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(54) **MULTIPLE RHYTHM TEMPLATE
MONITORING**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

4,649,924 A 3/1987 Taccardi
4,674,518 A 6/1987 Salo
(Continued)

FOREIGN PATENT DOCUMENTS

CN 1253761 A 5/2000
CN 101933803 A 1/2011
(Continued)

OTHER PUBLICATIONS

Andras Lasso et al., "SlicerWiki VolumeClip", Dec. 25, 2014, pp.
1-4, XP55332376, retrieved from the Internet: <https://www.slicer.org/wiki/Documentation/4.4/Extensions/VolumeClip>, retrieved on
Jan. 5, 2017.

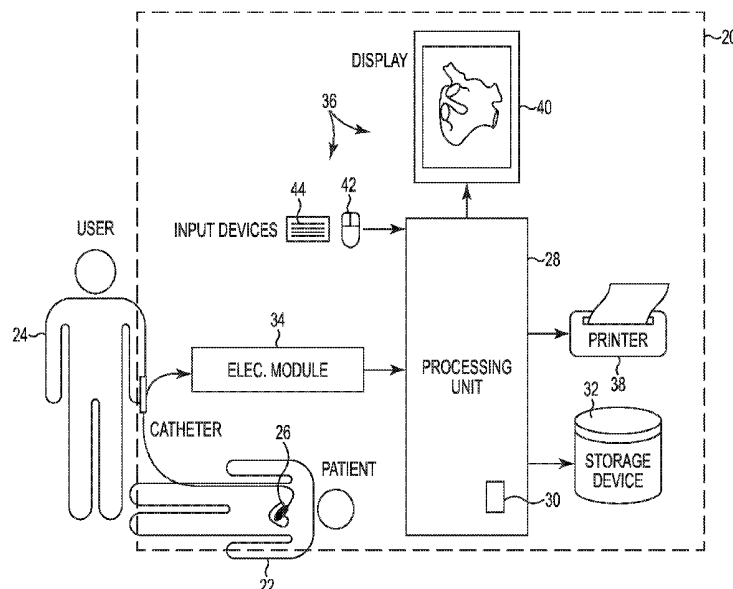
(Continued)

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(57) **ABSTRACT**

A system for providing information about a patient's heart includes one or more electrodes that receive signals from electrical activity of the heart over one or more heart beat cycles. The system is characterized by an electronic processor coupled to the one or more electrodes to: receive the signals from the one or more electrodes; execute an automated set-up routine that processes the signals to automatically provide at least some set-up results for new mapping configurations; and/or process the signals with beat detection and beat acceptance criteria for new or existing mapping configurations to provide information about how well the signals match one or more of the new or existing mapping configurations.

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 U.S. PATENT DOCUMENTS
- | | | | | | |
|--------------|---------|--------------------|-----------------|---------|-----------------------|
| 4,840,182 A | 6/1989 | Carlson | 6,368,285 B1 | 4/2002 | Osadchy et al. |
| 4,920,490 A | 4/1990 | Isaacson | 6,400,981 B1 | 6/2002 | Govari |
| 5,156,151 A | 10/1992 | Imran | 6,490,474 B1 | 12/2002 | Willis et al. |
| 5,284,142 A | 2/1994 | Goble et al. | 6,516,807 B1 | 2/2003 | Panescu et al. |
| 5,297,549 A | 3/1994 | Beatty et al. | 6,547,082 B1 | 4/2003 | Babini |
| 5,300,068 A | 4/1994 | Rosar et al. | 6,556,695 B1 | 4/2003 | Packer et al. |
| 5,341,807 A | 8/1994 | Nardella | 6,574,492 B1 | 6/2003 | Ben-Haim et al. |
| 5,381,333 A | 1/1995 | Isaacson et al. | 6,574,498 B1 | 6/2003 | Gilboa |
| 5,469,858 A | 11/1995 | Osborne | 6,593,884 B1 | 7/2003 | Gilboa et al. |
| 5,480,422 A | 1/1996 | Ben-Haim | 6,600,948 B2 | 7/2003 | Ben-Haim et al. |
| 5,483,968 A | 1/1996 | Adam et al. | 6,603,996 B1 | 8/2003 | Beatty et al. |
| 5,500,011 A | 3/1996 | Desai | 6,631,290 B1 | 10/2003 | Guck et al. |
| 5,553,611 A | 9/1996 | Budd et al. | 6,640,119 B1 | 10/2003 | Budd et al. |
| 5,568,809 A | 10/1996 | Ben-Haim | 6,650,927 B1 | 11/2003 | Keidar |
| 5,577,502 A | 11/1996 | Darrow et al. | 6,690,963 B2 | 2/2004 | Ben-Haim et al. |
| 5,588,429 A | 12/1996 | Isaacson et al. | 6,701,176 B1 | 3/2004 | Halperin et al. |
| 5,634,469 A | 6/1997 | Bruder et al. | 6,728,562 B1 | 4/2004 | Budd et al. |
| 5,647,870 A | 7/1997 | Kordis et al. | 6,735,465 B2 | 5/2004 | Panescu |
| 5,662,108 A | 9/1997 | Budd et al. | 6,773,402 B2 | 8/2004 | Govari et al. |
| 5,687,737 A | 11/1997 | Branham et al. | 6,807,439 B2 | 10/2004 | Edwards et al. |
| 5,697,377 A | 12/1997 | Wittkampf | 6,839,588 B1 | 1/2005 | Rudy |
| 5,704,365 A | 1/1998 | Albrecht et al. | 6,847,839 B2 | 1/2005 | Ciaccio et al. |
| 5,722,402 A | 3/1998 | Swanson et al. | 6,872,428 B2 | 3/2005 | Yang et al. |
| 5,810,740 A | 9/1998 | Paisner | 6,892,090 B2 | 5/2005 | Verard et al. |
| 5,840,025 A | 11/1998 | Ben-Haim | 6,892,091 B1 | 5/2005 | Ben-Haim et al. |
| 5,840,031 A | 11/1998 | Crowley | 6,893,588 B2 | 5/2005 | Lawson et al. |
| 5,846,198 A | 12/1998 | Killmann | 6,939,309 B1 | 9/2005 | Beatty et al. |
| 5,848,972 A | 12/1998 | Triedman et al. | 6,941,166 B2 | 9/2005 | MacAdam et al. |
| 5,876,336 A | 3/1999 | Swanson et al. | 6,957,101 B2 | 10/2005 | Porath et al. |
| 5,921,982 A | 7/1999 | Lesh et al. | 6,978,168 B2 | 12/2005 | Beatty et al. |
| 5,954,665 A | 9/1999 | Ben-Haim | 6,984,207 B1 | 1/2006 | Sullivan et al. |
| 5,971,933 A | 10/1999 | Gopakumaran et al. | 6,990,370 B1 | 1/2006 | Beatty et al. |
| 5,983,126 A | 11/1999 | Wittkampf | 7,016,719 B2 | 3/2006 | Rudy et al. |
| 6,014,581 A | 1/2000 | Whayne et al. | 7,043,292 B2 | 5/2006 | Tarjan et al. |
| 6,050,267 A | 4/2000 | Nardella et al. | 7,136,694 B2 | 11/2006 | Hadley et al. |
| 6,070,094 A | 5/2000 | Swanson et al. | 7,263,397 B2 | 8/2007 | Hauck et al. |
| 6,095,150 A | 8/2000 | Panescu et al. | 7,505,810 B2 | 3/2009 | Harlev et al. |
| 6,167,296 A | 12/2000 | Shahidi | 7,515,954 B2 | 4/2009 | Harlev et al. |
| 6,216,027 B1 | 4/2001 | Willis et al. | 7,628,757 B1 | 12/2009 | Koh |
| 6,226,542 B1 | 5/2001 | Reisfeld | 7,629,981 B1 | 12/2009 | West |
| 6,233,491 B1 | 5/2001 | Kordis et al. | 7,729,752 B2 | 6/2010 | Harlev et al. |
| 6,236,886 B1 | 5/2001 | Cherepenin et al. | 8,103,338 B2 | 1/2012 | Harlev et al. |
| 6,240,307 B1 | 5/2001 | Beatty et al. | 8,137,343 B2 | 3/2012 | Harlev et al. |
| 6,246,898 B1 | 6/2001 | Vesely et al. | 8,208,991 B2 | 6/2012 | Markowitz et al. |
| 6,254,536 B1 | 7/2001 | DeVito | 8,463,368 B2 | 6/2013 | Harlev et al. |
| 6,278,894 B1 | 8/2001 | Salo et al. | 8,498,699 B2 | 7/2013 | Wells et al. |
| 6,298,257 B1 | 10/2001 | Hall et al. | 8,571,647 B2 | 10/2013 | Harlev et al. |
| 6,301,496 B1 | 10/2001 | Reisfeld | 8,744,566 B2 | 6/2014 | Harlev et al. |
| 6,308,093 B1 | 10/2001 | Armoundas et al. | 8,768,440 B1 | 7/2014 | Brodnick et al. |
| 6,314,310 B1 | 11/2001 | Ben-Haim et al. | 9,113,809 B2 | 8/2015 | Harlev et al. |
| 6,317,619 B1 | 11/2001 | Boernert et al. | 9,510,769 B2 | 12/2016 | Harlev et al. |
| 6,318,375 B1 | 11/2001 | Plicchi et al. | 9,636,032 B2 | 5/2017 | Thakur et al. |
| 6,360,123 B1 | 3/2002 | Kimchi et al. | 9,898,825 B2 | 2/2018 | Rivet-Sabourin |
| | | | 9,918,649 B2 | 3/2018 | Thakur et al. |
| | | | 2002/0065459 A1 | 5/2002 | MacAdam et al. |
| | | | 2002/0151807 A1 | 10/2002 | Goldin |
| | | | 2003/0018251 A1 | 1/2003 | Solomon |
| | | | 2003/0065271 A1 | 4/2003 | Khoury |
| | | | 2003/0076277 A1 | 4/2003 | Muramatsu et al. |
| | | | 2003/0078509 A1 | 4/2003 | Panescu |
| | | | 2003/0093067 A1 | 5/2003 | Panescu |
| | | | 2003/0216630 A1 | 11/2003 | Jersey-Willuhn et al. |
| | | | 2004/0059237 A1 | 3/2004 | Narayan et al. |
| | | | 2004/0077942 A1 | 4/2004 | Hall et al. |
| | | | 2004/0097806 A1 | 5/2004 | Hunter et al. |
| | | | 2004/0158165 A1 | 8/2004 | Yonce et al. |
| | | | 2004/0243015 A1 | 12/2004 | Smith et al. |
| | | | 2004/0254437 A1 | 12/2004 | Hauck et al. |
| | | | 2005/0037489 A1 | 2/2005 | Gepstein et al. |
| | | | 2005/0038337 A1 | 2/2005 | Edwards |
| | | | 2005/0054918 A1 | 3/2005 | Sra |
| | | | 2005/0107834 A1 | 5/2005 | Freeman et al. |
| | | | 2005/0154282 A1 | 7/2005 | Li et al. |
| | | | 2005/0288599 A1 | 12/2005 | MacAdam et al. |
| | | | 2006/0085049 A1 | 4/2006 | Cory et al. |
| | | | 2006/0106375 A1 | 5/2006 | Werneth et al. |
| | | | 2006/0116575 A1 | 6/2006 | Willis |
| | | | 2006/0122526 A1 | 6/2006 | Berenfeld et al. |
| | | | 2006/0173251 A1 | 8/2006 | Govari et al. |

(56)

References Cited

U.S. PATENT DOCUMENTS

2006/0178587	A1	8/2006	Khoury
2006/0241401	A1	10/2006	Govari et al.
2007/0016007	A1	1/2007	Govari et al.
2007/0038078	A1	2/2007	Osadchy
2007/0049821	A1	3/2007	Willis
2007/0112276	A1	5/2007	Simms
2007/0197929	A1	8/2007	Porath et al.
2007/0232949	A1	10/2007	Saksena
2007/0255588	A1	11/2007	Hamilton
2007/0265539	A1	11/2007	Hastings et al.
2007/0270688	A1	11/2007	Gelbart et al.
2007/0270703	A1	11/2007	He et al.
2007/0287902	A1	12/2007	Fuimaono et al.
2007/0299351	A1	12/2007	Harlev et al.
2007/0299352	A1	12/2007	Harlev et al.
2007/0299353	A1	12/2007	Harlev et al.
2008/0137934	A1	6/2008	Sakaguchi et al.
2008/0188765	A1	8/2008	Stolarski et al.
2008/0190438	A1	8/2008	Harlev et al.
2008/0221566	A1	9/2008	Krishnan
2008/0222109	A1	9/2008	Sakurai
2008/0234588	A1	9/2008	Feldman et al.
2008/0249424	A1	10/2008	Harlev et al.
2008/0269813	A1	10/2008	Greenhut et al.
2009/0171274	A1	7/2009	Harlev et al.
2009/0177072	A1	7/2009	Harlev et al.
2009/0253976	A1	10/2009	Harlev et al.
2009/0262979	A1	10/2009	Markowitz et al.
2009/0264741	A1	10/2009	Markowitz et al.
2009/0264777	A1	10/2009	Markowitz et al.
2010/0023082	A1	1/2010	Dong et al.
2010/0094274	A1	4/2010	Narayan et al.
2010/0268059	A1	10/2010	Ryu et al.
2010/0286551	A1	11/2010	Harlev et al.
2011/0098771	A1	4/2011	Thakur et al.
2011/0206256	A1	8/2011	Ramanathan et al.
2011/0251505	A1 *	10/2011	Narayan A61B 5/0422 600/515
2011/0288605	A1	11/2011	Kaib et al.
2012/0029504	A1	2/2012	Afonso et al.
2012/0184858	A1	7/2012	Harlev et al.
2012/0184863	A1	7/2012	Harlev et al.
2012/0184865	A1	7/2012	Harlev et al.
2012/0191087	A1	7/2012	Pachon Mateos et al.
2012/0226110	A1	9/2012	Markowitz et al.
2013/0035576	A1	2/2013	O'Grady et al.
2013/0079645	A1	3/2013	Amirana et al.
2013/0274582	A1	10/2013	Afonso et al.
2013/0310702	A1	11/2013	Reinders et al.
2014/0052118	A1	2/2014	Laske et al.
2014/0073194	A1	3/2014	Lim et al.
2014/0200874	A1	7/2014	Zeng et al.
2014/0235986	A1	8/2014	Harlev et al.
2014/0330150	A1	11/2014	Thakur et al.
2014/0343388	A1	11/2014	Thakur et al.
2015/0254419	A1	9/2015	Laughner et al.
2015/0254893	A1	9/2015	Laughner et al.
2016/0012646	A1	1/2016	Huang et al.
2016/0051204	A1	2/2016	Harlev et al.
2016/0066814	A1	3/2016	Markowitz et al.
2016/0100770	A1	4/2016	Afonso et al.
2017/0189118	A1	7/2017	Chopra et al.
2017/0221262	A1	8/2017	Laughner et al.
2017/0311833	A1	11/2017	Afonso et al.
2018/0153426	A1	6/2018	Thakur et al.

FOREIGN PATENT DOCUMENTS

CN	102917638	A	2/2013
EP	2204120	A1	7/2010
EP	2427106	A	3/2012
EP	2485194	A2	8/2012
WO	1999005971	A1	2/1999
WO	WO2006037172	A1	4/2006

WO	2006066324	A1	6/2006
WO	2007035306	A2	3/2007
WO	2007108776	A2	9/2007
WO	2007146864	A3	12/2007
WO	2008138009	A1	11/2008
WO	2010054320	A1	5/2010
WO	2010129095	A2	11/2010
WO	WO2012037471	A2	3/2012
WO	2012092016	A1	7/2012
WO	2013006713	A2	1/2013
WO	2014185977	A1	11/2014
WO	2015130824	A1	9/2015
WO	2015134248	A1	9/2015

OTHER PUBLICATIONS

Anonymous: Solid Commands—Rhino 3-D Modeling (Rhinceros 5), Sep. 17, 2015, XP055332631, Retrieved from Internet: http://docs.mcneel.com/rhino/5/help/en-us/seealso/sak_solidtools.htm, retrieved on Jan. 5, 2017, see under Cap. 2 pages.

International Search Report and Written Opinion issued in PCT/US2016/053613, dated Jan. 4, 2017, 11 pages.

International Search Report and Written Opinion issued in PCT/US2016/053630, dated Jan. 17, 2017, 12 pages.

International Search Report and Written Opinion issued in PCT/US2016/053633, dated Jan. 17, 2017, 14 pages.

International Search Report and Written Opinion issued in PCT/US2015/017289, dated May 6, 2015, 10 pages.

International Search Report and Written Opinion issued in PCT/US2015/017482, dated Jun. 5, 2015, 9 pages.

Jain et al., "Cell Therapy Attenuates Deleterious Ventricular Remodeling and Improves Cardiac Performance after Myocardial Infarction", *Circulation*, 103:1920-1927, 2001.

Jalife, "Rotors and Spiral Waves in Atrial Fibrillation", *Journal of Cardiovascular Electrophysiology*, 14:776-780, 2003.

Jane et al., "Alignment Methods for Averaging of High-Resolution Cardiac Signals: A Comparative Study of Performance", *IEEE Transactions on Biomedical Engineering*, 38(6):571-579, 1991.

Japanese Office Action in JP Application No. 2009-515586, dated Jun. 26, 2012, 4 pages. (0002JP1).

Jia et al., "Electrophysiologic Endocardial Mapping from a Noncontact Nonexpandable Catheter: A Validation Study of a Geometry-Based Concept", *Journal of Cardiovascular Electrophysiology*, 11:1238-1251, 2000.

Kikuchi et al., "Targeted Modification of Atrial Electrophysiology by Homogeneous Transmural Atrial Gene Transfer", *Circulation*, 111:264-270, 2005.

Kistler et al., "Validation of Three-Dimensional Cardiac Image Integration: Use of Integrated CT Image into Electroanatomic Mapping System to Perform Catheter Ablation of Atrial Fibrillation", *Journal of Cardiovascular Electrophysiology*, 17:341-348, 2006.

Kuklik et al., "The reconstruction, from a set of points, and analysis of the interior surface of the heart chamber", *Physiol. Meas.* 25:617-627, 2004.

Kun, Stevan et al., "Conductance Volumetric Model of an Eccentrically Positioned Catheter Within a Three-Compartment Ellipsoidal Ventricle", *IEEE Transactions on Biomedical Engineering*, vol. 40, No. 6, Jun. 1993, pp. 589-592.

L. Piegl, W. Tiller: *The NURBS Book*, 2nd Edition, Monographs in Visual Communication, Springer (1997).

Laciar et al., Improved Alignment Method for Noisy High-Resolution ECG and Holter Records Using a Multiscale Cross-Correlation, *IEEE Transactions on Biomedical Engineering*, 50(3), pp. 344-353, 2003.

Liu et al., "Endocardial Potential Mapping from a Noncontact Nonexpandable Catheter: A Feasibility Study", *Annals of Biomedical Engineering*, 26:994-1009, 1998.

Lorensen et al. "Marching Cubes: A High Resolution 3D Surface Construction Algorithm", *Computer Graphics*, 21(4):163-169, Jul. 1987.

(56)

References Cited

OTHER PUBLICATIONS

- Makela et al., "A Review of Cardiac Image Registration Methods", IEEE Transactions on Medical Imaging, 21(9):1011-1021, Sep. 2002.
- Malladi, R. et al., "A Geometric Approach to Segmentation and Analysis of 3D Medical Images", Mathematical Methods in Biomedical Image Analysis, Proceedings of the Workshop on, Jun. 21-22, 1996, pp. 244-252.
- Mangan, Alan et al., "Partitioning 3D Surface Meshes Using Watershed Segmentation", IEEE Transactions on Visualization and Computer Graphics, vol. 05, No. 4, pp. 308-321, (Oct.-Dec. 1999).
- Meininger et al., "Initial Experience with a Novel Focused Ultrasound Ablation System for Ring Ablation Outside the Pulmonary Vein", Journal of Interventional Cardiac Electrophysiology, 8:141-148, 2003.
- Merrill, Daniel R. et al., "Electrical stimulation of excitable tissue: design of efficacious and safe protocols", Journal of Neuroscience Methods, vol. 141, pp. 171-198 (2005).
- Miller, "Editor's Forum—Application of Registration for Ablation: A Marriage of Technologies", Journal of Interventional Cardiac Electrophysiology, 11:87-89, 2004.
- Nademanee et al., "A New Approach for Catheter Ablation of Atrial Fibrillation: Mapping of the Electrophysiologic Substrate", Journal of the American College of Cardiology, 43(11):2044-2053, 2004.
- Non-final Office Action issued in U.S. Appl. No. 11/451,898, dated Sep. 25, 2008, 13 pages.
- Non-final Office Action issued in U.S. Appl. No. 11/451,908, dated Sep. 4, 2008, 12 pages.
- Noseworthy et al., "The Impact of Respiration on Left Atrial and Pulmonary Venous Anatomy: Implications for Image-Guided Intervention", Heart Rhythm, 2(11), pp. 1173-1178, Nov. 2005.
- Pappone et al., "Robotic Magnetic Navigation for Atrial Fibrillation Ablation", Journal of the American College of Cardiology, 47(7):1390-1400, 2006.
- Paragios, "A Level Set Approach for Shape-Driven Segmentation and Tracking of the Left Ventricle", IEEE Transactions on Medical Imaging, 22(6):773-776, Jun. 2003.
- Persson et al., "A Simple Mesh Generator in MATLAB", SIAM Review, 46(2):329-345, 2004.
- Persson, "Mesh Generation for Implicit Geometries", Massachusetts Institute of Technology—Thesis, Feb. 2005.
- Pham, Dzung et al., "Current Methods in Medical Image Segmentation", Annu. Rev. Biomed. Eng., 02: pp. 315-337, (2000).
- Rao et al., "Novel Noncontact Catheter System for Endocardial Electrical and Anatomical Imaging", Annals of Biomedical Engineering, 32(4):573-584, 2004.
- Reddy et al., "Integration of Cardiac Magnetic Resonance Imaging With Three-Dimensional Electroanatomic Mapping to Guide Left Ventricular Catheter Manipulation—Feasibility in a Porcine Model of Healed Myocardial Infarction", Journal of the American College of Cardiology, 44(11):2202-2213, 2004.
- Reddy et al., "Use of a Diode Laser Balloon Ablation Catheter to Generate Circumferential Pulmonary Venous Lesions in an Open-Thoracotomy Caprine Model", PACE, 27:52-57, 2004.
- Sanders et al., "Spectral Analysis Identifies Sites of High-Frequency Activity Maintaining Atrial Fibrillation in Humans", Circulation, 112:789-797, 2005.
- Sethian, "Level Set Methods and Fast Marching Methods: Evolving Interfaces in Computational Geometry, Fluid Mechanics, Computer Vision, and Materials Science", Department of Mathematics—University of California, Berkeley, Cambridge University Press, 1999.
- Simon et al., "Electroanatomic Mapping of the Right Atrium With a Right Atrial Basket Catheter and Three-Dimensional Intracardiac Echocardiography", PACE, 27:318-326, 2004.
- Smits et al., "Catheter-Based Intramyocardial Injection of Autologous Skeletal Myoblasts as a Primary Treatment of Ischemic Heart Failure", Journal of the American College of Cardiology, 42(12):2063-2069, 2003.
- Solomon et al., "Real-Time Cardiac Catheter Navigation on Three-Dimensional CT Images", Journal of Interventional Cardiac Electrophysiology, 8:27-36, 2003.
- Sra et al., "Registration of Three-Dimensional Left Atrial Computed Tomographic Images With Projection Images Obtained Using Fluoroscopy", Circulation, 112:3763-3768, 2005.
- Sra, Jasbir et al., "Registration of 3D Computed Tomographic Images With Interventional Systems: Implications for Catheter Ablation of Atrial Fibrillation", J Interv Card Electrophysiol, 16:141-148, 2006.
- Stevenson, "Radiofrequency Catheter Ablation of Ventricular Tachycardia After Myocardial Infarction", Circulation, 98:308-314, 1998.
- Supplemental European Search Report issued in EP Application 10772414.8, dated May 7, 2013, 6 pages.
- Supplemental European Search Report issued in EP Application No. 09824015, dated Jun. 1, 2012, 7 pages.
- Supplementary European Search Report issued in EP Application No. 09727423, dated May 15, 2012, 5 pages.
- Supplementary European Search Report issued in EP Application No. 07798369.0 dated Jul. 30, 2010, 6 pages.
- Supplementary European Search Report issued in EP Application No. 08728501, dated Feb. 25, 2011, 4 pages.
- Taccardi et al., "A New Intracavitary Probe for Detecting the Site of the Origin of Ectopic Ventricular Beats During One Cardiac Cycle", Circulation, 75(1):272-281, 1987.
- Thal et al., "Novel Applications in Catheter Ablation", Journal of Interventional Cardiac Electrophysiology, 13:17-21, 2005.
- Thiagalingam et al., "Noncontact Mapping of the Left Ventricle: Insights from Validation With Transmural Contact Mapping", PACE, 27:570-578, 2004.
- Voth, "The Inverse Problem of Electrocardiography: Industrial Solutions and Simulations", BEM and NFSI Conference Proceedings, Minneapolis, MN, May 12-15, 2005, pp. 191-194.
- Wittkamp et al., "LocaLisa: New Technique for Real-Time 3-Dimensional Localization of Regular Intracardiac Electrodes", Circulation, 99:1312-1317, 1999.
- Yezzi, Anthony et al., "A Geometric Snake Model for Segmentation of Medical Imagery", IEEE Transactions on Medical Imag, vol. 16, No. 2, Apr. 1997.
- Adams et al., "Seeded Region Growing", IEEE Transactions on Pattern Analysis and Machine Intelligence, 16(6):641-647, 1994.
- Arthur et al., "Clinical Use of Intracardiac Impedance: Current Applications and Future Perspectives", PACE, vol. 24, No. 4, Part 1, Apr. 2001, pp. 500-506.
- Baan, Jan et al., "Continuous Measurement of Left Ventricular Volume in Animals and Humans by Conductance Catheter", Diagnostic Methods-Conductance Catheter, Circulation, vol. 70, No. 5, 1984, pp. 812-823.
- Badics et al., "Real-Time Reconstruction of Endocardial Potential Maps in Non-Contact Cardiac Mapping", International Journal for computation and Mathematics in Electrical and Electronic Engineering (COMPEL), vol. 28, No. 4, 2009.
- Ben-Haim et al., "Nonfluoroscopic, in Vivo Navigation and Mapping Technology", Nature Medicine, 2(12):1393-1395, Dec. 1996.
- Besl et al., "A Method for Registration of 3-D Shapes", IEEE Transactions on Pattern Analysis and Machine Intelligence, 14(2):239-256, Feb. 1992.
- Blomstrom-Lundqvist et al., "ACC/AHA/ESC Guidelines for the Management of Patients With Supraventricular Arrhythmias—Executive Summary", Journal of the American College of Cardiology, 42(8):1493-1531, 2003.
- Breithardt et al., "AHA Medical/Scientific Statement—Special Report: Standards for Analysis of Ventricular Late Potentials Using High-Resolution or Signal-Averaged Electrocardiography", Circulation, 83(4):1481-1488, Apr. 1991.
- Brooks et al., "Electrical Imaging of the Heart", IEEE Signal Processing Magazine, pp. 24-42, 1997.
- Buneo, Christopher A., Analyzing Neural Responses with Vector Fields, Journal of Neuroscience Methods, vol. 197, 2011, pp. 109-117.
- Caspi et al., "Stem Cell Research: Regenerating the Heart Using Human Embryonic Stem Cells—from Cell to Bedside", IMAJ 8:208-214, 2006.

(56)

References Cited

OTHER PUBLICATIONS

Cheney et al., "Electrical Impedance Tomography", SIAM Review 41(1):85-101, 1999.

Communication pursuant to Article 94(3) EPC issued in EP Application No. 07 798 369.0, dated Nov. 17, 2011, 5 pages.

De Groot et al., "Three-Dimensional Catheter Positioning During Radiofrequency Ablation in Patients: First Application of a Real-Time Position Management System", Journal of Cardiovascular Electrophysiology, 11(11):1183-1192, Nov. 2000.

Donahue et al., "Focal Modification of Electrical Conduction in the Heart by Viral Gene Transfer", Nature Medicine, 6(12):1395-1398, 2000.

Dong et al., "Integrated Electroanatomic Mapping With Three-Dimensional Computed Tomographic Images for Real-Time Guided Ablations", Circulation 113:186-194, 2006.

Durrer et al., "Total Excitation of the Isolated Human Heart", Circulation, vol. XLI, pp. 899-912, 1970.

E. J. Haug et al.: Design Sensitivity Analysis of Structural Systems, Mathematics in Science and Engineering, vol. 177 (1986).

Ector et al., "Cardiac Three-Dimensional Magnetic Resonance Imaging and Fluoroscopy Merging—A New Approach for Electroanatomic Mapping to Assist Catheter Ablation", Circulation, (Dec. 13, 2005), pp. 3769-3776.

Extended European Search Report issued in EP Application No. 10 772 414, dated May 7, 2013, 6 pages.

Fletcher, R. "Chapter 6: Sums of Squares and Nonlinear Equations," Practical Methods of Optimization, 2nd Edition, J. Wiley & Sons, pp. 110-119 (1987).

Friedman, "Catheter Cryoablation of Cardiac Arrhythmias", Current Opinion in Cardiology, 20:48-54, 2005.

Friedman, "Novel Mapping Techniques for Cardiac Electrophysiology", Heart 2002, 87:575-582.

Geddes, L.A. et al., "Criteria for the Selection of Materials for Implanted Electrodes", Annals of Biomedical Engineering, vol. 31, pp. 879-890 (2003).

Gepstein et al., "A Novel Method for Nonfluoroscopic Catheter-Based Electroanatomical Mapping of the Heart", Circulation 95:1611-1622, 1997.

Gitosusastro et al., Performance Derivative Calculations and Optimization Process, IEEE Transactions on Magnetics, vol. 25, No. 4 (Jul. 1989) pp. 2834-2839.

Hansen: Rank-Deficient and Discrete III—Posed Problems: Numerical Aspects of Linear Inversion, SIAM, Philadelphia, USA, pp. 100-103, 1998.

He, Ye H. et al., "An Interactive Graphical System for Automated Mapping and Display of Cardiac Rhythms", Journal of Electrocardiology, vol. 32, No. 3, 1999, 17 pages.

He, Ye H., "An interactive graphical system for automated mapping and display of cardiac rhythms", Journal of Electrocardiology, vol. 32, No. 3, Jul. 1, 1999, pp. 225-241.

Holm, Magnus et al. A New Method for Analysis of Atrial Activation During Chronic Atrial Fibrillation in Man. IEEE Transactions on Biomedical Engineering, 43(2): 198-210, Feb. 1996.

Huang, Yi-Chih et al., "Development of a Third Generation Intraventricular Impedance Imaging (III) System: Evaluation of Hardware Design", Engineering in Medicine and Biology Society. Proceedings of the 19th Annual International Conference of the IEEE, Oct. 30-Nov. 2, 1997 vol. 6, pp. 336-338 (1997).

International Preliminary Report on Patentability in PCT/US2007/070854, dated Dec. 16, 2008, 9 pages.

International Preliminary Report on Patentability in PCT/US2009/061277, dated May 3, 2011 11 pages.

International Preliminary Report on Patentability in PCT/US2010/027568 dated Oct. 25, 2011, 4 pages.

International Preliminary Report on Patentability issued in PCT/US2008/052385 dated Aug. 11, 2009, 6 pages.

International Preliminary Report on Patentability issued in PCT/US2009/036099, dated Oct. 14, 2010, 20 pages.

International Preliminary Report on Patentability issued in PCT/US2010/027436, dated Nov. 9, 2011, 4 pages.

International Preliminary Report on Patentability issued in PCT/US2014/000114, dated Nov. 26, 2015, 9 pages.

International Preliminary Report on Patentability issued in PCT/US2014/036939, dated Nov. 19, 2015, 8 pages.

International Preliminary Report on Patentability issued in PCT/US2015/0017289 dated Sep. 15, 2016, 8 pages.

International Preliminary Report on Patentability issued in PCT/US2015/017482 dated Sep. 15, 2016, 4 pages.

International Search Report and the Written Opinion in PCT/US08/52385 dated Aug. 8, 2008, 11 pages.

International Search Report and Written Opinion in PCT/US2010/027568, dated Nov. 4, 2010, 6 pages.

International Search Report and Written Opinion in PCT/US2012/020946, dated May 7, 2012, 15 pages.

International Search Report and Written Opinion issued in PCT/US2007/070854, dated Sep. 12, 2008, 10 pages.

International Search Report and Written Opinion issued in PCT/US2009/036099, dated Apr. 28, 2009, 21 pages.

International Search Report and Written Opinion issued in PCT/US2009/061277, dated Apr. 8, 2010, 12 pages.

International Search Report and Written Opinion issued in PCT/US2010/027436 dated Oct. 27, 2010, 10 pages.

International Search Report and Written Opinion issued in PCT/US2014/000114, dated Sep. 8, 2014, 12 pages.

International Search Report and Written Opinion issued in PCT/US2014/036939, dated Jul. 30, 2014, 11pages.

* cited by examiner

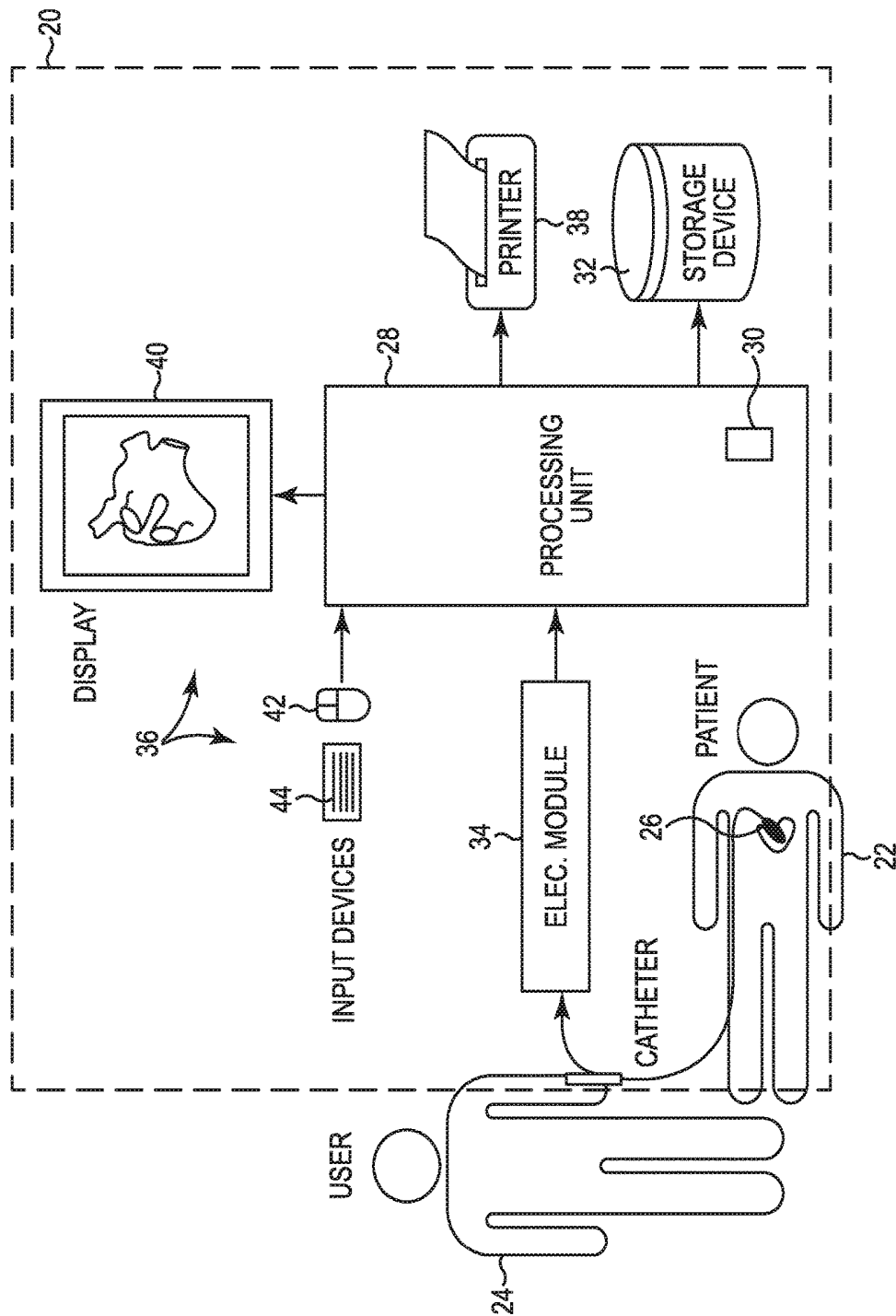
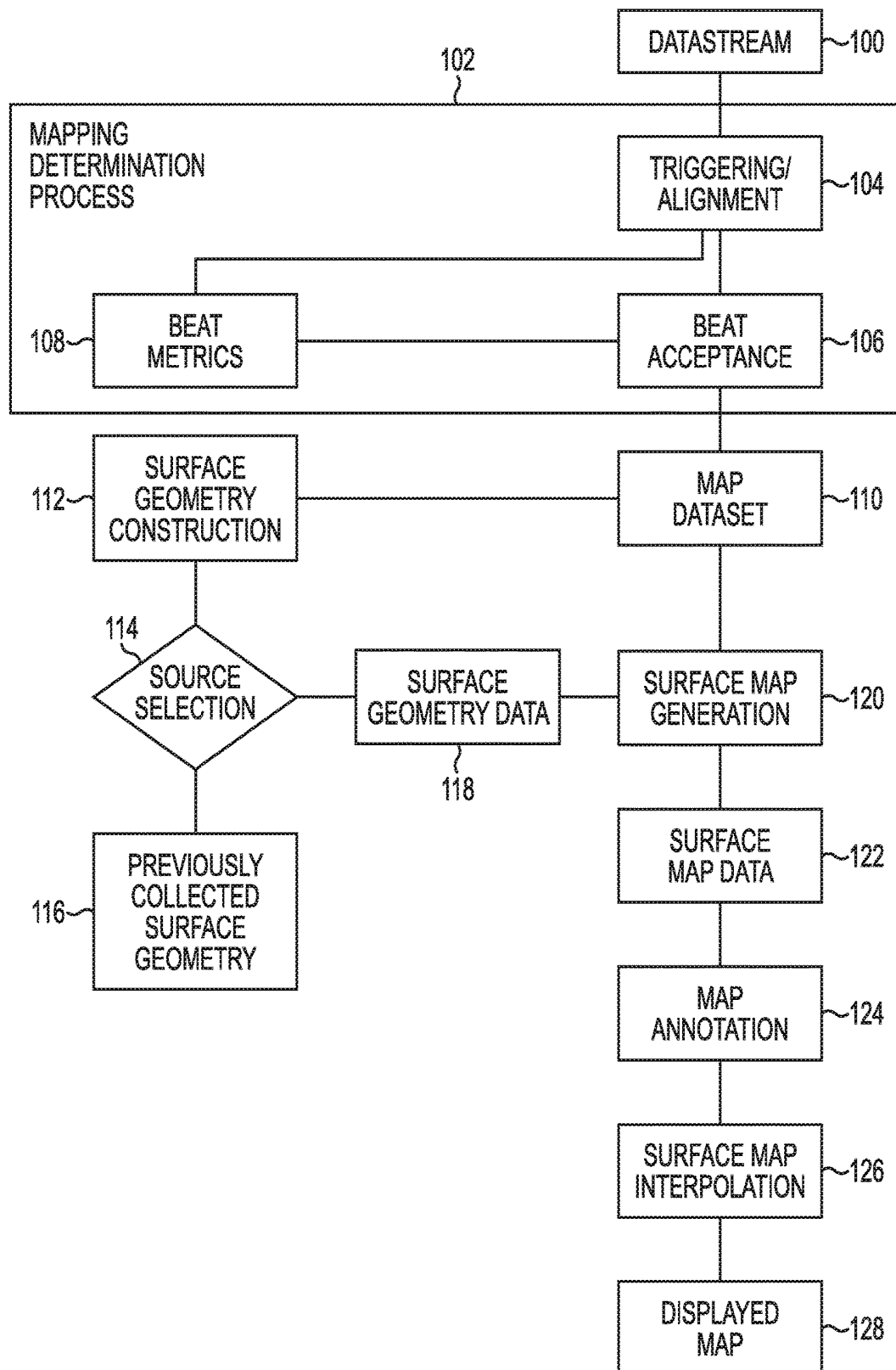
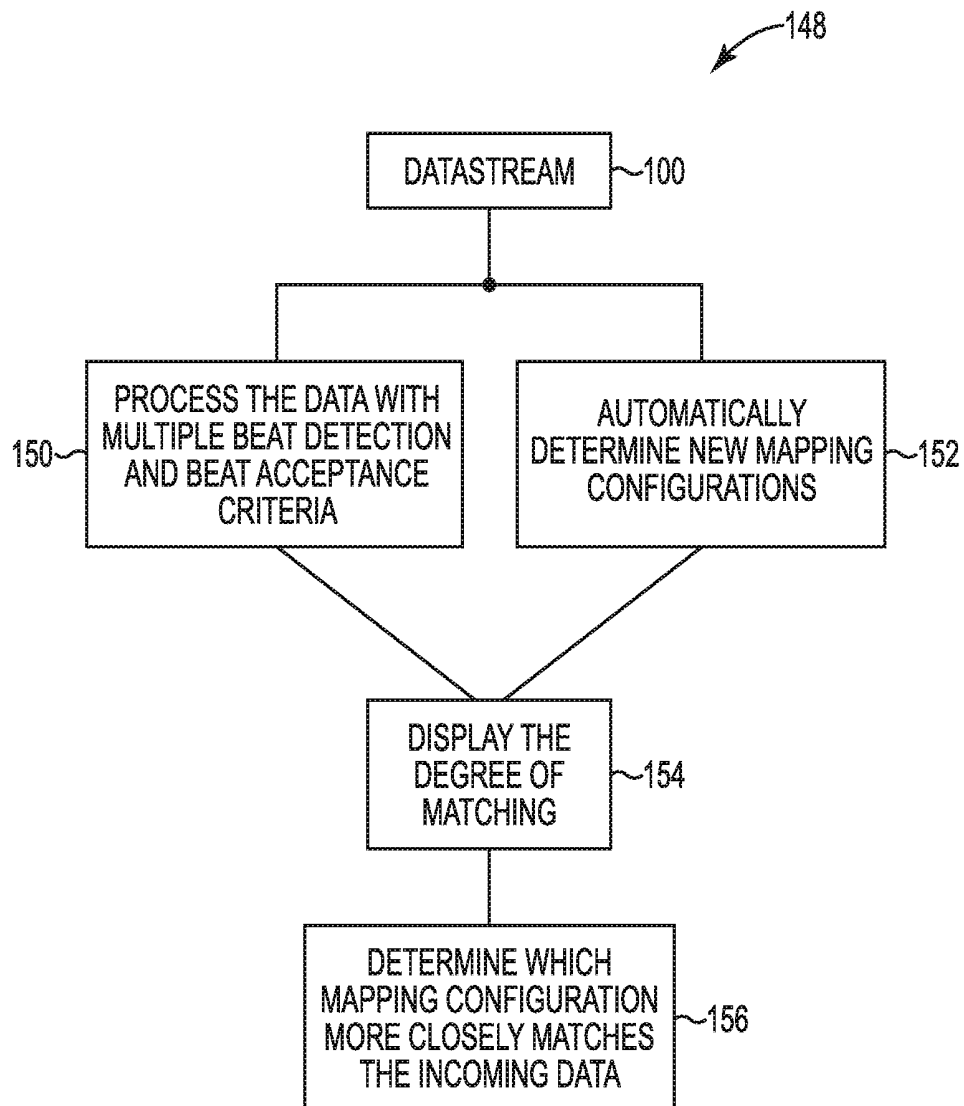
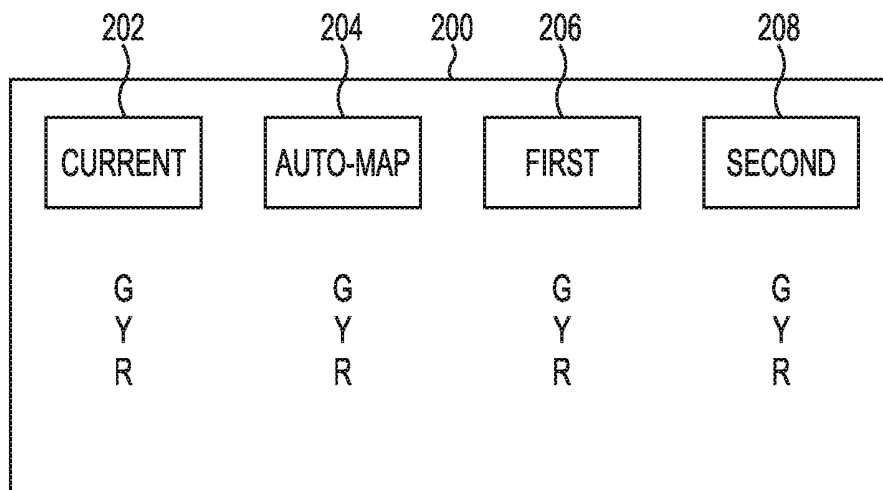


Fig. 1

**Fig. 2**

**Fig. 3**

**Fig. 4**

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MULTIPLE RHYTHM TEMPLATE MONITORING

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to Provisional Application No. 62/233,339, filed Sep. 26, 2015, which is herein incorporated by reference in its entirety.

TECHNICAL FIELD

This disclosure relates to systems and methods for providing information about a patient's heart and, in particular, to systems and methods for monitoring and electro-anatomically mapping the patient's heart.

BACKGROUND

Use of minimally invasive procedures, such as catheter ablation, to treat a variety of heart conditions, such as supraventricular and ventricular arrhythmias, is becoming increasingly prevalent. Often, these procedures involve the mapping of electrical activity in the heart at various locations on the endocardium surface, referred to as cardiac mapping, to identify the mechanism of the arrhythmia followed by a targeted ablation. To perform the cardiac mapping, a catheter with one or more electrodes can be inserted into the patient's heart chamber.

Cardiac mapping techniques include contact mapping, near-contact mapping, and non-contact mapping. In contact mapping, one or more catheters are advanced into the heart and physiological signals resulting from the electrical activity of the heart are acquired with one or more electrodes located at the catheter distal tip after determining that the tip is in stable and steady contact with the endocardium surface of a heart chamber. The location and electrical activity can be measured on a point-by-point basis at, for example, about 50 to 200 points on the internal surface of the heart to construct an electro-anatomical depiction of the heart. In near-contact mapping, a movable catheter having multiple spatially distributed electrodes is placed in a heart chamber of interest and moved to one or more locations within the chamber of interest, where the electrodes are on or near, such as within millimeters of, the endocardium surface of the heart chamber. Measurements are taken automatically at each of the locations of the catheter, without determining whether the electrodes are in contact with the surface of the heart. These measurements are analyzed to detect the endocardium surface of the heart chamber in the vicinity of the catheter. The location of the catheter, e.g., a location provided by a tracking system, and the measurements from the electrodes are used to reconstruct the chamber anatomy, where, for example, 20,000 measurements may be made to construct an electro-anatomical depiction of the heart. As the tracked catheter is moved inside the chamber, a partial or complete representation of the chamber anatomy can be constructed. In non-contact mapping, a multiple electrode catheter is placed in the heart chamber of interest and the catheter is deployed to assume a three dimensional shape. Using the signals detected by the non-contact electrodes and information on chamber anatomy and relative electrode location, the system calculates and provides physiological information regarding the endocardium surface of the heart chamber. In these cardiac mapping techniques, the generated map may then serve as the basis for deciding on a thera-

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peutic course of action, such as tissue ablation, to alter the propagation of the heart's electrical activity and to restore normal heart rhythm.

While mapping a patient's heart, the patient may present multiple different types of cardiac rhythms, mixed in time, which the user wants to map and/or the patient may present a paced rhythm. Typically, the mapping system is set to capture one type of cardiac rhythm for a current map. If the cardiac rhythm changes, the new type of cardiac rhythm is not added to the current map. To capture signals associated with the new cardiac rhythm type, the mapping system must be reconfigured to an existing cardiac mapping configuration that matches the current cardiac rhythm or the mapping system must be reconfigured to capture the current cardiac rhythm. However, determining whether an existing cardiac mapping configuration can be used for the current cardiac rhythm can be a difficult and time consuming process and programming a new mapping configuration into the mapping system can take anywhere from 10 seconds to more than a minute, either of which may result in lost data and frustration.

SUMMARY

Example 1 is a system for providing information about a patient's heart. The system includes one or more electrodes that receive signals from electrical activity of the heart over one or more heart beat cycles. In some embodiments, the system is characterized by an electronic processor coupled to the one or more electrodes to: receive the signals from the one or more electrodes; execute an automated set-up routine that processes the signals to automatically provide at least some set-up results for new mapping configurations; and process the signals with beat detection and beat acceptance criteria for the new or existing mapping configurations to provide information about how well the signals match one or more of the new or existing mapping configurations. In some embodiments, the system is characterized by an electronic processor coupled to the one or more electrodes to receive the signals from the one or more electrodes and execute an automated set-up routine that processes the signals to automatically provide at least some set-up results for new mapping configurations. In some embodiments, the system is characterized by an electronic processor coupled to the one or more electrodes to receive the signals from the one or more electrodes and process the signals with beat detection and beat acceptance criteria for new or existing mapping configurations to provide information about how well the signals match one or more of the new or existing mapping configurations.

Example 2 is the system of Example 1, wherein the electronic processor executes the automated set-up routine and processes the signals with the beat detection and beat acceptance criteria for the existing mapping configurations in parallel.

Example 3 is the system of any of Examples 1 and 2, wherein the electronic processor executes the automated set-up routine at one or more of a predetermined time interval, once every heart beat cycle, and once per second.

Example 4 is the system of any of Examples 1-3, wherein the automated set-up routine provides the new mapping configurations in response to changes in the signals.

Example 5 is the system of any of Examples 1-4, wherein the new mapping configurations are updated and displayed while matching the signals to at least one of the existing mapping configurations and displaying the degree of match-

ing between the signals and the at least one of the new or existing mapping configurations.

Example 6 is the system of any of Examples 1-5, wherein information for making a determination about which of the new or existing mapping configurations most closely matches the signals is displayed.

Example 7 is the system of any of Examples 1-6, comprising a user interface for switching from mapping the signals using one of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

Example 8 is the system of any of Examples 1-7, wherein the electronic processor determines which of the new mapping configurations and the existing mapping configurations are redundant.

Example 9 is the system of any of Examples 1-8, wherein the electronic processor automatically switches from mapping the signals using one of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

Example 10 is a method for providing information about a patient's heart. The method includes receiving signals from electrical activity of the heart over one or more heart beat cycles at one or more electrodes and is characterized by the steps of: receiving the signals at an electronic processor that is coupled to the one or more electrodes; executing, by the electronic processor, an automated set-up routine that processes the signals to automatically provide at least some set-up results for new mapping configurations; and processing the signals, by the electronic processor, with beat detection and beat acceptance criteria for existing mapping configurations to provide information about how well the signals match one or more of the existing mapping configurations.

Example 11 is the method of Example 10, wherein the steps of executing the automated set-up routine and processing the signals with the beat detection and beat acceptance criteria for the existing maps are performed in parallel.

Example 12 is the method of any of Examples 10 and 11, including displaying information about the degree of matching between the signals and a current mapping configuration of the existing mapping configurations and displaying information about the degree of matching between the signals and at least one other mapping configuration of the existing mapping configurations.

Example 13 is the method of any of Examples 10-12, including updating the new mapping configurations in response to changes in the signals and displaying updated new mapping configurations.

Example 14 is the method of any of Examples 10-13, including switching from mapping the signals using one of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

Example 15 is the method of any of Examples 10-14, including determining which of the new mapping configurations and the existing mapping configurations more closely matches the signals and determining which of the new mapping configurations and the existing mapping configurations are redundant.

Example 16 is a system for providing information about a patient's heart. The system includes one or more electrodes that receive signals from electrical activity of the heart over one or more heart beat cycles and an electronic processor coupled to the one or more electrodes. In some embodiments,

the electronic processor is to receive the signals from the one or more electrodes, execute an automated set-up routine that processes the signals to automatically provide at least some set-up results for new mapping configurations, and process the signals with beat detection and beat acceptance criteria for the new or existing mapping configurations to provide information about how well the signals match one or more of the new or existing mapping configurations. In some embodiments, the electronic processor is to receive the signals from the one or more electrodes and execute an automated set-up routine that processes the signals to automatically provide at least some set-up results for new mapping configurations. In some embodiments, the electronic processor is to receive the signals from the one or more electrodes and process the signals with beat detection and beat acceptance criteria for the new or existing mapping configurations to provide information about how well the signals match one or more of the new or existing mapping configurations.

Example 17 is the system of Example 16, wherein the electronic processor executes the automated set-up routine and processes the signals with the beat detection and beat acceptance criteria for the existing mapping configurations in parallel.

Example 18 is the system of Example 16, wherein the electronic processor executes the automated set-up routine at one or more of a predetermined time interval, once every heart beat cycle, and once per second.

Example 19 is the system of Example 16, wherein the automated set-up routine provides the new mapping configurations in response to changes in the signals and the new mapping configurations are updated and displayed while matching the signals to one or more of the new or existing mapping configurations.

Example 20 is the system of Example 16, including a user interface, wherein the degree of matching between the signals and at least two of the new or existing mapping configurations is displayed on the user interface.

Example 21 is the system of Example 16, including a user interface, wherein information for making a determination about which of the new or existing mapping configurations most closely matches the signals is displayed on the user interface.

Example 22 is the system of Example 16, including a user interface for switching from mapping the signals using one of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

Example 23 is the system of Example 16, wherein the electronic processor determines which of the new mapping configurations and the existing mapping configurations are redundant.

Example 24 is the system of Example 16, wherein the electronic processor automatically switches from mapping the signals using one of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

Example 25 is a system for providing information about a patient's heart. The system including one or more electrodes that receive signals from electrical activity of the heart over one or more heart beat cycles and an electronic processor coupled to the one or more electrodes. The electronic processor is to receive the signals from the one or more electrodes, execute an automated set-up routine that processes the signals to automatically provide at least some set-up results for new mapping configurations, and process

the signals with beat detection and beat acceptance criteria for existing mapping configurations to provide information about how well the signals match the existing mapping configurations, wherein the electronic processor executes the automated set-up routine and processes the signals with the beat detection and beat acceptance criteria for the existing mapping configurations in parallel. The system also includes a user interface, wherein information for making a determination about which of the existing mapping configurations more closely matches the signals is displayed on the user interface.

Example 26 is the system of Example 25, wherein the automated set-up routine provides the new mapping configurations in response to changes in the signals and the new mapping configurations are updated and displayed on the user interface.

Example 27 is the system of Example 25, wherein the degree of matching between the signals and a current mapping configuration of the existing mapping configurations is displayed on the user interface while mapping the signals to a current map associated with the current mapping configuration and the degree of matching between the signals and at least one other mapping configuration of the existing mapping configurations is displayed on the user interface while mapping the signals to the current map.

Example 28 is the system of Example 25, wherein a user can switch from mapping the signals using a current mapping configuration of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations via the user interface.

Example 29 is the system of Example 25, wherein the electronic processor is configured to automatically switch from mapping the signals using a current mapping configuration of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

Example 30 is a method for providing information about a patient's heart. The method including receiving signals from electrical activity of the heart over one or more heart beat cycles at one or more electrodes, receiving the signals at an electronic processor that is coupled to the one or more electrodes, executing, by the electronic processor, an automated set-up routine that processes the signals to automatically provide at least some set-up results for new mapping configurations, and processing the signals, by the electronic processor, with beat detection and beat acceptance criteria for existing mapping configurations to provide information about how well the signals match one or more of the existing mapping configurations.

Example 31 is the method of Example 30, wherein executing the automated set-up routine and processing the signals with the beat detection and beat acceptance criteria for the existing maps is performed in parallel.

Example 32 is the method of Example 30, including displaying information about the degree of matching between the signals and a current mapping configuration of the existing mapping configurations and displaying information about the degree of matching between the signals and at least one other mapping configuration of the existing mapping configurations.

Example 33 is the method of Example 30, including updating the new mapping configurations in response to changes in the signals and displaying updated new mapping configurations.

Example 34 is the method of Example 30, including switching from mapping the signals using one of the existing

mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

Example 35 is the method of Example 30, including determining which of the new mapping configurations and the existing mapping configurations more closely matches the signals and determining which of the new mapping configurations and the existing mapping configurations are redundant.

While multiple embodiments are disclosed, still other embodiments of the present disclosure will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the disclosure. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagram illustrating an electro-anatomical mapping system for mapping multiple different types of cardiac rhythms, which are mixed in time, according to embodiments of the disclosure.

FIG. 2 is a flowchart diagram illustrating an automated electro-anatomical mapping process, according to embodiments of the disclosure.

FIG. 3 is a diagram illustrating a process for determining which mapping configuration more closely matches the cardiac rhythm signals, according to embodiments of the disclosure.

FIG. 4 is a diagram illustrating a user interface display that displays a degree of matching between incoming data and three existing cardiac mapping configurations, according to embodiments of the disclosure.

While the disclosure is amenable to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the disclosure to the particular embodiments described. On the contrary, the disclosure is intended to cover all modifications, equivalents, and alternatives falling within the scope of the disclosure as defined by the appended claims.

DETAILED DESCRIPTION

During cardiac mapping of multiple different types of cardiac rhythms, mixed in time, the cardiac rhythm may change spontaneously or due to some intentional act, such as pacing of the heart. When this occurs, it is useful to quickly determine whether the new cardiac rhythm matches an existing mapping configuration. If the new cardiac rhythm matches an existing mapping configuration, the data being acquired can be added to an existing cardiac map or to a new cardiac map associated with the matching mapping configuration. If the new cardiac rhythm does not match an existing mapping configuration, a new cardiac mapping configuration can be configured and the data can be added to a new cardiac map or to an existing cardiac map, using the new cardiac mapping configuration.

The present disclosure describes embodiments of systems and methods for quickly determining whether a new cardiac rhythm matches an existing mapping configuration and for quickly configuring a new cardiac mapping configuration, thereby potentially maximizing mapping data collection and reducing frustration.

FIG. 1 is a diagram illustrating an electro-anatomical mapping system 20 for mapping multiple different types of

cardiac rhythms, which are mixed in time, of a patient **22**, according to embodiments described in the disclosure. The system **20** provides information for determining whether a new cardiac rhythm has been previously mapped using an existing cardiac mapping configuration and information for configuring a new cardiac mapping configuration. Using an existing mapping configuration or a new mapping configuration, the data associated with the new cardiac rhythm can be added to an existing cardiac map or to a new cardiac map. With this information, a user **24** of the system **20**, such as a physician and/or a technician, and/or the system **20** itself, can quickly switch to using either an existing cardiac mapping configuration that matches the new cardiac rhythm or to a new cardiac mapping configuration.

The system **20** includes a catheter **26** having one or more electrodes. During a signal acquisition stage, the catheter **26** can be displaced to multiple locations within the heart chamber of interest into which the catheter **26** is inserted. In some embodiments, the catheter **26** is configured for contact mapping. In some embodiments, the catheter **26** is configured for near-contact mapping. In some embodiments, the catheter **26** is configured for non-contact mapping. In some embodiments, the electrodes are mounted on the catheter **26** following a three dimensional olive shape, where the electrodes are mounted on a device capable of deploying the electrodes into the desired shape while inside the heart and capable of retracting the electrodes when the catheter is removed from the heart. To allow deployment into the three dimensional shape, the electrodes may be mounted on a balloon or shape memory material, such as Nitinol. In some embodiments, the catheter **26** may include any number of electrodes arranged according to any desired shape.

In some embodiments, the system **20** includes other catheters and/or electrodes for measuring the electrical activity of the heart. These electrodes can be externally mounted on or near the patient for measuring the electrical activity of the heart. For example, the system **20** can include electrocardiogram (ECG or EKG) leads that are used to measure the electrical activity of the heart. The system **20** can use the signals obtained from the ECG leads for system functions, such as determining which new or existing mapping configuration (s) more closely matches a cardiac rhythm and switching to using a different mapping configuration for adding data to an associated cardiac map.

At each of the locations to which the catheter **26** is moved, the catheter's one or more electrodes acquire signals resulting from the electrical activity of the heart. This provides, to the user **24**, physiological data pertaining to the heart's electrical activity based on information acquired at multiple locations, which may facilitate, for example, providing a relatively accurate reconstruction of the physiological behavior of the endocardium surface. The acquisition of signals at multiple catheter locations in the heart chamber enables the catheter **26** to effectively act as a "mega-catheter" whose effective number of electrodes and electrode span is proportional to the product of the number of locations in which signal acquisition is performed and the number of electrodes on the catheter **26**. In some embodiments of non-contact mapping, to enhance the quality of the physiological information at the endocardium surface, the catheter **26** is moved to more than three locations, such as more than 5, 10, or even 50 locations, within the heart chamber. Further, the spatial range over which the catheter is moved may be larger than one third ($\frac{1}{3}$) of the diameter of the heart cavity, such as larger than 35%, 40%, 50% or even 60% of the diameter of the heart cavity.

In embodiments, the physiological information is computed based on signals measured over several heart beats, either at a single catheter location within the heart chamber or over several locations. In circumstances where physiological information is based on multiple measurements over several heart beats, the measurements can be synchronized with one another so that the measurements are performed, and/or analyzed, with respect to approximately the same phase of the heart cycle. Also, the signal measurements over multiple beats can be synchronized based on features detected from physiological data, such as, for example, a surface electrocardiogram (ECG) or an intracardiac electrogram (EGM).

The system **20** includes a processing unit **28**, which may be, or include, a processor that executes code stored in internal memory **30** and/or in a storage device **32** to perform operations, according to embodiments of the disclosure. The internal memory **30** and/or the storage device **32** also, or alternatively, may store data acquired by the one or more electrodes of the mapping catheter **26**. In some embodiments, the internal memory **30** and/or the storage device **32** may store data acquired via other catheters and/or external electrodes, such as via ECG leads. In some embodiments, the processing unit **28** is an electronic processor, which may be, at least in part, a software processor.

The processing unit **28** is communicatively coupled to the catheter **26** and receives the signals from the one or more electrodes. The processing unit **28** executes, from memory such as the internal memory **30** and/or the storage device **32**, an automated set-up routine that processes the signals from the one or more electrodes to determine new mapping configurations and may provide at least some set-up information and/or set-up results for the new mapping configurations to the user **24**. Also, the processing unit **28** executes, from memory such as the internal memory **30** and/or the storage device **32**, code that processes the signals with beat detection and beat acceptance criteria for one or more existing mapping configurations. In some embodiments, the existing mapping configurations include a current existing mapping configuration being used to add data to an associated current existing cardiac map and one or more other existing mapping configurations. This provides information about how well the signals match the existing mapping configurations.

In some embodiments, the processing unit **28** executes a reconstruction procedure to determine the physiological information at the endocardium surface. To expedite embodiments of computational operations performed by the system **20**, the processing unit **28** may compute, prior to the insertion of the catheter **26** into the heart chamber and/or before signal acquisition by the catheter's electrodes has commenced, transformation functions that can be used, during a mapping procedure, to facilitate the reconstruction process. Once the catheter **26** is inserted and displaced to a particular location in the heart chamber, the mapping procedure may be performed expeditiously by computing those transformation components that were not computed ahead of the signal acquisition stage, and combining those components with the appropriate pre-processed transformation components to obtain the overall transformation function(s). The overall transformation function may be applied to the acquired raw data to perform an inverse reconstruction operation.

The processing unit **28** may also perform a catheter registration procedure. The location of the catheter **26** inserted into the heart chamber may be determined using a conventional sensing and tracking system (not shown) that

provides the three dimensional spatial coordinates of the catheter 26 and/or its multiple electrodes with respect to the catheter's coordinate system as established by the sensing and tracking system. However, to perform the mapping procedure and/or reconstruct physiological information on the endocardium surface, it may be desirable to align the coordinate system of the catheter 26 with the endocardium surface's coordinate system. The processing unit 28 or another processing module of the system 20 may be configured to determine a coordinate system transformation function that transforms the three dimensional spatial coordinates of the catheter's locations into coordinates expressed in terms of the endocardium surface's coordinate system, or vice-versa. In some embodiments, the processing unit 28 performs post-processing operations on the reconstructed physiological information to extract and display useful features of the information to the operator of the system 20 and/or other persons, such as a physician.

The signals acquired by the one or more electrodes of the catheter 26 may be passed to the processing unit 28 via a signal conditioning module 34 that receives the signals from the catheter 26 and performs signal enhancement operations on the signals before they are forwarded to the processing unit 28. Signal conditioning hardware may be used to amplify, filter, and sample intracardiac potential measured by one or more electrodes. In some embodiments, for example, the intracardiac signals have maximum amplitudes of 60 mV and mean amplitudes of a few millivolts. In some embodiments the signals are bandpass filtered in a frequency range, such as 0.5-500 Hz, and sampled with analog to digital converters, such as converters with 15-bit resolution at 1 kHz.

To avoid interference with electrical equipment in the room, the signals may be filtered to remove one or more frequencies corresponding to the equipment. Other types of signal processing operations may be implemented, such as, for example, spectral equalization, automatic gain control, and/or the like. The resultant processed signals are forwarded by the module 34 to the processing unit 28 for further processing.

The system 20 includes a user interface 36 and, optionally, peripheral devices, such as a printer 38, which are communicatively coupled to the processing unit 28. The user interface 36 includes one or more display devices 40 and input devices, such as a mouse 42 and a keyboard 44. The user interface 36 may receive signals from the processing unit 28 and display information about which existing mapping configuration(s) more closely matches a current cardiac rhythm. In some embodiments, the user interface 36 may receive signals from the processing unit 28 and display information about whether a current cardiac rhythm more closely matches a current existing mapping configuration being used to add data to an associated current existing cardiac map or a different existing mapping configuration. Also, the user interface 36 may display information about a new mapping configuration obtained via the automated set-up routine. In some embodiments, with the user interface 32 displaying this information, the user 24 can quickly and easily determine which mapping configuration of the existing mapping configurations and the new mapping configuration more closely matches the cardiac rhythm such that it can be used to add data to an associated cardiac map, including either an existing cardiac map or a new cardiac map. Also, in some embodiments, the user interface 32 can be used to switch to using one of the existing mapping configurations or a new mapping configuration. In embodiments, the user interface 36 displays this information while

the system 20 is adding signals into the current cardiac map. In some embodiments, the user interface 36 includes a graphical user interface that includes a touch screen, which can be used for switching from using one of the existing mapping configurations to using another one of the existing mapping configurations or a new mapping configuration and adding the data to an associated cardiac map that can be an existing cardiac map or a new cardiac map.

FIG. 2 is a flowchart diagram illustrating an automated electro-anatomical mapping process, according to embodiments described in the disclosure. The electro-anatomical mapping process of FIG. 2 may be performed, at least in part, by the electro-anatomical mapping system 20 of FIG. 1. In some embodiments, the processing unit 28 executes computer code stored in the internal memory 30 and/or storage device 32 to facilitate the electro-anatomical mapping process of FIG. 2.

In the electro-anatomical mapping process of FIG. 2, a data stream 100 containing multiple signals is input into the system (e.g., the mapping system 20 depicted in FIG. 1). The data stream 100 provides a collection of physiological and non-physiological signals and information that serve as inputs to the mapping process. The data stream 100 may include signals received from one or more electrodes on the catheter 26. Also, the data stream 100 may include signals and/or information such as unipolar or bipolar intracardiac EGM signals, ECG signals, electrode and/or catheter location information originating from a variety of methodologies including magnetic, impedance, ultrasound, fluoroscopy, and real time magnetic resonance imaging (MRI) methodologies, tissue proximity information, catheter force or contact information such as from force spring sensing, piezo-electric sensing, and optical sensing, catheter tip and/or tissue temperature, acoustic information, catheter electrical coupling information, respiration phase, blood pressure, and/or other physiological information. In addition, the data stream 100 may contain information such as catheter shape and electrode properties. The signals and information can be collected directly by the mapping system and/or obtained from another system using an analog or digital interface.

A mapping determination process 102 receives the data stream 100 and processes the data to provide information for determining whether the acquired signals in the data stream 100 should be added to the current map, another existing cardiac map, or a new cardiac map. The mapping determination process 102 processes the data with beat detection and beat acceptance criteria for the current mapping configuration and for one or more other existing mapping configurations to provide information about how well the incoming data matches the current mapping configuration and the other existing mapping configurations. Also, the mapping determination process 102 automatically determines new mapping configurations for the incoming data, which may include determining at least some set-up information and/or set-up results for the new mapping configurations. In some embodiments, the mapping determination process 102 determines the new mapping configurations in parallel with processing the data with the beat detection and the beat acceptance criteria of the existing mapping configurations, where in parallel can be by serially switching between determining the new mapping configurations and processing the data with the beat detection and the beat acceptance criteria of the existing mapping configurations. In embodiments, the mapping determination process 102 continuously (or continually) processes the data or signals with beat detection and beat acceptance criteria of the existing mapping configurations such as by sequentially

comparing different beat detection and beat acceptance criteria to the incoming data. In embodiments, the mapping determination process **102** continuously (or continually) determines new mapping configurations for the incoming data, such as by analyzing predetermined time intervals of data. In embodiments, the mapping determination process **102** continuously (or continually) determines new mapping configurations for the incoming data by processing the data at one or more of a predetermined time interval, once every heart beat cycle, and once per second.

The mapping determination process **102** processes the data with beat detection and beat acceptance criteria to provide information about how well the signals match the existing mapping configurations, including existing mapping configurations associated with existing cardiac maps. In embodiments, the mapping determination process **102** processes the data with beat detection and beat acceptance criteria for the current mapping configuration associated with a current existing maps into which the data are currently being added, and with beat detection and beat acceptance criteria for one or more other existing mapping configurations. In embodiments, the mapping determination process **102** processes the data with beat detection and beat acceptance criteria for all existing cardiac mapping configurations.

In some embodiments, the mapping determination process **102** displays the degree of matching between the incoming data and the existing mapping configurations via a user interface, such as the user interface **36**. The mapping determination process **102** may display the degree of matching for determining whether the cardiac rhythms of the incoming data have been previously mapped and to determine which of the existing mapping configurations more closely matches the incoming data. The mapping determination process **102** may also, or alternatively, display, on the user interface, information such as set-up information for a new mapping configuration for the cardiac rhythm. With this information displayed on the user interface, the user may quickly and easily determine whether the incoming data should continue to be added to the current map, or added to another existing map or a new cardiac map. In embodiments, the mapping determination process **102** displays at least some of the above information on the user interface while using the current mapping configuration of the existing mapping configurations to add incoming data to the associated current map.

In some embodiments of the mapping determination process **102** and the generation of cardiac maps, one or more of the signals in the incoming data may be used as a reference for triggering and alignment **104** of the data stream **100** relative to the cardiac rhythm of the incoming data, another biological cycle, and/or an asynchronous system clock. The triggering and alignment **104** defines a time instance around which a window of data from the data stream **100** is sampled. In embodiments, a trigger event is detected from a physiological signal designated as a reference signal. The trigger event may be asynchronous to the patient and derived from a system clock. For example, when constructing an activation map it is common to use an ECG or EGM signal as a reference, and when constructing an anatomical shell, a system clock may provide the trigger events.

Also, when aggregating data from multiple cardiac beats to create an electro-anatomical map, it may be useful to trigger based on a stable reference in the data stream **100**. In that case, the reference provides alignment across beats to a desired phase in the cardiac cycle. In embodiments, a single

signal source is selected for triggering, such as ECG lead II, and waveform attributes such as minimum/maximum, absolute maximum, maximum/minimum slope, and/or first deviation from baseline may be used to detect a trigger. According to embodiments, using multiple signals to determine triggering can provide various advantages in comparison to triggering schemes based on a single signal.

The triggering and alignment **104** of the signals results in beat datasets at **104**, and a number of beat metrics **108** are computed for each of the beat datasets at **104**. The beat metrics **108** may be computed using information from a single signal spanning one or more beats, over multiple signals within the same beat, and/or from multiple signals spanning multiple beats. The beat metrics **108** provide multiple types of information on the quality of a beat dataset at **104** and the likelihood that the beat data in the beat dataset is acceptable for inclusion in a map dataset **110**. After the beat metrics **108** are computed, a beat acceptance process **106** aggregates the criteria and decides whether a beat dataset can be added to a particular map dataset **110**. In embodiments, a number of map datasets **110** may be created, where each map dataset **110** corresponds to a different existing cardiac map.

As indicated previously, in embodiments, the mapping determination process **102** is configured to indicate a degree of matching between the incoming data and one or more of the existing mapping configurations, which include beat detection and beat acceptance criteria that are used to analyze the incoming data. Also, the mapping determination process **102** may provide a new mapping configuration for the incoming data. A user, e.g., user **24**, and/or the system, e.g., system **20**, can determine, based at least in part on the degree of matching, whether to 1) continue using a current mapping configuration to continue adding data to the associated current map; 2) switch to using another one of the existing mapping configurations and add data to the current map, another existing map or a new map; or 3) switch to using a new mapping configuration and add data to the current map, another existing map or a new map. In embodiments, for example, the mapping determination process **102** indicates the degree of matching between the incoming data and at least one of the existing cardiac mapping configurations by displaying the percentage of beat datasets at **104** that match each of the existing mapping configurations over a predetermined period of time. In some embodiments, for example, the mapping determination process **102** indicates the degree of matching between the incoming data and at least one of the existing cardiac mapping configurations by displaying the percentage of beat datasets at **104** that can be added into each of the different map datasets **110** over a predetermined period of time. In some embodiments, metrics other than the percentage of beat datasets at **104** that match each of the existing mapping configurations over a predetermined period of time or the percentage of beat datasets at **104** that can be added into each of the different map datasets **110** over a predetermined period of time can be used to indicate the degree of matching. In some embodiments, metrics that use a subset of the beat acceptance criteria can be used to indicate the degree of matching.

The automated electro-anatomical mapping process of FIG. **2** continues with a surface map generation process **120** that is employed to generate surface map data from the map datasets **110** and surface geometry data **118**. In embodiments, the surface geometry data **118** may be generated concurrently, or at least during the same data acquisition process, using identical or different triggering and beat acceptance metrics employing a surface geometry construc-

tion process 112. The surface geometry construction process 112 may construct surface geometry using data such as electrode locations and catheter shape contained in the data stream 100. Also, previously collected surface geometry 116 may be used as an input to the surface map data. Such surface geometry 116 may be collected in the same procedure using a different map dataset or using a different modality such as CT, MRI, ultrasound, and/or rotational angiography, which is registered to the catheter locating system.

A system, such as system 20, may select the source of the surface geometry data at 114 and provide surface geometry data 118 to the surface map generation process 120. The generation process 120 generates surface map data 122 that may provide information on cardiac electrical excitation, cardiac motion, tissue proximity information, tissue impedance information, force information, and/or any other collected and/or derived information. Once obtained, the surface map data 122 may be further processed to annotate desired features from the underlying data, a process defined herein as surface map annotation 124. Desired annotations may include instantaneous potential, activation time, voltage amplitude, dominant frequency and/or other properties of the signal. Once computed, the annotations may be displayed superimposed on chamber geometry. If the number of annotations is lower than the number of elements that make up the display of surface geometry, surface map interpolation 126 may be employed. Displayed maps 128 may be computed and displayed separately, combined, and/or overlaid on top of each other.

FIG. 3 is a diagram illustrating a process 148 for determining which mapping configuration more closely matches the incoming cardiac rhythm signals, according to embodiments of the disclosure. In some embodiments, the process 148 is part of the mapping determination process 102 that is part of the electro-anatomical mapping process of FIG. 2.

The process 148 receives the data stream 100 and processes data, such as signals and information, in the data stream 100 to provide information for determining which mapping configuration of the existing mapping configurations more closely matches the incoming data stream 100 and information for a new mapping configuration. The process 148 provides parallel processing paths for the data in the data stream 100.

At 150, the process 148 processes the data with multiple beat detection and beat acceptance criteria for the existing mapping configurations, which can include a current mapping configuration and one or more other existing mapping configurations. For example, in system 20, the processing unit 28 may execute, from memory such as the internal memory 30 and/or the storage device 32, code that processes the signals with the beat detection and beat acceptance criteria for the current mapping configuration that is used to add data to the current existing cardiac map and for one or more other existing mapping configurations that may or may not have been used to add data to an existing cardiac map. This processing provides information about how well the incoming data matches the current mapping configurations and the one or more other existing mapping configurations. In embodiments, the process 148 processes the data with beat detection and beat acceptance criteria for all existing mapping configurations. In some embodiments, the process 148 continuously (or continually) processes the data with the beat detection and beat acceptance criteria of existing mapping configurations, such as by sequentially comparing different beat detection and beat acceptance criteria to the incoming data.

At 152, the process 148 automatically determines new mapping configurations for at least a portion of the incoming data, which includes determining at least some set-up information and/or set-up results for the new mapping configurations. For example, in system 20, the processing unit 28 may execute, from memory such as the internal memory 30 and/or the storage device 32, the automated set-up routine that processes signals from one or more electrodes to determine new mapping configurations and provide at least some set-up information and/or set-up results for the new mapping configurations to the user 24.

In the process 148, the automated set-up routine can be configured to operate in a number of different ways. In an example, the automated set-up routine can be configured to use automatically selected parameters, such as predetermined default parameters to, at least, begin determining the new mapping configuration. In another example, the automated set-up routine can be configured to use multiple parameters and/or iteratively changing the parameters to determine the best matching mapping configuration for the incoming data. Also, in embodiments, after the automated set-up routine has determined a suggested new mapping configuration, the process 148 provides signals or other data to the user, which enables the user to validate or modify the suggested new mapping configuration. Embodiments of the system display data that indicates a percentage of the datasets of the incoming data that would be accepted using the new mapping configuration.

In embodiments, in the process 148, the automated set-up routine runs continually and, in a given time interval, provides many new mapping configurations. Each new mapping configuration is slightly or significantly different than previously determined new mapping configurations. In some embodiments, the automated set-up routine combines a number of these previously determined new mapping configurations to come up with a new mapping configuration that can be checked against the incoming data. In some embodiments, the automated set-up routine averages a number of these previously determined new mapping configurations to come up with a new mapping configuration that can be checked against the incoming data. In some embodiments, the automated set-up routine analyzes the sequence of previously determined new mapping configuration to determine a new mapping configuration.

As illustrated in FIG. 3, the process 148 determines the new mapping configurations in parallel with processing the data with the beat detection and the beat acceptance criteria of the existing mapping configurations. In some embodiments, the process 148 continuously (or continually) determines new mapping configurations for the incoming data, such as by analyzing predetermined time intervals of data. In some embodiments, the process 148 continuously (or continually) determines new mapping configurations for the incoming data by processing the data at one or more of a predetermined time interval, once every heartbeat, and once per second.

At 154, the process 148 displays the degree of matching between the incoming data and the existing mapping configurations via a user interface, such as the user interface 36. The process 148 displays the degree of matching to facilitate determining whether the type of cardiac rhythm in the incoming data has been previously mapped and to facilitate determining which of the existing mapping configurations more closely matches the incoming data. In embodiments, the process 148 also displays information about the new cardiac mapping configuration, including set-up information for the new cardiac mapping configuration for the cardiac

rhythm. For example, in system 20, the user interface 36 may receive signals from the processing unit 28 and display the information about whether a current cardiac rhythm more closely matches the current mapping configuration or a different existing mapping configuration. Also, the user interface 36 may display information about the new mapping configuration determined by the automated set-up routine. In some embodiments, the process 148 indicates the degree of matching between the incoming data and at least one of the existing cardiac maps, by displaying the percentage of beat datasets that more closely matches each of the existing mapping configurations over a predetermined period of time. In some embodiments, the process 148 indicates the degree of matching between the incoming data and at least one of the existing cardiac maps, by displaying the percentage of beat datasets that can be mapped into each of the different map datasets 110 over a predetermined period of time. In some embodiments, metrics other than the percentage of beat datasets that more closely matches each of the existing mapping configurations over a predetermined period of time or the percentage of beat datasets that can be mapped into each of the different map datasets 110 over a predetermined period of time can be used to indicate the degree of matching. In some embodiments, metrics that use a subset of the beat acceptance criteria can be used to indicate the degree of matching. In embodiments, the process 148 displays at least some of the above information on the user interface while adding incoming data to a current map.

In embodiments, at 154, the process 148 determines which mapping configurations, including new and existing mapping configurations, are effectively identical or sufficiently similar to be considered interchangeable. The process 148 then analyzes the mapping configurations and determines which mapping configurations to show to the user. In some embodiments, the process 148 prioritizes the mapping configurations for display to the user, where prioritizing can depend on factors such as which mapping configurations are the best match to the incoming data, which are the most recently used, and/or which are the most different from one another.

At 156, a user, such as user 24, determines which mapping configuration more closely matches the incoming data. The user and/or the system determines whether to 1) continue using a current mapping configuration to continue adding data to the associated current map, 2) switch to using another one of the existing mapping configurations and add data to the current map, another existing map or a new map, or 3) switch to using a new mapping configuration and add data to the current map, another existing map or a new map. The user analyzes the displayed information and can select a different mapping configuration and a different cardiac map, such as by using a mouse or a keyboard or a touchscreen. Also, in some embodiments, the system 20, using a set of heuristic rules, automatically determines which mapping configuration to use and, if needed, switches to adding the incoming data into a different map.

FIG. 4 is a diagram illustrating a user interface display 200 that displays the degree of matching between the incoming data and three existing cardiac mapping configurations, according to embodiments of the disclosure. The display 200 displays results for the current mapping configuration and two other existing mapping configurations. In embodiments, the display 200 can be configured to display results for any number of existing mapping configurations such as, for example, one existing mapping configuration, two existing mapping configurations, three existing mapping

configurations, four existing mapping configurations, five existing mapping configurations, and/or the like. As shown in FIG. 4, embodiments of the display 200 include a current mapping configuration result display 202, an auto-map (automated set-up routine) display 204, a first existing mapping configuration result display 206, and a second existing mapping configuration result display 208. In some embodiments, the first and second existing mapping configuration result displays 206 and 208 display information for the two existing cardiac mapping configurations, other than the current mapping configuration, that have (or would have if they were the current map) the highest beat dataset acceptance rates, such as acceptance of the most beat datasets in a predetermined time period. In some embodiments, the display 200 displays at least the current mapping configuration result display 202 and the first existing mapping configuration result display 206. In some embodiments, the predetermined time period is a value such as, for example, 10 seconds.

The current mapping configuration result display 202 provides an indication of the beat dataset acceptance rate of the current mapping configuration. The first existing mapping configuration result display 206 provides an indication of what the beat dataset acceptance rate would be for the first existing mapping configuration, and the second existing map result display 208 provides an indication of what the beat dataset acceptance rate would be for the second existing mapping configuration.

In some embodiments, the current mapping configuration result display 202, the first existing mapping configuration result display 206, and the second existing mapping configuration result display 208, display colors to indicate the beat dataset acceptance rates. For example, the displays can be color coded to display green (G), yellow (Y), or red (R), where green indicates an acceptable acceptance rate, yellow a lower acceptance rate than green and a higher acceptance rate than red, and red an unacceptable acceptance rate. In some embodiments, for example, a green acceptance rate is greater than or equal to 60%, a red acceptance rate is less than or equal to 40%, and a yellow acceptance rate is between 40 and 60%. In some embodiments, other ranges for assigning acceptance categories may be used, other indicators for indicating ranges of beat acceptance rates may be used, and/or the like. For example, instead of, or in addition to, colors, embodiments may utilize shapes (e.g., a number of horizontal bars such as those commonly used to indicate network signal strength), sounds, symbols, and/or combinations of these.

In some embodiments, one or more of the current mapping configuration result display 202, the first existing mapping configuration result display 206, and the second existing mapping configuration result display 208, display percentages that indicate the acceptance rate for the corresponding cardiac mapping configuration. In other embodiments, a different number of colors, other suitable colors, and/or other acceptance rate percentages for the different colors can be used for displaying the degree of matching between the incoming data and the existing cardiac maps, including the current map.

In some embodiments, the auto-map (automated set-up routine) display 204 provides one or more visual indications such as, for example, colors to indicate whether a new cardiac mapping configuration is ready or satisfactory for use. For example, the display may be color coded to display green, yellow, or red, where green indicates a new cardiac mapping configuration has been configured and is ready for use, yellow indicates that the new cardiac mapping configu-

ration may not be ready for use, and red indicates the new cardiac mapping configuration is not ready for use. In some embodiments, a green display indicates that greater than or equal to 60% of the beat datasets would be accepted by the new cardiac mapping configuration, a yellow indicates that between 40 and 60% of the beat datasets would be accepted by the new cardiac mapping configuration, and a red indicates that less than or equal to 40% of the beat datasets would be accepted by the new cardiac mapping configuration. In some embodiments, the auto-map display **204** displays percentages that indicate what the acceptance rate would be for the new cardiac mapping configuration. In other embodiments, a different number of colors, other suitable colors, other acceptance rate percentages and/or ranges for the different colors, different indicators such as, for example, shapes, sounds, symbols, and/or the like may be used.

In one example, assuming that the predetermined time period for determining acceptance rates is 10 seconds and that one beat dataset is provided per second, then 10 beat datasets are provided during a 10 second time period. Also, assuming that the cardiac rhythm has been steady for greater than 10 seconds and that all beat datasets during the most recent 10 second interval have been added to the current map, then the current mapping configuration result display **202** might be green and/or display 100%, the auto-map display **204** might be green and/or display 100%, and the first and second existing mapping configuration result displays **206** and **208** might be red and/or display 0%. In addition, the percentages given for color changes in the preceding paragraphs are used in this example.

To begin, according to this example, the cardiac rhythm changes, and the first new beat dataset is not added to the current map. Instead, the first new beat dataset would be added to the map associated with the first existing mapping configuration. Thus, only 9 out of the last 10 beat datasets have been added to the current map and the current mapping configuration result display **202** will remain green and/or display 90%, the first existing mapping configuration result display **206** will remain red and/or display 10%, the second existing mapping configuration result display **208** will remain red and/or display 0%, and the auto-map display **204** will remain green and/or display 90%.

Assuming that the cardiac rhythm remains as previously changed, the new beat datasets are not added to the current map but would be mapped into the map associated with the first existing mapping configuration and not the map associated with the second existing mapping configuration. Thus, after a second new beat dataset, the current mapping configuration result display **202** will remain green and/or display 80%, the first existing mapping configuration result display **206** will remain red and/or display 20%, the second existing mapping configuration result display **208** will remain red and/or display 0%, and the auto-map display **204** will remain green and/or display 80%. At this point, the user would likely continue mapping into the current map using the current mapping configuration.

After third and fourth new beat datasets, the current mapping configuration result display **202** will remain green and/or display 60%, the first existing mapping configuration result display **206** will remain red and/or display 40%, the second existing mapping configuration result display **208** will remain red and/or display 0%, and the auto-map display **204** will remain green and/or display 60%. At this point, the user would likely continue adding data to the current map using the current mapping configuration, but may notice the change in acceptance percentages.

After a fifth new beat dataset, the current mapping configuration result display **202** will turn yellow and/or display 50%, the first existing mapping configuration result display **206** will also turn yellow and/or display 50%, the second existing mapping configuration result display **208** will remain red and/or display 0%, and the auto-map display **204** will turn yellow and/or display 50%. At this point, the user may start to look for a different cardiac mapping configuration and the user will likely notice that the first existing mapping configuration result display **206** has turned yellow.

After a sixth new beat dataset, the current mapping configuration result display **202** will turn red and/or display 40%, the first existing mapping configuration result display **206** will turn green and/or display 60%, the second existing mapping configuration result display **208** will remain red and/or display 0%, and the auto-map display **204** will turn red and/or display 40%. At this point, the user will see that the first existing mapping configuration is likely the next cardiac mapping configuration to be selected. Also, at this point, the automated set-up routine may determine a new cardiac mapping configuration based on five or six new beat datasets.

After the seventh or more new beat datasets, the current mapping configuration result display **202** will remain red and/or display 30% or less, the first existing mapping configuration result display **206** will remain green and/or display 70% or more, and the second existing mapping configuration result display **208** will remain red and/or display 0%. If the automated set-up routine determines a new cardiac mapping configuration based on the five or six new beat datasets, the auto-map display **204** will turn green and/or display 70% or more. At this point, the user will likely switch to the first existing mapping configuration, which is then used as the new current mapping configuration, and the process continues.

In another example, assuming that the predetermined time period for determining acceptance rates is 10 seconds and that one beat dataset is provided per second, then 10 beat datasets are provided during a 10 second time period. Also, assuming that the cardiac rhythm has been steady for greater than 10 seconds and that all beat datasets during the most recent 10 second interval have been added to the current map, then the current mapping configuration result display **202** will be green and/or display 100%, the auto-map display **204** will be green and/or display 100%, and the first and second existing mapping configuration result displays **206** and **208** will be red and/or display 0%. In addition, the percentages given for the color changes in the preceding paragraphs are used for the color changes in this example.

To begin, the cardiac rhythm changes, and the first new beat dataset is not added to the current map or to either of the maps associated with the first and second existing mapping configurations. Instead, the first new beat dataset is part of a completely new cardiac rhythm. Thus, only 9 out of the last 10 beat datasets have been added to the current map and the current mapping configuration result display **202** will remain green and/or display 90%, the first existing mapping configuration result display **206** will remain red and/or display 0%, the second existing mapping configuration result display **208** will remain red and/or display 0%, and the auto-map display **204** will remain green and/or display 90%.

Assuming that the cardiac rhythm remains as previously changed, the new beat datasets will not be added into the current map or to either of the maps associated with the first and second existing mapping configurations. Thus, after second, third, and fourth new beat datasets, the current

mapping configuration result display **202** will remain green and/or display 60%, the first existing mapping configuration result display **206** will remain red and/or display 0%, the second existing mapping configuration result display **208** will remain red and/or display 0%, and the auto-map display **204** will remain green and/or display 60%. At this point, the user would likely continue adding data to the current map.

After a fifth new beat dataset, the current mapping configuration result display **202** will turn yellow and/or display 50%, the first existing mapping configuration result display **206** will remain red and/or display 0%, the second existing mapping configuration result display **208** will remain red and/or display 0%, and the auto-map display **204** will turn yellow and/or display 50%. At this point, the user can start looking for a different cardiac mapping configuration and will notice that the auto-map display **204** has turned yellow.

After a sixth new beat dataset, the current mapping configuration result display **202** will turn red and/or display 40%, the first existing mapping configuration result display **206** will remain red and/or display 0%, the second existing mapping configuration result display **208** will remain red and/or display 0%, and the auto-map display **204** will turn red and/or display 40%. At this point, the user will see that the auto-map display **204** has turned red and the automated set-up routine may determine a new cardiac mapping configuration based on five or six new beat datasets.

After the seventh or more new beat datasets, the current mapping configuration result display **202** will remain red and/or display 30% or less, the first existing mapping configuration result display **206** will remain red and/or display 0%, and the second existing mapping configuration result display **208** will remain red and/or display 0%. If the automated set-up routine determines a new cardiac mapping configuration based on five or six new beat datasets, the auto-map display **204** will turn green and/or display 70% or more. At this point, the user will likely switch to adding the data into a map associated with the new cardiac mapping configuration determined by the automated set-up routine, which then becomes the new current mapping configuration, and the process continues.

Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present disclosure. For example, while the embodiments described above refer to particular features, the scope of this disclosure also includes embodiments having different combinations of features and embodiments that do not include all of the described features. Accordingly, the scope of the present disclosure is intended to embrace all such alternatives, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof.

We claim:

1. A system for providing information about a patient's heart, comprising:
 - one or more electrodes that receive signals from electrical activity of the heart over one or more heart beat cycles; and
 - an electronic processor coupled to the one or more electrodes to:
 - receive the signals from the one or more electrodes;
 - process the signals to provide new or existing mapping configurations to map beats of multiple, different types of cardiac rhythms in the signals to new or existing cardiac maps of the multiple, different types of cardiac rhythms;
 - execute an automated set-up routine that processes the signals to automatically provide one or more set-up result for the new mapping configurations; and

process the signals with beat detection and beat acceptance criteria for the new or existing mapping configurations to provide information about matching the signals to one or more of the new or existing mapping configurations to map the beats of the multiple, different types of cardiac rhythms to the new or existing cardiac maps.

2. The system of claim 1, wherein the electronic processor executes the automated set-up routine and processes the signals with the beat detection and beat acceptance criteria for the existing mapping configurations in parallel.

3. The system of claim 1, wherein the electronic processor executes the automated set-up routine at one or more of a predetermined time interval, once every heart beat cycle, and once per second.

4. The system of claim 1, wherein the automated set-up routine provides the new mapping configurations in response to changes in the signals and the new mapping configurations are updated and displayed while matching the signals to one or more of the new or existing mapping configurations.

5. The system of claim 1, comprising:

a user interface, wherein the degree of matching between the signals and at least two of the new or existing mapping configurations is displayed on the user interface.

6. The system of claim 1, comprising:

a user interface, wherein information for making a determination about which of the new or existing mapping configurations most closely matches the signals is displayed on the user interface.

7. The system of claim 1, comprising:

a user interface for switching from mapping the signals using one of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

8. The system of claim 1, wherein the electronic processor determines which of the new mapping configurations and the existing mapping configurations are redundant.

9. The system of claim 1, wherein the electronic processor automatically switches from mapping the signals using one of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

10. A system for providing information about a patient's heart, comprising:

one or more electrodes that receive signals from electrical activity of the heart over one or more heart beat cycles;

an electronic processor coupled to the one or more electrodes to:

receive the signals from the one or more electrodes;

process the signals to provide new or existing mapping configurations to map beats of multiple, different types of cardiac rhythms in the signals to new or existing cardiac maps of the multiple, different types of cardiac rhythms;

execute an automated set-up routine that processes the signals to automatically provide one or more set up result for the new mapping configurations; and

process the signals with beat detection and beat acceptance criteria for existing mapping configurations to provide information about matching the signals to the existing mapping configurations to map the beats of the multiple, different types of cardiac rhythms to the new or existing cardiac maps, wherein the electronic processor executes the automated set-up rou-

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tine and processes the signals with the beat detection and beat acceptance criteria for the existing mapping configurations in parallel; and

a user interface, wherein information for making a determination about which of the existing mapping configurations more closely matches the signals is displayed on the user interface.

11. The system of claim 10, wherein the automated set-up routine provides the new mapping configurations in response to changes in the signals and the new mapping configurations are updated and displayed on the user interface.

12. The system of claim 10, wherein the degree of matching between the signals and a current mapping configuration of the existing mapping configurations is displayed on the user interface while mapping the signals to a current map associated with the current mapping configuration and the degree of matching between the signals and at least one other mapping configuration of the existing mapping configurations is displayed on the user interface while mapping the signals to the current map.

13. The system of claim 10, wherein a user can switch from mapping the signals using a current mapping configuration of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations via the user interface.

14. The system of claim 10, wherein the electronic processor is configured to automatically switch from mapping the signals using a current mapping configuration of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

15. A method for providing information about a patient's heart, comprising:

receiving signals from electrical activity of the heart over one or more heart beat cycles at one or more electrodes; receiving the signals at an electronic processor that is coupled to the one or more electrodes;

processing the signals, by the electronic processor, to provide new or existing mapping configurations to map

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beats of multiple, different types of cardiac rhythms in the signals to new or existing cardiac maps of the multiple, different types of cardiac rhythms;

executing, by the electronic processor, an automated set-up routine that processes the signals to automatically provide one or more set up result for the new mapping configurations; and

processing the signals, by the electronic processor, with beat detection and beat acceptance criteria for existing mapping configurations to provide information about matching the signals to one or more of the existing mapping configurations to map the beats of the multiple, different types of cardiac rhythms to the new or existing cardiac maps.

16. The method of claim 15, wherein executing the automated set-up routine and processing the signals with the beat detection and beat acceptance criteria for the existing maps is performed in parallel.

17. The method of claim 15, comprising:

displaying information about the degree of matching between the signals and a current mapping configuration of the existing mapping configurations; and

displaying information about the degree of matching between the signals and at least one other mapping configuration of the existing mapping configurations.

18. The method of claim 15, comprising:

updating the new mapping configurations in response to changes in the signals; and displaying updated new mapping configurations.

19. The method of claim 15, comprising:

switching from mapping the signals using one of the existing mapping configurations to mapping the signals using another one of the existing mapping configurations or one of the new mapping configurations.

20. The method of claim 15, comprising:

determining which of the new mapping configurations and the existing mapping configurations more closely matches the signals; and

determining which of the new mapping configurations and the existing mapping configurations are redundant.

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摘要(译)

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