monitor the infusion system has eliminated the false positive detection of air which occurred when the same infusion system was tested using only a single type of sensor. This improves accuracy and avoids unnecessary shut-downs of the infusion system.

FIG. **11** illustrates a flowchart of one embodiment of a method **350** for determining whether air is in an infusion system. The method **350** may utilize the system of FIG. **1**. In other embodiments, the method **350** may utilize varying systems. In step **352**, a proximal pressure sensor determines the amount of pressure acting proximally on the infusion system. In step **354**, a distal pressure sensor determines the amount of pressure acting distally on the infusion system. In step **356**, a force sensor determines how much force is acting upon a plunger or pumping member of a pump. In step **358**, a force algorithm is applied by integrating the proximal pressure measurements, the distal pressure measurements, and the force sensor measurements of steps **352**, **354**, and **356** in order to detect whether air is in a chamber of the pump. The force algorithm of step **358** integrates the readings of steps **352**, **354**, and **356** which were based on the measurements of the proximal pressure sensor, the distal pressure sensor, and the force sensor and in doing so considers the delays between the proximal force sensor, the distal pressure sensor, and the force sensor which results due to the distances between them.

In step **360**, an air sensor determines how much of a signal propagates through a fluid delivery line of the infusion system. In step **362**, an air-in-line algorithm is applied using the air sensor measurements of step **360** in order to detect whether air is located in the fluid delivery line at the air sensor based on the air sensor measurements. In step **364**, a single qualifier algorithm is applied which uses both the results of the application of the force algorithm in step **358** and the results of the application of the air-in-line algorithm of step **362** in order to determine whether air is in the infusion system. The qualifier algorithm of step **364** integrates the decisions of steps **358** and **362** which were based on the measurements of the proximal pressure sensor, the distal pressure sensor, the force sensor, and the air sensor and in doing so considers the delays between the proximal force sensor, the distal pressure sensor, the force sensor, and the air sensor which results due to the distances between them.

In such manner, by considering the air results of different types of sensors at different locations a more accurate determination is made as to whether air is contained in the infusion system. This avoids false positives or nuisance alarms caused by a reading by one sensor at one location which is either inaccurate or caused by an issue such as bouncing air bubbles, a stuck droplet, or froth in the infusion system which otherwise would lead to an inaccurate determination as to the presence of air in the infusion system. In step **366**, the alarm device turns on an alarm if step **364** determines that air is in the infusion system. In other embodiments, the method **350** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **12** illustrates a flowchart of another embodiment of a method **368** for determining whether air is in an infusion system using plunger force sensor readings and pressure sensor readings. It can be applied as long as a plunger force profile and a pressure profile is taken at each sampling step. The method **368** uses the plunger force profile to determine whether there is air in the infusion system, and uses the plunger force profile and the pressure profile to determine whether or not an occlusion is present in the infusion system.

The method **368** may utilize the system of FIG. **1**. In other embodiments, the method **368** may utilizing varying systems.

In step **370**, the method starts. The method proceeds from step **370** to step **372**. In step **372**, the variables are set including setting a sampling step k=1, a baseline which is a force profile associated with fluid, setting a force threshold for air detection Air_Thr, setting a force threshold for occlusion detection Occl_Thr, setting a pressure threshold Press_Thr, and setting a forgetting factor λ. It is noted that throughout this disclosure that k represents one stroke of the pump of the infusion system. The method proceeds from step **372** through location step **374** to step **376**. In step **376**, a force profile X(k) is acquired for the current sample of the pumping cycle of the infusion system. It is noted that the force profile X(k) represents a plurality of force readings which are taken during each stroke k of the pump. For instance, in one embodiment six force readings may be taken at various points of each stroke k of the pump. In other embodiments, any number of force readings may be taken throughout each stroke k of the pump. The method proceeds from step **376** through location step **378** to step **382**.

While the method proceeds from location step **374** to step **376**, the method also simultaneously proceeds from location step **374** to step **380**. In step **380**, a pressure profile Y(k) is acquired for the current sample of the pumping cycle of the infusion system. It is noted that the pressure profile Y(k) represents a plurality of pressure readings which are taken during each stroke k of the pump. For instance, in one embodiment six pressure readings may be taken at various points of each stroke k of the pump. In other embodiments, any number of pressure readings may be taken throughout each stroke k of the pump. The method proceeds from step **380** through location step **378** to step **382**.

In step **382**, a force difference D(k) for the current sample k of the pumping cycle is determined by subtracting the baseline from the force profile X(k) for the current sample k, wherein the equation is D(k)=X(k)−baseline. The method proceeds from step **382** to step **384**. In step **384**, a determination is made as to whether the minimum value of the force difference min(D(k)) for the current sample k is less than the force threshold for air detection Air_Thr. If the determination is made in step **384** that the minimum value of the force difference min(D(k)) for the current sample k is less than the force threshold for air detection Air_Thr then the method proceeds to step **386**. This drop in the force profile indicates a transition from fluid to air since air is more compressible than fluid resulting in less force. In step **386**, a determination is made that air has been detected and a qualifier algorithm may be applied to determine whether to stop the infusion.

If the determination is made in step **384** that the minimum value of the force difference min(D(k)) for the current sample k is not less than the force threshold for air detection Air_Thr then the method proceeds to step **388**. In step **388**, a determination is made whether the maximum value of the force difference max(D(k)) for the current sample k is greater than or equal to the force threshold for occlusion detection Occl_Thr. If the determination is made in step **388** that the maximum value of the force difference max(D(k)) for the current sample k is not greater than or equal to the force threshold for occlusion detection Occl_Thr then the method proceeds to step **390**. It is noted that during an occlusion the plunger force readings are higher than in non-occlusion conditions. In step **390**, a determination is made that an occlusion has not been detected and the occlusion indicator OccIndicator is set to 0 because air was not detected and a significant increase in the force difference was not detected. The method proceeds from step **390** to step **392**. In step **392**, the baseline is updated using the equation baseline=((1−forgetting factor λ)*baseline)+(forgetting factor λ*force profile X(k)). It is noted that unless an occlusion is detected, the method updates the baseline to account for the variability seen in the force-profiles due to medication type, tubing type, PMC, ambient temperature, or other factors. The method proceeds from step **392** to step **394**. In step **394**, the sampling step k is increased using the equation k=k+1. The method proceeds from step **394** to location step **374** and repeats the process steps.

If the determination is made in step **388** that the maximum value of the force difference max(D(k)) for the current sample k is greater than or equal to the force threshold for occlusion detection Occl_Thr then the method proceeds to step **396**. In step **396**, a determination is made as to whether the maximum value of the pressure profile max(Y(k)) for the current sample k is greater than the pressure threshold Press_Thr. If the determination is made in step **396** that the maximum value of the pressure profile max(Y(k)) for the current sample k is not greater than the pressure threshold Press_Thr then the method proceeds to step **390**. In step **390**, a determination is made that an occlusion has not been detected and the occlusion indicator OccIndicator is set to 0 because air was not detected, and although a significant increase in the force difference was detected a significant increase in the pressure profile was not detected. The method proceeds from step **390** to step **392**. In step **392**, the baseline is updated using the equation baseline=((1−forgetting factor λ)*baseline)+(forgetting factor λ*force profile X(k)). It is noted that unless an occlusion is detected, the method updates the baseline to account for the variability seen in the force-profiles due to medication type, tubing type, PMC, ambient temperature, or other factors. The method proceeds from step **392** to step **394**. In step **394**, the sampling step k is increased using the equation k=k+1. The method proceeds from step **394** to location step **374** and repeats the process steps.

If the determination is made in step **396** that the maximum value of the pressure profile max(Y(k)) for the current sample k is greater than the pressure threshold Press_Thr then the method proceeds to step **398**. In step **398**, a determination is made that an occlusion has been detected and the occlusion indicator OccIndicator is set to 1 because air was not detected, a significant increase in the force profile was detected, and a significant increase in the pressure profile was detected. The method proceeds from step **398** to step **400**. In step **400**, the baseline is not updated so that the baseline=baseline. The baseline is not updated to eliminate/discard the changes in the force measurement which may be caused by the applied pressure/occlusion in order to eliminate false air-detections. The method proceeds from step **400** to step **394**. In step **394**, the sampling step k is increased using the equation k=k+1. The method proceeds from step **394** to location step **374** and repeats the process steps. In other embodiments, the method **368** of FIG. **12** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **13** illustrates two related graphs **402** and **404** illustrating how the use of a single-sensor based algorithm for detecting the presence of air within an infusion system can lead to a false positive detection of air in the infusion system. The graphs **402** and **404** were taken from an infusion system which did not contain a significant amount of air to warrant stopping the infusion system but rather underwent a temporary distal occlusion during a portion of the testing. The X-axis of graph **402** represents time in seconds during the

infusion of infusion fluid delivered by the infusion system. The Y-axis of graph **402** represents force sensor readings of the single force sensor in pounds for the infusion system during the infusion of the infusion fluid. The portion **406** of the plotted force profile readings shows that the force profile readings substantially increase and then decrease around 125 seconds to 155 seconds when the distal occlusion occurred.

Similarly, the X-axis of graph **404** represents the corresponding time in seconds during the infusion of infusion fluid delivered by the infusion system. The Y-axis of graph **404** represents air indicator determinations made based on the force profile sensor readings of the corresponding graph **402**. The portion **408** of the plotted air indicator readings shows that the air indicator readings substantially increase around 155 seconds based on the force profile sensor readings of the corresponding graph **402** which were due to the temporary distal occlusion. This portion **404** would result in a false positive detection of air when using a typical single-sensor based force-profile algorithm. This false positive is caused by the temporary occlusion. This is problematic as the infusion system would be shut down due to this false positive creating an improper delay in therapy to the patient.

FIG. **14** illustrates three related graphs **410**, **412**, and **414** illustrating how the use of a multi-sensor based algorithm for detecting the presence of air within the infusion system tested in FIG. **13** eliminates the false positive detection of air in the in the infusion system. The graphs **410**, **412**, and **414** were taken from the infusion system tested in FIG. **13** which did not contain a significant amount of air to warrant stopping the infusion system but which underwent a temporary occlusion during a portion of the testing. The X-axis of graph **410** represents time in seconds during the infusion of infusion fluid delivered by the infusion system. The Y-axis of graph **410** represents force profile sensor readings in pounds for the infusion system during the infusion of the infusion fluid. The portion **416** of the plotted force profile sensor readings shows that the force-sensor readings substantially increase and then decrease around 125 seconds to 155 seconds due to the temporary occlusion.

Similarly, the X-axis of graph **412** represents the corresponding time in seconds during the infusion of infusion fluid delivered by the infusion system. The Y-axis of graph **412** represents distal pressure readings in psi taken by a distal pressure sensor connected to the infusion system. The plotted portion **418** of the distal pressure readings shows that the distal pressure substantially increases and then decreases around 125 seconds to 155 seconds which indicates that an occlusion was present and then dissolved and may have been the reason that the force profile of graph **410** increased from the period of around 125 seconds to 155 seconds. The decrease of the force profile of graph **410** around 155 seconds may have been due to the release of the occlusion rather than air being in the infusion system.

Similarly, the X-axis of graph **414** represents the corresponding time in seconds during the infusion of infusion fluid delivered by the infusion system. The Y-axis of graph **414** represents air indicator determinations made by integrating the force profile readings and the distal pressure readings of the corresponding graphs **410**, and **412**. The plotted portion **420** of the air indicator readings shows that the air indicator readings stayed at 0 during the entire time plotted from 0 seconds to 200 seconds based on the integrated force profile readings and the distal pressure readings of the corresponding graphs **410** and **412**. As a result, the use of multiple different types of sensors to monitor the infusion system has eliminated the false positive detection of air which occurred when the same infusion system was tested using only a single type of sensor when a temporary occlusion was present. This improves accuracy and avoids unnecessary shut-downs of the infusion system.

FIG. **15** illustrates a flowchart of an embodiment of a method **422** for determining a probability of air being in an infusion system. The method **422** may utilize the system of FIG. **1**. In other embodiments, the method **422** may utilize varying systems. In step **424**, a force sensor determines how much force is acting upon a plunger or pumping member of a pump of the infusion system. In step **426**, a distal pressure sensor and/or a proximal pressure sensor determines the distal pressure and/or the proximal pressure acting upon the infusion system. In step **428**, an air-in-line sensor determines how much of a signal propagates through a fluid-delivery line of the infusion system. In step **430**, additional information is determined. The additional information may comprise medication information regarding the infusion fluid. The medication information may comprise a formulation of the infusion fluid, a rate of the infusion fluid, a duration of the infusion fluid, a viscosity of the infusion fluid, a therapy type of the infusion fluid, or a property of the infusion fluid. The additional information may comprise infusion information regarding the infusion of the infusion fluid. The infusion information may comprise a volume of the infusion fluid in the infusion container or another parameter regarding the infusion. In step **432**, the measurements and information from steps **424**, **426**, **428**, and **430** are used in an algorithm to integrate the measurements and information. In step **434**, a determination is made as to the probability/percent chance of air being disposed in the fluid delivery line of the infusion system based on the results of the algorithm applied in step **432**. In other embodiments, the method **422** of FIG. **15** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **16** illustrates a flowchart of an embodiment of a method **436** for determining whether a partial or total distal occlusion is present in an infusion system. The method **436** may utilize the system of FIG. **1**. In other embodiments, the method **436** may utilize varying systems. In step **438**, a distal pressure sensor determines the amount of distal pressure acting on the infusion system. In step **440**, a plunger force sensor determines how much force is acting upon a plunger or pumping member of a pump of the infusion system. In step **442**, a qualifier integrates the results of steps **438** and **440** using one or more algorithms. In step **444**, a determination is made as to whether there is a partial or total distal occlusion in the infusion system based on the qualifier used in step **442** and if there is an alarm is turned on allowing the infusion system to be turned off. The use of the results of multiple different types of sensors in one or more algorithms improves the robustness and false positive performance of the occlusion detection system. In other embodiments, the method **436** of FIG. **16** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **17** illustrates a flowchart of another embodiment of a method **446** for determining whether a partial or total proximal occlusion is present in an infusion system. The method **446** may utilize the system of FIG. **1**. In other embodiments, the method **446** may utilize varying systems. In step **448**, a proximal pressure sensor determines the amount of proximal pressure acting on the infusion system. In step **450**, a plunger force sensor determines how much force is acting upon a plunger or pumping member of a pump of the infusion system. In step **452**, a qualifier integrates the results of steps **448** and **450** using one or more algorithms. In step **454**, a determination is made as to

whether there is a partial or total proximal occlusion in the infusion system based on the qualifier used in step **452** and if there is an alarm is turned on allowing the infusion system to be turned off. The use of the results of multiple different types of sensors in one or more algorithms improves the robustness and false positive performance of the occlusion detection system. In other embodiments, the method **446** of FIG. **17** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

FIG. **18** illustrates a flowchart of another embodiment of a method **456** of detecting a partial or total occlusion in an infusion system. It can be applied as long as a plunger force profile and a pressure profile is taken at each sampling step. The method **456** uses the plunger force profile and the pressure profile to determine whether or not a partial or total occlusion is present in the infusion system. The method **456** may utilize the system of FIG. **1**. In other embodiments, the method **456** may utilizing varying systems.

In step **458**, the method starts. The method proceeds from step **458** to step **460**. In step **460**, the variables are set including sampling step k=0, setting the initial force profile associated with fluid X(0), setting the force threshold for total occlusion Force_Thr1, setting the force threshold for partial occlusion Force_Thr2, setting the pressure threshold for total occlusion Press_Thr1, and setting the pressure threshold for partial occlusion Press_Thr2. It is noted that the force threshold for total occlusion Force_Thr1 is greater than the force threshold for partial occlusion Force_Thr2. It is further noted that the pressure threshold for total occlusion Press_Thr1 is greater than the pressure threshold for partial occlusion Press_Thr2. The method proceeds from step **460** through location step **462** to step **464**. In step **464**, the sampling step k is set to k=k+1. The method proceeds from step **464** to step **466**. In step **466**, a force sensor is used to determine a force profile X(k) at sampling step k based on measurements of the force sensor. It is noted that the force profile X(k) represents a plurality of force readings which are taken during each stroke k of the pump. For instance, in one embodiment six force readings may be taken at various points of each stroke k of the pump. In other embodiments, any number of force readings may be taken throughout each stroke k of the pump. The method proceeds from step **466** through location step **468** to step **472**.

While the method proceeds from step **464** to step **466**, the method also simultaneously proceeds from step **464** to step **470**. In step **470**, a pressure sensor is used to determine a pressure profile Y(k) at sampling step k based on measurements of the pressure sensor. It is noted that the pressure profile Y(k) represents a plurality of pressure readings which are taken during each stroke k of the pump. For instance, in one embodiment six pressure readings may be taken at various points of each stroke k of the pump. In other embodiments, any number of pressure readings may be taken throughout each stroke k of the pump. The method proceeds from step **470** through location step **468** to step **472**. In step **472**, a force difference D(k) at sampling step k is determined by using the equation force profile X(k)−force profile X(k−1) (i.e. subtracting the force profile for the previous sampling step X(k−1) from the current sampling step force profile X(k)). The method proceeds from step **472** to step **474**. In step **474**, a determination is made as to whether the maximum pressure profile max(Y(k)) for the current sample k is greater than or equal to the pressure threshold for total occlusion Press_Thr1. If in step **474** a determination is made that the maximum pressure profile max(Y(K)) for the current sample k is greater than or equal to the pressure threshold for total occlusion Press_Thr1 then the method proceeds to step **476**. In step **476**, a determination is made as to whether the maximum force difference max(D(k)) for the current sample k is greater than or equal to the force threshold for total occlusion Force_Thr1. If step **476** determines that the maximum force difference max(D(k)) for the current sample k is not greater than or equal to the force threshold for total occlusion Force_Thr1 then the method proceeds through location step **478** through location step **462** to step **464** and repeats the process steps.

If step **476** determines that the maximum force difference max(D(k)) for the current sample k is greater than or equal to the force threshold for total occlusion Force_Thr1 then the method proceeds to step **480** and determines that there is a total occlusion. At this point, an alarm may be turned on and/or the infusion system may be turned off.

If in step **474** a determination is made that the maximum pressure profile max(Y(K)) for the current sample k is not greater than or equal to the pressure threshold for total occlusion Press_Thr1 then the method proceeds to step **482**. In step **482**, a determination is made as to whether the maximum pressure profile max(Y(k)) for the current sample k is greater than or equal to the pressure threshold for partial occlusion Press_Thr2. If step **482** determines that the maximum pressure profile max(Y(k)) for the current sample k is not greater than or equal to the pressure threshold for partial occlusion Press_Thr2 then the method proceeds from step **482** through location step **484** though location step **462** to step **464** and repeats the process steps.

If step **482** determines that the maximum pressure profile max(Y(k)) for the current sample k is greater than or equal to the pressure threshold for partial occlusion Press_Thr2 then the method proceeds from step **482** to step **486**. In step **486**, a determination is made as to whether the maximum force difference max(D(k)) for the current sample k is greater than or equal to the force threshold for partial occlusion Force_Thr2. If step **486** determines that the maximum force difference max(D(k)) for the current sample k is not greater than or equal to the force threshold for partial occlusion Force_Thr2 then the method proceeds through location step **488** through location step **462** to step **464** and repeats the process steps.

If step **486** determines that the maximum force difference max(D(k)) for the current sample k is greater than or equal to the force threshold for partial occlusion Force_Thr2 then the method proceeds to step **490** and determines that there is a partial occlusion. At this point an alarm may be generated or turned on and/or the infusion system may be turned off. In other embodiments, the method **456** of FIG. **18** may be altered to vary the order or substance of any of the steps, to delete one or more steps, or to add one or more steps.

The Abstract is provided to allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. In addition, in the foregoing Detailed Description, it can be seen that various features are grouped together in various embodiments for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed embodiments require more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separately claimed subject matter.

While particular aspects of the present subject matter described herein have been shown and described, it will be apparent to those skilled in the art that, based upon the teachings herein, changes and modifications may be made without departing from the subject matter described herein and its broader aspects and, therefore, the appended claims are to encompass within their scope all such changes and modifications as are within the true scope of the subject matter described herein. Furthermore, it is to be understood that the disclosure is defined by the appended claims. Accordingly, the disclosure is not to be restricted except in light of the appended claims and their equivalents.

The invention claimed is:

1. An infusion system for being operatively connected to a fluid delivery line and to an infusion container containing an infusion fluid, the infusion system comprising:

a pump;

a plurality of different types of sensors connected to the pump or the fluid delivery line, the plurality of different types of sensors configured to indicate whether air is in the fluid delivery line, wherein the plurality of different types of sensors comprise an air sensor and a force sensor;

at least one processor in electronic communication with the pump and the air sensor and the force sensor; and

a memory in electronic communication with the at least one processor, wherein the memory comprises programming code for execution by the at least one processor, and the programming code is configured to:

determine a first plurality of measurements from the air sensor;

determine a second plurality of measurements from the force sensor;

detect a presence of air at a first time based on the first plurality of measurements;

determine that there was a change in force profile at a second time corresponding to the first time from the second plurality of measurements; and

generate an alarm based on the detected presence of air and the determined change in force profile.

2. The infusion system of claim **1** wherein the programming code is further configured to determine whether there is the air in the fluid delivery line and the plurality of the different types of sensors comprise a pressure sensor, a force sensor.

3. The infusion system of claim **1** wherein the programming code is further configured to determine a percentage of the air present in the fluid delivery line or a probability of the air being in the fluid delivery line.

4. The infusion system of claim **3** wherein the programming code is further configured to determine the percentage of the air present in the fluid delivery line or the probability of the air being in the fluid delivery line based additionally on medication information regarding the infusion fluid or on infusion information regarding the infusion of the infusion fluid.

5. The infusion system of claim **4** wherein the programming code is further configured to determine the percentage of the air present in the fluid delivery line or the probability of the air being in the fluid delivery line based additionally on the medication information regarding the infusion fluid, the medication information comprising a formulation of the infusion fluid, a rate of the infusion fluid, a duration of the infusion fluid, a viscosity of the infusion fluid, a therapy of the infusion fluid, or a property of the infusion fluid.

6. The infusion system of claim **4** wherein the programming code is further configured to determine the percentage of the air present in the fluid delivery line or the probability of the air being in the fluid delivery line based additionally on the infusion information regarding the infusion of the infusion fluid, the infusion information comprising a volume of the infusion fluid in the infusion container or another parameter regarding the infusion.

7. The infusion system of claim **1** wherein the programming code is further configured to compensate for at least one distance between the plurality of different types of sensors, which leads to one or more delays in the measurements, by using or comparing the measurements taken by the plurality of the different types of sensors at different portions of cycles of pumping of the pump to accommodate for the one or more delays in the measurements.

8. The infusion system of claim **1** wherein the programming code is further configured to: (1) adjust a sensitivity of at least one of the plurality of different types of sensors; (2) determine a nuisance air alarm; (3) determine a missed air alarm; or (4) update a baseline profile based on the first plurality of measurements and the second plurality of measurements.

9. The infusion system of claim **1**, wherein the second time includes a delay time that corresponds to a distance between a first location of the force sensor and a second location of the air sensor.

* * * * *