



US008990039B2

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

(10) **Patent No.:** **US 8,990,039 B2**
(45) **Date of Patent:** **Mar. 24, 2015**

(54) **CALIBRATION SYSTEM FOR A PRESSURE-SENSITIVE CATHETER**

(71) Applicant: **Biosense Webster (Israel) Ltd.**, New Brunswick, NJ (US)
(72) Inventors: **Assaf Govari**, Haifa (IL); **Yaron Ephrath**, Karkur (IL); **Andres Claudio Altmann**, Haifa (IL)

(73) Assignee: **Biosense Webster (Israel) Ltd.** (IL)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 5 days.

(21) Appl. No.: **13/975,778**

(22) Filed: **Aug. 26, 2013**

(65) **Prior Publication Data**
US 2014/0032152 A1 Jan. 30, 2014

Related U.S. Application Data

(63) Continuation of application No. 12/646,242, filed on Dec. 23, 2009, now Pat. No. 8,521,462.

(51) **Int. Cl.**
G01L 27/00 (2006.01)
A61B 5/1495 (2006.01)
A61B 5/00 (2006.01)
G01D 5/244 (2006.01)

(52) **U.S. Cl.**
CPC **G01D 5/24452** (2013.01); **A61B 5/1495** (2013.01); **A61B 2560/0223** (2013.01); **A61B 5/6885** (2013.01)
USPC **702/98**

(58) **Field of Classification Search**
USPC 702/85, 98, 104, 41-44, 150, 152, 153; 600/463, 407, 424
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,841,150 A 10/1974 Pearson
3,971,364 A 7/1976 Fletcher et al.
4,764,114 A 8/1988 Jeffcoat et al.
4,856,993 A 8/1989 Maness et al.
4,930,494 A 6/1990 Takehana et al.

(Continued)

FOREIGN PATENT DOCUMENTS

DE 19750441 A 6/1999
EP 928601 A1 7/1999

(Continued)

OTHER PUBLICATIONS

Instron Marketing Brochure, "Medical Device Testing Systems", Instron 2007 <http://web.archive.org/web/20080318092822/http://www.instron.com.tr/wa/library/streamfile.aspx?doc=1678&download=true>.

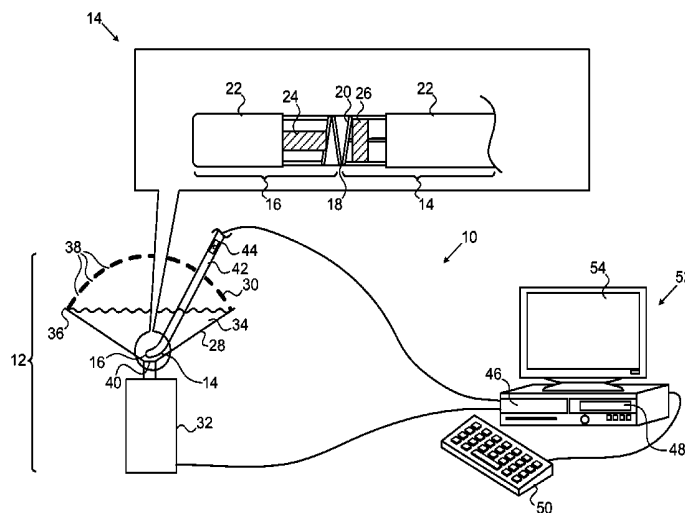
(Continued)

Primary Examiner — Manuel L Barbee

(57) **ABSTRACT**

A calibration apparatus includes a fixture, which is coupled to accept a probe so that a distal tip of the probe presses against a point in the fixture and produces first measurements indicative of a deformation of the distal tip relative to a distal end of the probe, in response to pressure exerted on the distal tip. A sensing device is coupled to the fixture and is configured to produce second measurements of a mechanical force exerted by the distal tip against the point. A calibration processor is configured to receive the first measurements from the probe, to receive the second measurements from the sensing device and to compute, based on the first and second measurements, one or more calibration coefficients for assessing the pressure as a function of the first measurements.

12 Claims, 5 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

5,263,493	A	11/1993	Avitall	7,306,599	B2	12/2007	Karasawa et al.
5,368,564	A	11/1994	Savage	7,311,704	B2	12/2007	Paul et al.
5,391,199	A	2/1995	Ben Haim	7,397,364	B2	7/2008	Govari
5,462,527	A	10/1995	Stevens-Wright et al.	7,435,232	B2	10/2008	Liebschner
5,487,757	A	1/1996	Truckai et al.	7,465,288	B2	12/2008	Dudney et al.
5,499,542	A	3/1996	Morlan	7,481,774	B2	1/2009	Brockway et al.
5,542,434	A	8/1996	Imran et al.	7,536,218	B2	5/2009	Govari et al.
5,558,091	A	9/1996	Acker et al.	7,604,605	B2	10/2009	Zvuloni
5,563,354	A	10/1996	Kropp	7,662,151	B2	2/2010	Crompton, Jr. et al.
5,662,124	A	9/1997	Wilk	7,681,432	B2	3/2010	Hay et al.
5,673,695	A	10/1997	McGee et al.	7,686,767	B2	3/2010	Maschke
5,680,860	A	10/1997	Imran	7,914,440	B2	3/2011	Otawara
5,685,878	A	11/1997	Falwell et al.	7,959,601	B2	6/2011	McDaniel et al.
5,728,149	A	3/1998	Laske et al.	7,984,659	B2	7/2011	Fujimoto et al.
5,769,843	A	6/1998	Abela et al.	8,043,216	B2	10/2011	Matsumura
5,826,576	A	10/1998	West	8,046,049	B2	10/2011	Govari et al.
5,833,608	A	11/1998	Acker	8,083,691	B2	12/2011	Goldenberg et al.
5,836,894	A	11/1998	Sarvazyan	8,137,275	B2	3/2012	Fan et al.
5,860,974	A	1/1999	Abele	8,374,819	B2	2/2013	Govari et al.
5,861,024	A	1/1999	Rashidi	8,521,462	B2 *	8/2013	Govari et al. 702/104
5,902,248	A	5/1999	Millar et al.	2001/0047129	A1	11/2001	Hall et al.
5,916,147	A	6/1999	Boury	2001/0047133	A1	11/2001	Gilboa et al.
5,944,022	A	8/1999	Nardella et al.	2002/0002329	A1	1/2002	Avitall
5,947,320	A	9/1999	Bordner et al.	2002/0065455	A1	5/2002	Ben Haim et al.
5,964,757	A	10/1999	Ponzi	2002/0068866	A1	6/2002	Zikorus et al.
5,974,320	A	10/1999	Ward et al.	2002/0068931	A1	6/2002	Wong et al.
5,983,126	A	11/1999	Wittkamp	2002/0165461	A1	11/2002	Hayzelden et al.
6,048,329	A	4/2000	Thompson et al.	2002/0193781	A1	12/2002	Loeb
6,063,022	A	5/2000	Ben Haim	2003/0120150	A1	6/2003	Govari
6,123,699	A	9/2000	Webster, Jr.	2003/0120195	A1	6/2003	Milo et al.
6,171,277	B1	1/2001	Ponzi	2003/0130615	A1	7/2003	Tom
6,177,792	B1	1/2001	Govari et al.	2003/0158494	A1	8/2003	Dahl et al.
6,183,463	B1	2/2001	Webster, Jr.	2003/0187389	A1	10/2003	Morency et al.
6,198,974	B1	3/2001	Webster, Jr.	2004/0049255	A1	3/2004	Jain et al.
6,201,387	B1	3/2001	Govari	2004/0064024	A1	4/2004	Sommer
6,203,493	B1	3/2001	Ben Haim	2004/0068178	A1	4/2004	Govari
6,216,027	B1	4/2001	Willis et al.	2004/0097806	A1	5/2004	Hunter et al.
6,226,542	B1	5/2001	Reisfeld	2004/0102769	A1	5/2004	Schwartz et al.
6,239,724	B1	5/2001	Doron et al.	2004/0147920	A1	7/2004	Keidar
6,241,724	B1	6/2001	Fleischman et al.	2004/0244464	A1	12/2004	Hajdukiewicz et al.
6,266,551	B1	7/2001	Osadchy et al.	2004/0254458	A1	12/2004	Govari
6,272,371	B1	8/2001	Shlomo	2005/0033135	A1	2/2005	Govari
6,272,672	B1	8/2001	Conway	2005/0080429	A1	4/2005	Freyman et al.
6,301,496	B1	10/2001	Reisfeld	2005/0096590	A1	5/2005	Gullickson et al.
6,332,089	B1	12/2001	Acker et al.	2005/0228274	A1	10/2005	Boese et al.
6,334,837	B1	1/2002	Hein	2005/0277875	A1	12/2005	Selkee
6,335,617	B1	1/2002	Osadchy et al.	2006/0009690	A1	1/2006	Fuimaono et al.
6,351,549	B1	2/2002	Souluer	2006/0009735	A1	1/2006	Viswanathan et al.
6,436,059	B1	8/2002	Zanelli	2006/0015096	A1	1/2006	Hauck et al.
6,456,864	B1	9/2002	Swanson et al.	2006/0064038	A1	3/2006	Omata et al.
6,484,118	B1	11/2002	Govari	2006/0074297	A1	4/2006	Viswanathan
6,551,302	B1	4/2003	Rosinko et al.	2006/0173480	A1	8/2006	Zhang
6,569,098	B2	5/2003	Kawchuk	2006/0184106	A1	8/2006	McDaniel et al.
6,574,492	B1	6/2003	Ben-Haim et al.	2006/0200049	A1	9/2006	Leo et al.
6,584,856	B1	7/2003	Biter et al.	2006/0247618	A1	11/2006	Kaplan et al.
6,602,242	B1	8/2003	Fung et al.	2007/0060832	A1	3/2007	Levin
6,612,992	B1	9/2003	Hossack et al.	2007/0060847	A1	3/2007	Leo et al.
6,618,612	B1	9/2003	Acker et al.	2007/0100332	A1	5/2007	Paul et al.
6,690,963	B2	2/2004	Ben Haim et al.	2007/0106114	A1	5/2007	Sugimoto et al.
6,695,808	B2	2/2004	Tom	2007/0142749	A1	6/2007	Khatib et al.
6,711,429	B1	3/2004	Gilboa et al.	2007/0151391	A1	7/2007	Larkin et al.
6,727,371	B2	4/2004	Müller et al.	2007/0156114	A1	7/2007	Worley et al.
6,814,733	B2	11/2004	Schwartz et al.	2007/0161882	A1	7/2007	Pappone
6,835,173	B2	12/2004	Couvillon, Jr.	2007/0167740	A1	7/2007	Grunewald et al.
6,892,091	B1	5/2005	Ben Haim et al.	2007/0167818	A1	7/2007	Osborn et al.
6,915,149	B2	7/2005	Ben Haim	2007/0179492	A1	8/2007	Pappone
6,945,956	B2	9/2005	Waldhauser et al.	2007/0185397	A1	8/2007	Govari et al.
6,964,205	B2	11/2005	Papakostas et al.	2007/0191829	A1	8/2007	McGee et al.
6,973,339	B2	12/2005	Govari	2007/0197927	A1	8/2007	Ofek et al.
6,997,924	B2	2/2006	Schwartz et al.	2007/0197939	A1	8/2007	Wallace et al.
7,077,823	B2	7/2006	McDaniel	2007/0282211	A1	12/2007	Ofek et al.
7,156,816	B2	1/2007	Schwartz et al.	2008/0009750	A1	1/2008	Aeby et al.
7,235,070	B2	6/2007	Vanney	2008/0015568	A1	1/2008	Paul et al.
7,297,116	B2	11/2007	Varghese et al.	2008/0051704	A1	2/2008	Patel et al.
7,306,593	B2	12/2007	Keidar et al.	2008/0065111	A1	3/2008	Blumenkranz et al.
				2008/0071267	A1	3/2008	Wang et al.
				2008/0077049	A1	3/2008	Hirshman
				2008/0146918	A1	6/2008	Magnin et al.
				2008/0183075	A1	7/2008	Govari et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2008/0200843 A1 8/2008 Williams et al.
 2008/0249467 A1 10/2008 Burnett et al.
 2008/0249522 A1 10/2008 Pappone et al.
 2008/0255540 A1 10/2008 Selkee
 2008/0269606 A1 10/2008 Matsumura
 2008/0275428 A1 11/2008 Tegg et al.
 2008/0275442 A1 11/2008 Paul et al.
 2008/0275465 A1 11/2008 Paul et al.
 2008/0281319 A1 11/2008 Paul et al.
 2008/0287777 A1 11/2008 Li et al.
 2008/0288038 A1 11/2008 Paul et al.
 2008/0294144 A1 11/2008 Leo et al.
 2008/0294158 A1 11/2008 Pappone et al.
 2009/0010021 A1 1/2009 Smith et al.
 2009/0093806 A1 4/2009 Govari et al.
 2009/0138007 A1 5/2009 Govari et al.
 2009/0158511 A1 6/2009 Maze et al.
 2009/0177111 A1 7/2009 Miller et al.
 2009/0275966 A1 11/2009 Mitusina
 2009/0287118 A1 11/2009 Malek
 2009/0294361 A1 12/2009 Larsen
 2009/0306515 A1 12/2009 Matsumura
 2009/0306650 A1 12/2009 Govari et al.
 2010/0063478 A1 3/2010 Selkee
 2010/0069921 A1 3/2010 Miller et al.
 2010/0121138 A1 5/2010 Goldenberg et al.
 2010/0137845 A1 6/2010 Ramstein et al.
 2010/0152574 A1 6/2010 Erdman et al.
 2010/0160770 A1 6/2010 Govari et al.
 2010/0160778 A1 6/2010 Eskandari et al.
 2010/0168620 A1 7/2010 Klimovitch et al.
 2010/0168918 A1 7/2010 Zhao et al.
 2010/0292566 A1 11/2010 Nagano et al.
 2010/0298826 A1 11/2010 Leo et al.
 2011/0054354 A1 3/2011 Hunter et al.
 2011/0054355 A1 3/2011 Hunter et al.
 2011/0071436 A1 3/2011 Althoefer et al.
 2011/0130648 A1 6/2011 Beeckler et al.
 2011/0153252 A1 6/2011 Govari et al.
 2011/0153253 A1 6/2011 Govari et al.
 2011/0160556 A1 6/2011 Govari
 2011/0172538 A1 7/2011 Sumi
 2011/0184406 A1 7/2011 Selkee
 2011/0307207 A1 12/2011 Govari et al.
 2012/0004576 A1 1/2012 Govari et al.
 2012/0041295 A1 2/2012 Schultz
 2012/0089358 A1 4/2012 Ludwin et al.
 2012/0108988 A1 5/2012 Ludwin et al.
 2012/0149966 A1 6/2012 Ludwin et al.
 2012/0149967 A1 6/2012 Ludwin et al.
 2012/0150075 A1 6/2012 Ludwin et al.
 2012/0184864 A1 7/2012 Harlev et al.
 2012/0184865 A1 7/2012 Harlev et al.
 2012/0253167 A1 10/2012 Bonyak et al.
 2012/0259194 A1 10/2012 Selkee
 2012/0271145 A1 10/2012 Govari et al.
 2012/0310116 A1 12/2012 Ludwin et al.
 2012/0316407 A1 12/2012 Anthony et al.
 2013/0018306 A1 1/2013 Ludwin

FOREIGN PATENT DOCUMENTS

EP 980693 A1 2/2000
 EP 1502555 A1 2/2005
 EP 1586281 A1 10/2005
 EP 1690564 A1 8/2006
 EP 1743575 A2 1/2007
 EP 1820464 A1 8/2007
 EP 1897581 A2 3/2008
 EP 2000789 A2 12/2008
 EP 2047797 A2 4/2009
 EP 2127604 A1 12/2009
 EP 2130508 B1 12/2009
 EP 2196143 A1 6/2010

EP 2305115 A1 4/2011
 EP 2338412 A1 6/2011
 EP 2172240 B1 12/2012
 EP 2338411 B1 11/2013
 JP 8243168 A 9/1996
 JP 2000126301 A 5/2000
 JP 2000508224 A 7/2000
 JP 2005040215 2/2005
 JP 2005237964 A 9/2005
 JP 2005345215 A 12/2005
 JP 2006064465 A 3/2006
 JP 2006255401 A 9/2006
 JP 2007181696 A 7/2007
 WO 95/10326 A 4/1995
 WO WO 96/05768 A 2/1996
 WO 97/29709 A 8/1997
 WO 97/29710 A 8/1997
 WO WO 97/29678 A 8/1997
 WO 98/29032 A 7/1998
 WO 03/020139 A 3/2003
 WO 2006/029563 A 3/2006
 WO 2006/086152 A 8/2006
 WO 2006/092563 A 9/2006
 WO 2006/135483 A2 12/2006
 WO 2007/015139 A2 2/2007
 WO 2007/025230 A 3/2007
 WO 2007/050960 A 5/2007
 WO 2007/067938 A 6/2007
 WO 2007/076312 A2 7/2007
 WO 2007/082216 A 7/2007
 WO WO 2007/098494 A1 8/2007
 WO 2007/111182 A 10/2007
 WO 2008/053402 A1 5/2008
 WO 2008/147599 A1 12/2008
 WO 2009/065140 A1 5/2009
 WO 2009/078280 A 6/2009
 WO 2009/085470 A 7/2009
 WO 2010/008975 A 1/2010
 WO 2011/046874 A1 4/2011

OTHER PUBLICATIONS

Instron, "Series 3300 Load Frames, References Manual Equipment", Instron, pp. 1-5 and 1-10, 2004.
 Peirs, J. et al., "Design of an Optical Force Sensor for Force Feedback during Minimally Invasive Robotic Surgery", Euroensors XVII, 2003, pp. 1063-1066, http://mech.kuleuven.be/micro/pub/medic/Paper_Euroensors_2003_MIS_senorextended.pdf.
 European Search Report mailed on Mar. 28, 2011 from corresponding European Patent Application No. 10252191.1.
 European Search Report mailed on Sep. 23, 2011 from related European Patent Application No. 11169251.3.
 Biter, William J. et al., "Magnetic Wire Strain Sensor", 33rd International Sampe Technical Conference, Nov. 5-8, 2001, vol. 33, pp. 12-23, Seattle, WA.
 Biter, William J. et al., "Magnetic Wire for Monitoring Strain in Composites", *Sensors*, Jun. 2001, www.sensormag.com, pp. 110-114.
 Guo, Shuxiang et al., "Control and Experimental results of a Catheter Operating System", Feb. 21-26, 2009, Proceedings of the 2008 IEEE, International Conference on Robotics and Biomimetics, Bangkok, Thailand, pp. 91-95.
 Kanagaratnam, Prapa et al., "Experience of robotic catheter ablation in humans using novel remotely steerable catheter sheath", *Journal of Interventional Cardiac Electrophysiology*, vol. 21, No. 1, p. 19-26 (2008).
 Okumura, M.D. Yasuo et al. "A Systematic Analysis of In Vivo Contact Forces on Virtual Catheter Tip/Tissue Surface Contact during Cardiac Mapping and Intervention", *Journal of Cardiovascular Electrophysiology*, Jun. 2008, pp. 632-640, vol. 19, No. 6.
 Partial European Search Report mailed on Sep. 18, 2009 from related European Patent Application No. 08253265.6.
 Partial European Search Report mailed on Dec. 7, 2009 from related European Patent Application No. 09251502.2.
 European Search Report mailed on Mar. 8, 2010 from related European Patent Application No. 09252143.4.

(56)

References Cited

OTHER PUBLICATIONS

Partial European Search Report mailed on Mar. 29, 2010 from related European Patent Application No. 09252879.3.
European Search Report mailed on Mar. 2, 2011 from related European Patent Application No. 10175931.4.
European Search Report mailed on Mar. 28, 2011 from related European Patent Application No. 10252189.5.
European Search Report mailed on Mar. 30, 2011 from related European Patent Application No. 10252020.2.
European Search Report mailed on May 16, 2011 from related European Patent Application No. 10252232.3.
European Search Report mailed on Aug. 5, 2011 from related European Patent Application No. 11158804.2.
European Search Report mailed on Sep. 20, 2011 from related European Patent Application No. 11250066.5.

European Search Report mailed on Oct. 28, 2011 from related European Patent Application No. 11171842.5.
European Search Report mailed on Nov. 17, 2011 from related European Patent Application No. 11177600.1.
European Search Report mailed on Feb. 15, 2012 from related European Patent Application No. 11182854.7.
European Search Report mailed on May 2, 2012 from related European Patent Application No. 11189326.9.
European Search Report mailed on Jun. 4, 2012 from related European Patent Application No. 12163784.7.
European Search Report mailed on Nov. 20, 2012 from related European Patent Application No. 12176163.9.
European Search Report mailed on Feb. 11, 2013 from related European Patent Application No. 11187525.8.
European Search Report mailed on Apr. 9, 2013 from related European Patent Application No. 13150145.4.

* cited by examiner

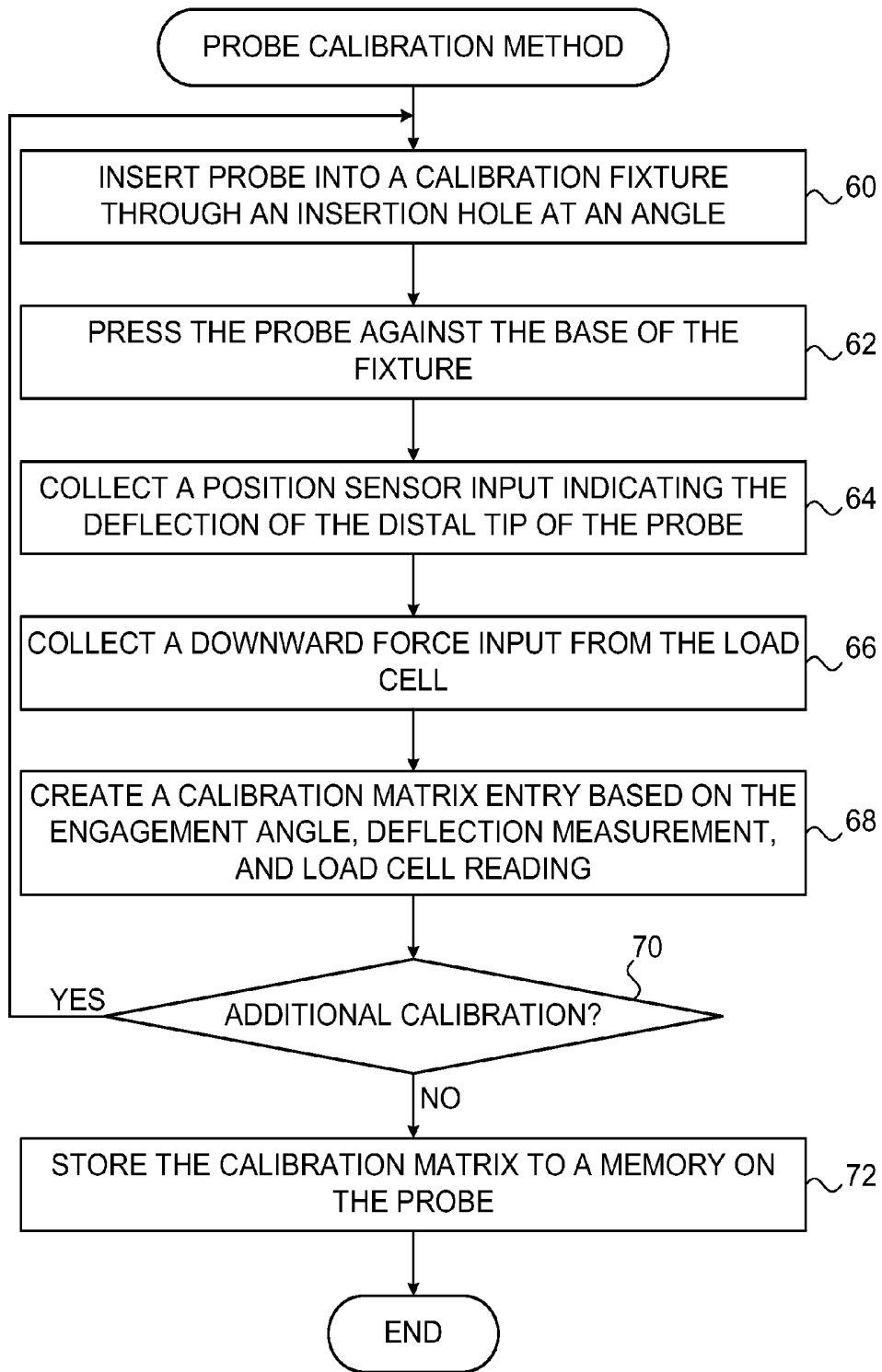


FIG. 2

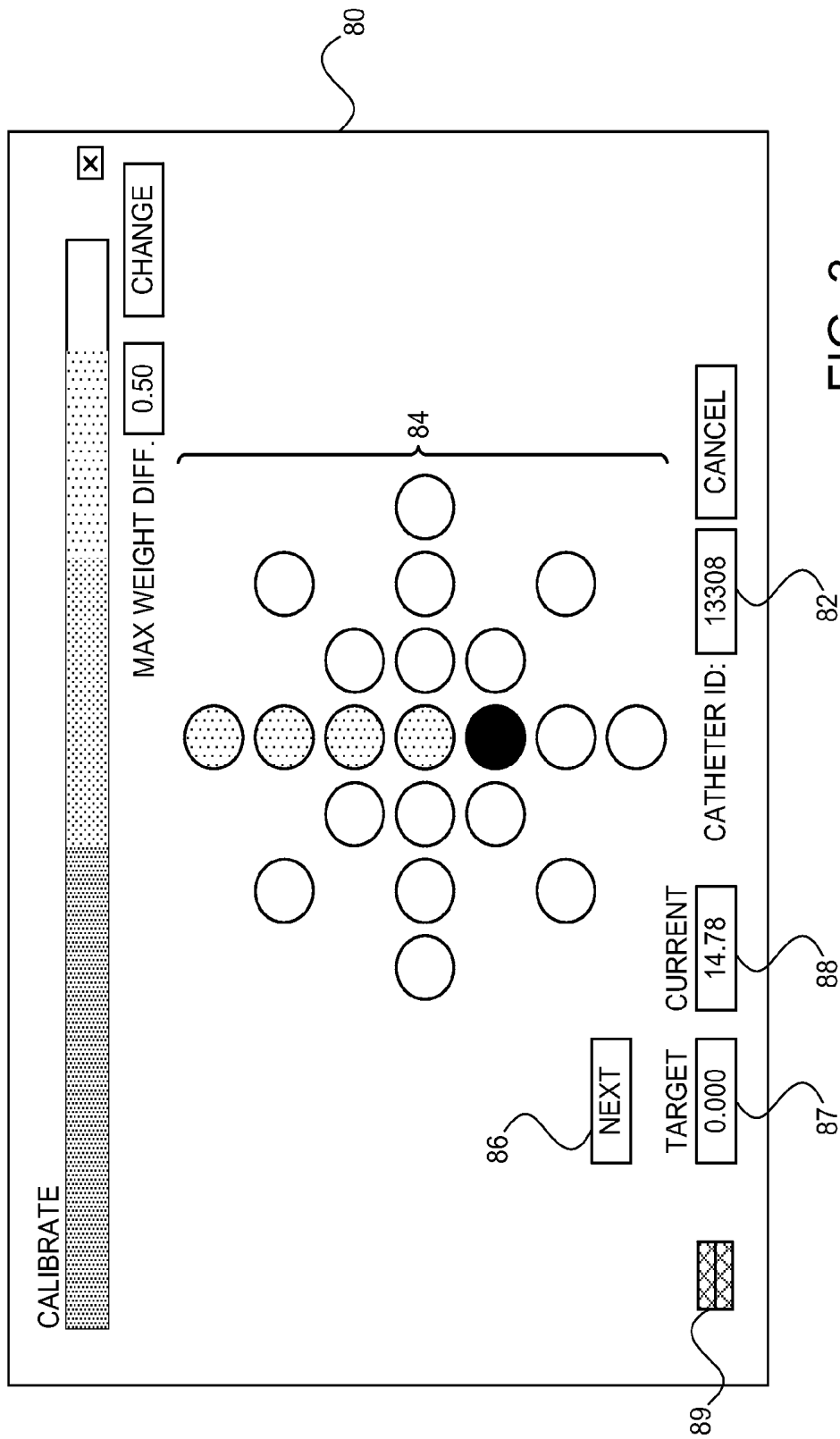


FIG. 3

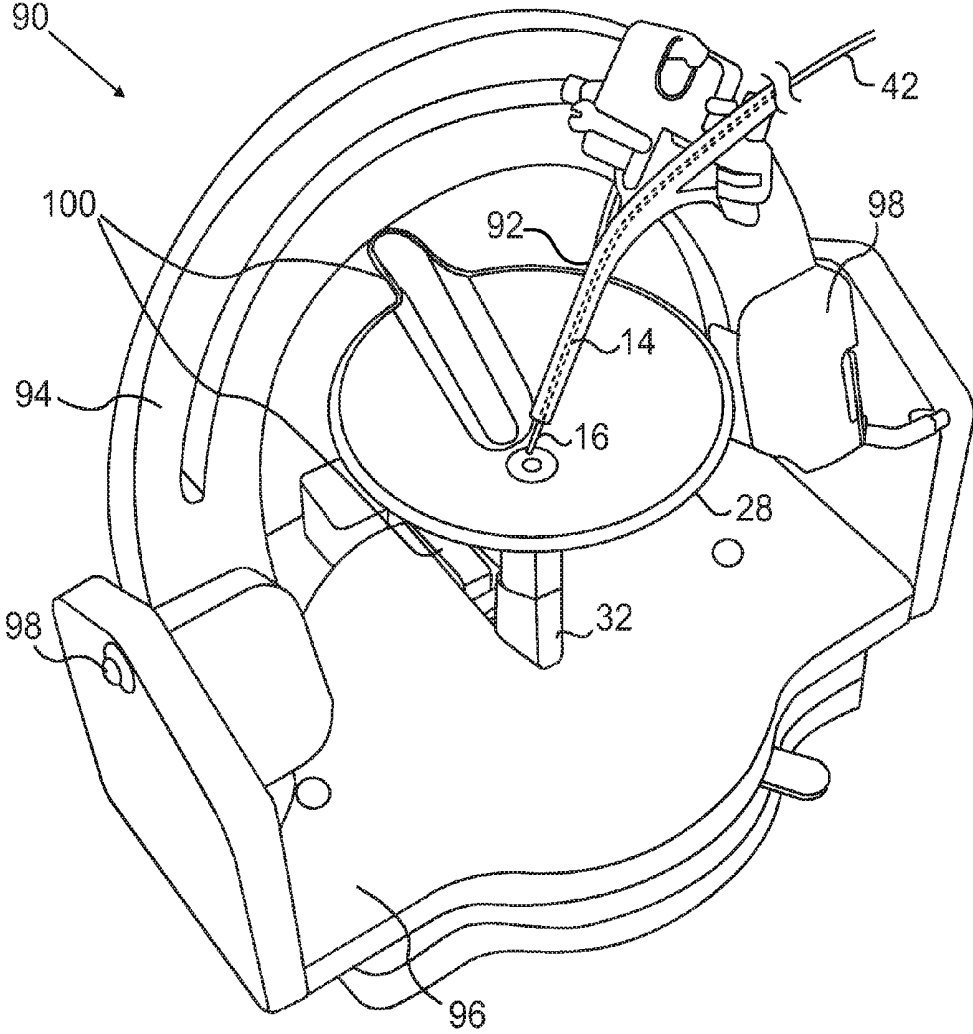


FIG. 4

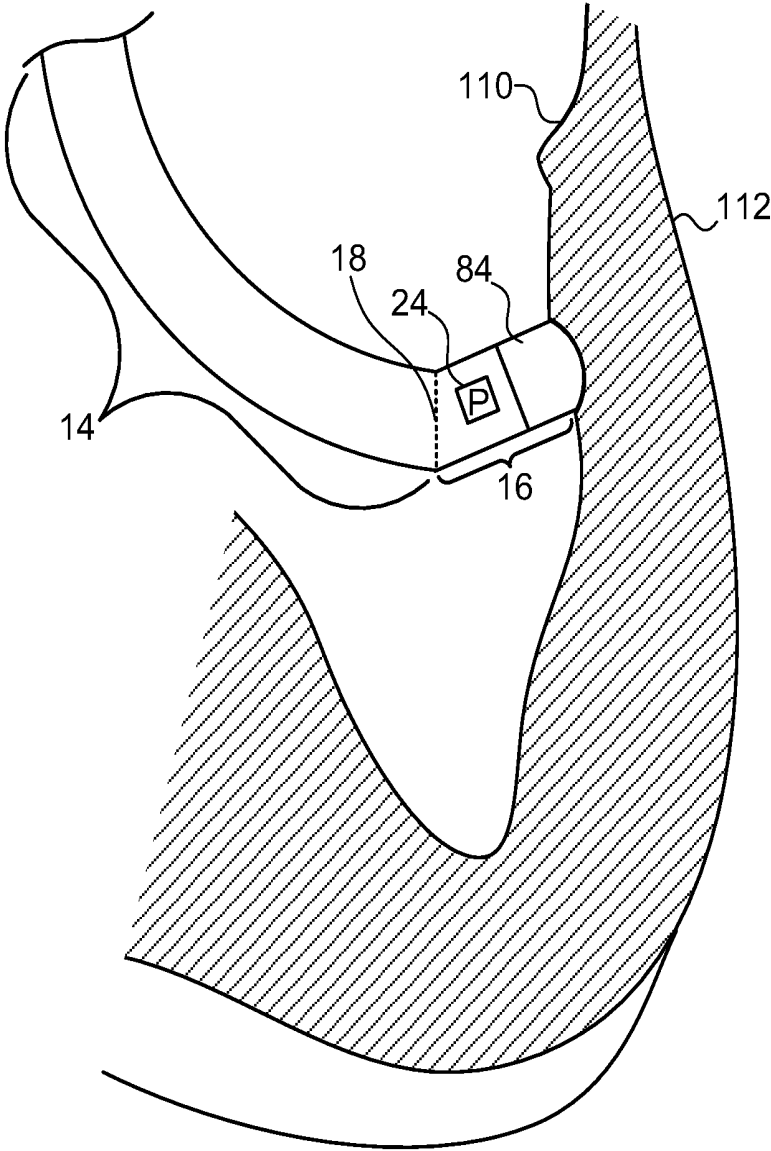


FIG. 5

CALIBRATION SYSTEM FOR A PRESSURE-SENSITIVE CATHETER

CROSS REFERENCE TO RELATED APPLICATION

This application is a continuation U.S. patent application Ser. No. 12/646,242, filed Dec. 23, 2009, now issued as U.S. Pat. No. 8,521,462, which is assigned to the assignee of the present patent application and whose disclosure is incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to invasive probes, and specifically to calibrating pressure sensors in invasive probes.

BACKGROUND

A wide range of medical procedures involve placing objects, such as sensors, tubes, catheters, dispensing devices and implants, within the body. Position sensing systems have been developed for tracking such objects. Magnetic position sensing is one of the methods known in the art. In magnetic position sensing, magnetic field generators are typically placed at known positions external to the patient. A magnetic field sensor within the distal end of a probe generates electrical signals in response to these magnetic fields, which are processed in order to determine the position coordinates of the distal end of the probe. These methods and systems are described in U.S. Pat. Nos. 5,391,199, 6,690,963, 6,484,118, 6,239,724, 6,618,612 and 6,332,089, in PCT International Publication WO 1996/005768, and in U.S. Patent Application Publications 2002/0065455 A1, 2003/0120150 A1 and 2004/0068178 A1, whose disclosures are all incorporated herein by reference.

When placing a probe within the body, it may be desirable to have the distal tip of the probe in direct contact with body tissue. The contact can be verified, for example, by measuring the contact pressure between the distal tip and the body tissue. U.S. Patent Application Publications 2007/0100332 and 2009/0093806, whose disclosures are incorporated herein by reference, describe methods of sensing contact pressure between the distal tip of a catheter and tissue in a body cavity using a force sensor embedded in the catheter. The distal tip of the catheter is coupled to the distal end of the catheter insertion tube by a resilient member, such as a spring, which deforms in response to force exerted on the distal tip when it presses against endocardial tissue. A magnetic position sensor within the catheter senses the deflection (location and orientation) of the distal tip relative to the distal end of the insertion tube. Movement of the distal tip relative to the insertion tube is indicative of deformation of the resilient member, and thus gives an indication of the pressure.

SUMMARY OF THE INVENTION

An embodiment of the present invention provides a calibration apparatus including a fixture, a sensing device and a calibration processor. The fixture is coupled to accept a probe so that a distal tip of the probe presses against a point in the fixture and produces first measurements indicative of a deformation of the distal tip relative to a distal end of the probe, in response to pressure exerted on the distal tip. The sensing device is coupled to the fixture and is configured to produce second measurements of a mechanical force exerted by the

distal tip against the point. The calibration processor is configured to receive the first measurements from the probe, to receive the second measurements from the sensing device and to compute, based on the first and second measurements, one or more calibration coefficients for assessing the pressure as a function of the first measurements.

In some embodiments, the fixture is coupled to cause the probe to press against the point at one or more predefined angles, and the calibration processor is configured to compute the calibration coefficients as a function of the predefined angles. The apparatus may include a dome covering the fixture, the dome having a plurality of insertion holes that are configured to direct the probe to the point at the predefined angles. Alternatively, the apparatus may include a receptacle configured to hold the distal end, a track coupled to the receptacle and configured to position the receptacle at multiple angles relative to the point, and a lift configured to raise the fixture so as to cause the distal tip to press against the point. The apparatus may include an input device coupled to the calibration processor and configured to accept the predefined angles.

In another embodiment, the fixture includes a cone-shaped cup. In yet another embodiment, the fixture holds the probe in a temperature-controlled liquid. In still another embodiment, the sensing device includes a load cell. In an embodiment, the calibration processor is configured to store the calibration coefficients in a memory that is coupled to the probe. The memory may include an Electronically Erasable Programmable Read Only Memory (E²PROM).

There is also provided, in accordance with an embodiment of the present invention, a method of calibrating, including inserting a probe having a distal tip into a fixture, pressing the distal tip against a point in the fixture so as to cause a deformation of the distal tip relative to a distal end of the probe in response to pressure exerted on the distal tip, receiving from the probe first measurements indicative of the deformation, receiving from a sensing device coupled to the fixture second measurements indicative of a mechanical force exerted by the distal tip against the point, and computing, based on the first and second measurements, one or more calibration coefficients for assessing the pressure as a function of the first measurements.

BRIEF DESCRIPTION OF THE DRAWINGS

The disclosure is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1 is a schematic pictorial illustration of a calibration system for a pressure-sensitive catheter, in accordance with an embodiment of the present invention;

FIG. 2 is a flow diagram that schematically illustrates a method of calibrating a pressure-sensitive catheter, in accordance with an embodiment of the present invention;

FIG. 3 is a schematic pictorial representation of a graphical user interface of a calibration system for a pressure-sensitive catheter, in accordance with an embodiment of the present invention;

FIG. 4 is schematic pictorial illustration of a calibration system for a pressure-sensitive catheter, in accordance with an alternative embodiment of the present invention; and

FIG. 5 is a schematic detail view showing the distal tip of a pressure-sensitive catheter in contact with endocardial tissue, in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Some invasive probes comprise pressure sensors for measuring the contact pressure between the probe and intra-body

tissue. For example, the distal tip of a cardiac catheter may comprise a pressure sensor, which deforms in response to the pressure exerted by the distal tip on the endocardial tissue. A position sensor in the catheter measures the deflection of the distal tip, and thus provides an indication of the contact pressure. In many practical cases, however, the relationship between the actual contact pressure and the reading of the position sensor varies from one catheter to another.

In order to ensure accurate pressure measurements, embodiments of the present invention provide methods and systems for calibrating probes (e.g., catheters) fitted with pressure sensors. In some embodiments, a calibration apparatus comprises a fixture for accepting a catheter at a certain angle, and a sensing device (e.g., a load cell) for measuring the mechanical force exerted by the catheter against a given point in the fixture. When the catheter is inserted into the fixture at a given angle and pressed against the given point, the catheter produces deformation (e.g., deflection) measurements of its distal tip, and the sensing device produces force measurements.

In some embodiments, a calibration processor receives the deflection measurements from the catheter and the force measurements from the sensing device, and computes calibration coefficients for assessing the pressure exerted by the catheter as a function of the deflection measurements.

In some embodiments, the calibration is performed for different engagement angles between the catheter and the point in the fixture. In some embodiments, the calibration coefficients are stored in a non-volatile memory that is coupled to the catheter. When the catheter is later used in a medical system, the actual pressure exerted by the catheter's distal tip on the body tissue can be derived with high accuracy from the deflection measurements, using the calibration coefficients.

FIG. 1 is an illustration of a calibration system 10 for a pressure-sensitive catheter, in accordance with an embodiment of the present invention. System 10 comprises a calibration apparatus 12 coupled to a calibration unit 52. In the embodiment described hereinbelow, system 10 is used for calibrating a probe 42, in the present example a catheter for therapeutic and/or diagnostic purposes in a heart or in other body organs.

Probe 42 comprises a distal end 14, with a distal tip 16 connected to the distal end via a joint 18. Distal end 14 and distal tip 16 are both covered by a flexible, insulating material 22. The area of joint 18 is covered, as well, by a flexible, insulating material, which may be the same as material 22 or may be specially adapted to permit unimpeded bending and compression of the joint, (This material is cut away in FIG. 1 in order to expose the internal structure of the catheter.) Distal tip 16 is typically relatively rigid, by comparison with distal end 14.

Distal tip 16 is connected to distal end 14 by a resilient member 20. In FIG. 1, the resilient member has the form of a coil spring, but other types of resilient components may alternatively be used for this purpose. Resilient member 20 permits a limited range of relative movement between tip 16 and distal end 14 in response to forces exerted on the distal tip.

Distal tip 16 contains a magnetic position sensor 24. Sensor 24 may comprise one or more miniature coils, and typically comprises multiple coils oriented along different axes. Distal end 14 contains a miniature magnetic field generator 26 near resilient member 20. Typically, field generator 26 comprises a coil, which is driven by a current conveyed through the catheter from calibration unit 52. Alternatively, position sensor 24 may comprise either another type of magnetic sensor, an electrode which serves as a position transducer, or position

transducers of other types, such as impedance-based or ultrasonic position sensors. Although FIG. 1 shows a probe with a single position sensor, embodiments of the present invention may utilize probes with more than one position sensors.

The magnetic field created by field generator 26 causes the coils in sensor 24 to generate electrical signals at the drive frequency of the field generator. The amplitudes of these signals will vary depending upon the location and orientation of distal tip 16 relative to distal end 14. A calibration processor 46 in calibration unit 52 processes these signals in order to determine the axial displacement and the magnitude of the angular deflection of the distal tip relative to distal end 14. (Because of the axial symmetry of the field generated by a coil, only the magnitude of the deflection can be detected using a single coil in field generator 26, and not the direction of the deflection. Optionally, field generator 26 may comprise two or more coils, in which case the direction of deflection may be determined, as well). The magnitudes of the displacement and deflection may be combined by vector addition to give a total magnitude of the movement of distal tip 16 relative to distal end 14.

The relative movement of distal tip 16 relative to distal end 14 gives a measure of the deformation of resilient member 20. Thus, the combination of field generator 26 with sensor 24 serves as a pressure sensing system. By virtue of the combined sensing of displacement and deflection, this pressure sensing system reads the pressure correctly regardless of whether the pressure is exerted on distal tip 16 head-on or at an angle. Further details of this sort of probe and position sensor are described in U.S. Patent Application Publications 2009/0093806 and 2009/0138007, cited above.

Probe 42 also comprises a non-volatile memory 44, such as electronically erasable programmable read only memory (E²PROM), which stores calculation coefficients computed during calibration. As discussed supra, when the catheter is later used in a medical system, the actual pressure exerted by the catheter's distal tip on body tissue can be derived with high accuracy from deflection measurements, using the calibration coefficients stored in memory 44.

Calibration apparatus 12 comprises a fixture 28 that is configured to accept a probe to be calibrated. In the embodiment of FIG. 1, fixture 28 comprises a cup (e.g., a cone-shaped cup) having a top 36 and a base 40. In the present example, top 36 is wider than base 40. In alternative embodiments, fixtures having any other suitable mechanical configurations can also be used.

Fixture 28 may contain a temperature controlled liquid 34, which is held at a typical human body temperature (e.g., using a thermostat and a heating element). Using this technique, the calibration procedure of probe 42 is carried out at a temperature that closely resembles the operating temperature of the probe in the body. Temperature control may be important because the resiliency or other mechanical properties of elements of the probe may vary sharply with temperature. For example, joint 18 may contain elements such as a nickel titanium alloy (also referred to as NiTi or Nitinol) spring and a plastic outer covering (i.e., insulating material 22), whose resiliency may vary with the temperature of liquid 34.

To control the angle of engagement between catheter 42 and fixture 28, an operator (not shown) inserts the catheter into one of multiple insertion holes 38 in a dome 30 covering fixture 28. Each of the insertion holes may accept the catheter at a different angular position. The insertion holes are configured to direct distal tip 16 to press against a given point of fixture 28. In the configuration shown in FIG. 1, insertion holes 38 direct distal tip 16 to press against base 40.

In addition to fixture 28 and dome 30, calibration apparatus 12 comprises a load cell 32 coupled to base 40. The load cell measures the downward mechanical force exerted by the distal tip on base 40. Although the system shown in FIG. 1 measures the downwards force using load cell 32, system 10 may use any other suitable type of sensor to measure the downward force, and such sensors are thus considered to be within the spirit and scope of this invention.

Both load cell 32 and probe 42 are connected to calibration unit 52 via suitable interfaces (e.g., cables and connectors). Calibration unit 52 comprises calibration processor 46, a memory 48, a display 54 and an input device 50, such as a keyboard. Processor 46 typically comprises a general-purpose computer, with suitable front end and interface circuits for receiving signals from position sensor 24 and load cell 32, as well as for controlling the other components of calibration unit 52. Processor 46 may be programmed in software to carry out the functions that are described herein. The software may be downloaded to processor 46 in electronic form, over a network, for example, or it may be provided on tangible media, such as optical, magnetic or electronic memory media. Alternatively, some or all of the functions of processor 46 may be carried out by dedicated or programmable digital hardware components.

FIG. 2 is a flow diagram that schematically illustrates a method of calibrating a pressure-sensitive catheter, in accordance with an embodiment of the present invention. To calibrate probe 42, the operator inserts the catheter into one of insertion holes 38 (step 60) and presses distal tip 16 against base 40 (step 62). The configuration of fixture 28 and dome 30 helps ensure that distal tip 16 will press against base (i.e., the same point of the fixture) regardless of which insertion hole is used for calibration. Typically, each insertion hole defines a different angle of engagement of the catheter with respect to base 40.

Pressing distal tip 16 against base 40 causes catheter 42 to bend at joint 18, thereby deflecting the distal tip. Position sensor 24 in distal tip 16 outputs a signal indicative of the deflection of the distal tip relative to distal end 14. Simultaneously, load cell 32 outputs a measurement indicative of the downward mechanical force exerted by distal tip 16 on base 40. Both the deflection and downward force measurements are sent to calibration unit 52, where the operator enters the engagement angle for this calibration step via keyboard 50.

In some embodiments, insertion holes 38 are labeled with respective identifiers. During the calibration process, the operator enters the identifier of the insertion hole being used into calibration unit 52 via input device 50. In an alternative embodiment, dome 30 may comprise one more proximity sensors, which automatically detect the insertion hole into which the catheter is inserted. When the operator inserts catheter 42 into one of the insertion holes, the proximity sensors will send electrical signals to calibration unit 52, and processor 46 will analyze the electrical signals to determine which of the insertion hole is being used. Any suitable type of proximity sensors, such as optical sensors or Hall-effect sensors, can be used.

Calibration unit 52 accepts the deflection measurement from sensor 24 in the probe (step 64), the downward force measurement from load cell 32 (step 66), and the angle of engagement from the operator. Based on these three inputs, processor 46 computes calibration coefficients for calibrating the deflection measurements of probe 42 (step 68). By mapping a position measurement from position sensor 24 against a force vector from load cell 32 at a given engagement angle, the calibration coefficient determines the force on distal tip 16 based on the position sensor measurements. In other words, a

given calibration coefficient translates the deflection measurement of tip 16 into an actual pressure reading, for a given engagement angle.

If more calibration points are desired (step 70), then the method returns to step 60 above. Otherwise, processor 46 stores the calibration matrix to memory 44 on the probe (step 72), and the method terminates. In some embodiments, the operator may collect multiple data points for a given engagement angle (a given insertion hole 38) by exerting different amounts of pressure on the probe.

To store the calibration matrix, processor 46 may store an analytic calculation to memory 44 based on the computed coefficients. Alternatively, processor 46 may store a lookup table with inter-measurement interpolation to memory 44. In some embodiments, processor 46 may store a combination of the two (e.g., coefficients chosen according to a region) to memory 44.

FIG. 3 is a schematic representation of a graphical user interface (GUI) 80 operative to manage calibration of catheter 42, in accordance with an embodiment of the present invention. In this embodiment, display 54 presents GUI 80 to the operator. The operator enters the identity (e.g., a serial number) of the catheter being calibrated into a text box 82 using input device 50. GUI 80 presents a map 84 comprising a diagrammatical representation of insertion holes 38. Each of the insertion holes on the map is color coded to indicate its status during the calibration procedure. For example, in this embodiment, the insertion hole currently being used by the calibration procedure is black, the insertion holes previously used are gray, and the insertion holes not yet used are white. Returning to step 70 in FIG. 2, if additional calibration points are desired, the user presses a "Next" button 86 to identify the next insertion hole to be used in the calibration.

GUI 80 may comprise additional fields or features, such as text boxes 87 and 88 for displaying the target and actual pressure exerted on the catheter, respectively. A bar 89 on the left-hand side of the screen indicates the actual pressure. The GUI shown in FIG. 3 is chosen purely by way of example, and any other suitable GUI can also be used.

FIG. 4 is schematic pictorial illustration of a calibration system 90 for catheter 42, in accordance with an alternative embodiment of the present invention. In system 90, a receptacle 92 holds distal end 14, leaving distal tip 16 exposed at joint 18. The proximal end of receptacle 92 is coupled to a track 94. Track 94 is arch-shaped and is coupled to a stand 96 via joints 98. Joints 98 enable track 94 to be rotated in the stand. Positioning receptacle 92 along track 94 and rotating the track enables distal tip 16 to press against cup 28 at a variety of engagement angles. To deflect distal tip (i.e., since track 90 has motion limited to rotation, and the path of receptacle 92 is limited to the track), a lift 100 raises cup 28 and load cell 32, pressing the cup against distal tip 16. A load cell (not shown in the figure) is coupled to the lift and measures the pressure exerted on the catheter tip by the cup. When using the calibration setup of FIG. 4, calibration unit 52 operates similarly to its operation in the setup of FIG. 1 above.

FIG. 5 is a schematic detail view showing distal tip 16 in contact with an endocardial tissue 110 of a heart 112, in accordance with an embodiment of the present invention. In the present example, tip 16 comprises an electrode 114. In some electrophysiological diagnostic and therapeutic procedures, such as intracardiac electrical mapping, it is important to maintain the proper level of force between electrode 114 and tissue 110. As a medical professional (not shown) presses distal tip 16 against endocardial tissue 110, the catheter bends at joint 18. Sufficient force is needed in order to ensure good electrode contact between the distal tip and the tissue. Poor

electrical contact can result in inaccurate readings. On the other hand, excessive force can deform the tissue and thus distort the map.

When tip 16 presses against tissue 110, sensor 24 produces measurements that are indicative of the deflection of tip 16 with respect to distal end 14. The medical imaging system (e.g., mapping system—not shown) translates these measurements into accurate pressure readings using the calibration coefficients stored in memory 44 of the probe. Thus, calibration of the invasive probe using embodiments of the present invention ensures that the medical professional can accurately control the force exerted by the probe on the tissue.

The corresponding structures, materials, acts, and equivalents of all means or steps plus function elements in the claims below are intended to include any structure, material, or act for performing the function in combination with other claimed elements as specifically claimed. The description of the present disclosure has been presented for purposes of illustration and description, but is not intended to be exhaustive or limiting to the disclosure in the form disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art without departing from the scope and spirit of the disclosure. The embodiment was chosen and described in order to best explain the principles of the disclosure and the practical application, and to enable others of ordinary skill in the art to understand the disclosure for various embodiments with various modifications as are suited to the particular use contemplated.

It is intended that the appended claims cover all such features and advantages of the disclosure that fall within the spirit and scope of the present disclosure. As numerous modifications and changes will readily occur to those skilled in the art, it is intended that the disclosure not be limited to the limited number of embodiments described herein. Accordingly, it will be appreciated that all suitable variations, modifications and equivalents may be resorted to, falling within the spirit and scope of the present disclosure.

What is claimed is:

1. A method for calibration, comprising:

exerting a measurable force on a probe having a distal tip, the measurable force being directed at an engagement angle relative to a reference base angle, so as to cause deflection of the distal tip relative to a distal end of the probe;

determining the engagement angle;

determining the exerted force;

receiving from the probe a position measurement indicative of the deflection between the distal tip and the distal end of the probe;

determining a force vector from the exerted force at the determined engagement angle; and

computing one or more calibration coefficients for calibrating the deflection measurement of the probe by mapping the position measurement indicative of the deflection between the distal tip and the distal end against the force vector.

2. The method of claim 1 wherein exerting a force comprises pressing the probe into a force measuring device.

3. The method of claim 2 wherein determining the force comprises receiving from the force measuring device a force measurement indicative of a mechanical force exerted by the distal tip being pressed against the force measuring device.

4. The method of claim 2, wherein pressing the probe into a force measuring device comprises holding the probe in a fixture, the fixture having a receptacle coupled to a track, so as to position the receptacle at one of multiple engagement angles relative to the force measuring device, and raising the fixture in order for the distal tip to press against the force measuring device.

5. The method of claim 4, wherein the fixture comprises a cone-shaped cup.

6. The method of claim 4, wherein the force measuring device comprises a load cell.

7. The method of claim 1 wherein determining the engagement angle comprises inserting the probe into a fixture having of a plurality of insertion holes at predefined angles.

8. The method of claim 7 wherein the insertion holes are labeled with the respective engagement angles, the method further comprises manually inputting the engagement angle manually into a calibration unit.

9. The method of claim 7 wherein the insertion holes are operatively associated with proximity sensors that automatically detect the insertion hole into which the probe is inserted, the method further comprises automatically receiving signals from the proximity sensors and determining which insertion hole is being used based on the signals.

10. The method of claim 1 further comprising immersing the distal end of the probe in a temperature controlled liquid.

11. The method of claim 1 further comprising storing the calibration coefficients in a memory coupled to the probe.

12. The method of claim 11, wherein the memory comprises an E²PROM.

* * * * *

专利名称(译)	用于压敏导管的校准系统		
公开(公告)号	US8990039	公开(公告)日	2015-03-24
申请号	US13/975778	申请日	2013-08-26
[标]申请(专利权)人(译)	韦伯斯特生物官能(以色列)有限公司		
申请(专利权)人(译)	生物传感韦伯斯特(以色列)LTD.		
当前申请(专利权)人(译)	生物传感韦伯斯特(以色列)LTD.		
[标]发明人	GOVARI ASSAF EPHRATH YARON ALTMANN ANDRES CLAUDIO		
发明人	GOVARI, ASSAF EPHRATH, YARON ALTMANN, ANDRES CLAUDIO		
IPC分类号	G01L27/00 A61B5/00 A61B5/1495 G01D5/244		
CPC分类号	G01D5/24452 A61B5/1495 A61B5/6885 A61B2560/0223		
其他公开文献	US20140032152A1		
外部链接	Espacenet USPTO		

摘要(译)

校准装置包括固定装置，该固定装置被连接以接纳探针，使得探针的远侧尖端压靠固定装置中的点并产生指示远侧尖端相对于探针的远端变形的第一测量值，响应于施加在远侧尖端上的压力。传感装置耦合到固定装置并且被配置为产生由远侧末端施加到该点的机械力的第二测量值。校准处理器被配置为从探测器接收第一测量值，以从感测装置接收第二测量值并基于第一和第二测量值计算用于根据第一测量值评估压力的一个或多个校准系数。测量。

