CLAIMS

1. A method for automatically determining the 3D position and orientation of a radio-opaque medical object in a living body using single-plane fluoroscopy comprising:

- capturing a stream of digitized 2D images from a single-plane fluoroscope;
- detecting the image of the medical object in a subset of the digital 2D images;
- applying pixel-level geometric calculations to measure the medical-object image;
- applying conical projection and radial elongation corrections to the image measurements; and
- calculating the 3D position and orientation of the medical object from the corrected 2D image measurements.

2. The method of claim 1 wherein the medical object is a cardiac catheter.

3. The method of claim 2 wherein the catheter is a cardiac ablation catheter.

4. The method of claim 1 wherein the medical object is selected from the group consisting of pacemaker leads, defibrillator leads, mapping catheters, and stents.

5. The method of claim 1 further comprising initialization steps before the detecting step, the initialization steps including a two-view fluoroscopic measurement of the medical-object image and setting medical-object image size-limit criteria.

6. The method of claim 5 wherein, with respect to each 2D image in the subset, the detecting step includes:

- applying a threshold filter to the 2D image;
- forming clusters of image pixels;
- evaluating each of the clusters against the medical-object image size-limit criteria; and
- selecting the cluster that contains the image of the medical object.

7. The method of claim 6 wherein the automatic detecting step further includes modifying the threshold of the threshold filter based on cluster evaluation.

8. The method of claim 6 wherein the measuring step includes computing center, longitudinal midline and bounding-box data of the selected cluster.

9. The method of claim 8 wherein the measuring step further includes applying the center, midline and bounding-box data to the unfiltered 2D image, expanding the bounding box area around the medical-object image, and up-sampling such 2D image.

10. The method of claim 9 wherein the measuring step further includes forming a plurality of cross-sectional image profiles perpendicular to the midline and identifying medical-object image edges substantially parallel to the midline.

11. The method of claim 10 wherein the up-sampling is performed only along each cross-sectional image profile perpendicular to the midline.

12. The method of claim 10 wherein identifying medical-object image edges includes selecting edge points on each profile at a fixed percentage of profile intensity range.

13. The method of claim 12 wherein the profile intensity range of a profile is the difference between the maximum and minimum intensity values for such profile.

14. The method of claim 12 wherein the fixed percentage of profile intensity range is about 50% to 55%.

15. The method of claim 14 wherein the fixed percentage of profile intensity range is about 55%.

16. The method of claim 10 wherein the measuring step further includes evaluating the measured cluster against the medical-object image size-limit criteria.

17. The method of claim 16 wherein the measuring step further includes adopting the current threshold of the threshold filter as the threshold value to be used for subsequent images.

18. The method of claim 16 wherein the measuring step further includes computing the least-squares-fit representations of the edges substantially parallel to the midline.

19. The method of claim 18 wherein the measuring step further includes forming a plurality of cross-sectional image profiles parallel to the midline, identifying medical-object image edges substantially perpendicular to the midline, and computing least-squares-fit representations of the edges substantially perpendicular to the midline.

20. The method of claim 19 wherein the up-sampling is performed along each cross-sectional image profiles parallel to the midline.

21. The method of claim 19 wherein the measuring step further includes recomputing the medical-object image center based on the least-squares-fit edges and determining medical-object image width, length and keystoning in the 2D image.

22. The method of claim 6 wherein the step of applying measurement corrections includes correcting medical-object images measurements for out-of-plane angle.

23. The method of claim 10 wherein the measuring step further includes recomputing the midline based on the identified medical-object image edges, reforming the cross-sectional image profiles perpendicular to the recomputed midline, and re-identifying medical-object image edges.

24. The method of claim 23 wherein the up-sampling is performed only along each reformed cross-sectional image profile perpendicular to the recomputed midline.

25. The method of claim 23 wherein the measuring step further includes computing the least-squares-fit representations of the edges substantially parallel to the midline.

26. The method of claim 25 wherein the measuring step further includes forming a plurality of cross-sectional image profiles parallel to the midline, identifying medical-object edges substantially perpendicular to the midline, and computing least-squares-fit representations of the edges substantially perpendicular to the midline.

27. The method of claim 26 wherein the measuring step further includes recomputing the medical-object image center based on the least-squares-fit edges and determining medical-object image width, length and keystoning in the 2D image.

28. The method of claim 6 wherein the step of applying measurement corrections includes correcting medical-object image measurements for out-of-plane angle.

29. The method of claim 1 wherein the subset of 2D images is selected by respiration gating from a respiration signal from the living body.

30. The method of claim 1 further including the step of creating a 3D map of an anatomical structure within the living body.

31. The method of claim 30 further including the step of displaying the 3D map on a display device.

32. The method of claim 30 further including the step of displaying the 3D position and orientation on a display device.

33. The method of claim 30 wherein the anatomical structure is a cardiac structure.

34. The method of claim 33 further including the step of displaying the 3D map on a display device.

35. The method of claim 33 further including the step of displaying the 3D position and orientation on a display device.

36. The method of claim 1 wherein the subset of 2D images is selected by R-wave gating of an ECG signal from the living body.

37. The method of claim 36 wherein the R-wave gating includes:

- acquiring the ECG signal from the living body;
- digitizing the ECG signal into a digital ECG signal;
- filtering the digital ECG signal with a bandpass filter and applying an absolute value filter thereto to create a filtered ECG signal;
- for each sequential value of the filtered ECG signal, comparing the filtered ECG signal to an ECG tracking threshold (TT);
- if the filtered ECG signal is no greater than TT, incrementing a counter, but if greater than TT, setting the counter to zero; and
- comparing the counter to a predetermined refractory count RC and, if the count is equal to RC, outputting an R-wave trigger.

38. The method of claim 37 wherein TT is determined by applying the following computation:

$$TT = TT_p + c_2(ST - TT_p),$$

where TT_p is the previous value of TT, c_2 is a constant, and ST is a fraction (c_1) of the maximum value of the filtered ECG signal during a previous predetermined time period (t_m).

39. The method of claim 38 wherein, if no R-wave trigger has occurred for a predetermined dropout period (t_D), TT is set to ST.

40. The method of claim 39 wherein c_1 is about 0.5, c_2 is about 0.25, t_m is about 2 seconds, RC corresponds to a time period of about 90 milliseconds, and t_D is about 5 seconds.

41. The method of claim 39 wherein t_D is within the range of about 2 to 10 seconds.

42. The method of claim 39 wherein c_1 is within the range of about 0.4 to 0.7.

43. The method of claim 39 wherein c_2 is within the range of about 0.15 to 0.8.

44. The method of claim 39 wherein t_m is at least about 1.5 seconds.

45. The method of claim 39 wherein the refractory count RC corresponds to a period within the range of about 30 to 250 milliseconds.

46. The method of claim 36 wherein the subset of 2D images is further selected by respiration gating from a respiration signal from the living body.

47. The method of claim 36 wherein the ECG signal comprises a plurality of ECG channel signals and the R-wave gating is generated by a composite R-wave gate driven by a plurality of channel R-wave gates each operating on a distinct ECG channel signal.

48. The method of claim 47 wherein each of the plurality of channel R-wave gates has an output signal which is an input to a trigger-window filter, and a trigger output of the composite R-wave gate is triggered by an output signal from any one of the channel R-wave gates, all output signals for the other channel R-wave gates not triggering the composite R-wave gate for a predetermined time period after the composite R-wave gate is triggered.

49. The method of claim 48 wherein the channel R-wave gate output signal triggering the composite R-wave gate is the first-received channel R-wave output signal after the predetermined time period has ended.

50. The method of claim 47 wherein each of the plurality of channel R-wave gates has an output signal, and each output signal is an input to an OR-gate the output of which is the output of the composite R-wave gate.

51. The method of claim 50 wherein each channel R-wave gate output signal includes a single pulse of predetermined duration for each R-wave detected by its corresponding channel R-wave gate, and the composite R-wave gate output is triggered by the leading edge of the OR-gate output.

52. The method of claim 47 wherein each channel R-wave gate performs the steps of:

- acquiring its corresponding ECG channel signal from the living body;
- digitizing its ECG channel signal into a corresponding digital ECG channel signal;
- filtering its corresponding digital ECG channel signal with a bandpass filter and applying an absolute value filter thereto to create a corresponding filtered ECG channel signal;
- for each sequential value of its corresponding filtered ECG channel signal, comparing the filtered signal to an ECG tracking threshold (TT),
  - applying the computation $TT = TT_p + c_2 (ST - TT_p)$ where TT_p is the previous value of TT, c_2 is a constant, and ST is a fraction (c_1) of the maximum value of its corresponding filtered ECG channel signal during a previous predetermined time period (t_m);
  - if the corresponding filtered ECG signal is no greater than TT, incrementing a corresponding counter, but if greater than TT, setting its corresponding counter to zero; and
  - if no channel R-wave trigger has occurred for a predetermined dropout period (t_D), then setting TT to ST; and
- comparing its corresponding counter value to a predetermined refractory count RC and, if its corresponding counter value is equal to RC, outputting a channel R-wave trigger.

53. The method of claim 52 wherein each of the plurality of channel R-wave gates has the same settings for c_1, c_2, t_m, t_D, and RC.

54. The method of claim 52 wherein each of the plurality of channel R-wave gates has an output signal, and each output signal is an input to an OR-gate the output of which is the output of the composite R-wave gate.

55. The method of claim 54 wherein each channel R-wave gate output signal includes a single pulse of predetermined duration for each R-wave detected by its corresponding channel R-wave gate, and the composite R-wave gate output is triggered by the leading edge of the OR-gate output.

56. The method of claim 36 wherein the R-wave gating is by an R-wave gating process having a threshold to which the ECG signal is compared and the threshold is independent of levels of the ECG signal at which previous R-wave triggers occurred.

57. The method of claim 1 wherein the image subset is processed at a rate to generate 3D medical-object position and orientation for use during interventional medical procedures contemporaneous with such processing.

58. The method of claim 57 wherein the medical object is a cardiac catheter.

59. The method of claim 58 wherein the catheter is a cardiac ablation catheter.

60. The method of claim 57 wherein the medical object is selected from the group consisting of pacemaker leads, defibrillator leads, mapping catheters, and stents.

61. The method of claim 57 further comprising initialization steps before the detecting step, the initialization steps including a two-view fluoroscopic measurement of the medical-object image and setting medical-object image size-limit criteria.

62. The method of claim 61 wherein, with respect to each 2D image in the subset, the detecting step includes:

- applying a threshold filter to the 2D image;
- forming clusters of image pixels;
- evaluating each of the clusters against the medical-object image size-limit criteria; and
- selecting the cluster that contains the image of the medical object.

63. The method of claim 62 wherein the automatic detecting step further includes modifying the threshold of the threshold filter based on cluster evaluation.

64. The method of claim 62 wherein the measuring step includes computing center, longitudinal midline and bounding-box data of the selected cluster.

65. The method of claim 64 wherein the measuring step further includes applying the center, midline and bounding-box data to the unfiltered 2D image, expanding the bounding box area around the medical-object image, and up-sampling such 2D image.

66. The method of claim 65 wherein the measuring step further includes forming a plurality of cross-sectional image profiles perpendicular to the midline and identifying medical-object image edges substantially parallel to the midline.

67. The method of claim 66 wherein the up-sampling is performed only along each cross-sectional image profile perpendicular to the midline.

68. The method of claim 66 wherein identifying medical-object image edges includes selecting edge points on each profile at a fixed percentage of profile intensity range.

69. The method of claim 68 wherein the profile intensity range of a profile is the difference between the maximum and minimum intensity values for such profile.

70. The method of claim 68 wherein the fixed percentage of profile intensity range is about 50% to 55%.

71. The method of claim 70 wherein the fixed percentage of profile intensity range is about 55%.

72. The method of claim 66 wherein the measuring step further includes evaluating the measured cluster against the medical-object image size-limit criteria.

73. The method of claim 72 wherein the measuring step further includes adopting the current threshold of the threshold filter as the threshold value to be used for subsequent images.

74. The method of claim 72 wherein the measuring step further includes computing the least-squares-fit representations of the edges substantially parallel to the midline.

75. The method of claim 74 wherein the measuring step further includes forming a plurality of cross-sectional image profiles parallel to the midline, identifying medical-object image edges substantially perpendicular to the midline, and computing least-squares-fit representations of the edges substantially perpendicular to the midline.

76. The method of claim 75 wherein the up-sampling is performed along each cross-sectional image profiles parallel to the midline.

77. The method of claim 75 wherein the measuring step further includes recomputing the medical-object image center based on the least-squares-fit edges and determining medical-object image width, length and keystoning in the 2D image.

78. The method of claim 62 wherein the step of applying measurement corrections includes correcting medical-object images measurements for out-of-plane angle.

79. The method of claim 66 wherein the measuring step further includes recomputing the midline based on the identified medical-object image edges, reforming the cross-sectional image profiles perpendicular to the recomputed midline, and re-identifying medical-object image edges.

80. The method of claim 79 wherein the up-sampling is performed only along each reformed cross-sectional image profile perpendicular to the recomputed midline.

81. The method of claim 79 wherein the measuring step further includes computing the least-squares-fit representations of the edges substantially parallel to the midline.

82. The method of claim 81 wherein the measuring step further includes forming a plurality of cross-sectional image profiles parallel to the midline, identifying medical-object edges substantially perpendicular to the midline, and computing least-squares-fit representations of the edges substantially perpendicular to the midline.

83. The method of claim 82 wherein the measuring step further includes recomputing the medical-object image center based on the least-squares-fit edges and determining medical-object image width, length and keystoning in the 2D image.

84. The method of claim 62 wherein the step of applying measurement corrections includes correcting medical-object image measurements for out-of-plane angle.

85. The method of claim 57 wherein the subset of 2D images is selected by respiration gating from a respiration signal from the living body.

86. The method of claim 57 further including the step of creating a 3D map of an anatomical structure within the living body.

87. The method of claim 86 further including the step of displaying the 3D map on a display device.

88. The method of claim 86 further including the step of displaying the 3D position and orientation on a display device.

89. The method of claim 86 wherein the anatomical structure is a cardiac structure.

90. The method of claim 89 further including the step of displaying the 3D map on a display device.

91. The method of claim 89 further including the step of displaying the 3D position and orientation on a display device.

92. The method of claim 57 wherein the subset of 2D images is selected by R-wave gating of an ECG signal from the living body.

93. The method of claim 92 wherein the R-wave gating includes:

- acquiring the ECG signal from the living body;
- digitizing the ECG signal into a digital ECG signal;
- filtering the digital ECG signal with a bandpass filter and applying an absolute value filter thereto to create a filtered ECG signal;
- for each sequential value of the filtered ECG signal, comparing the filtered ECG signal to an ECG tracking threshold (TT);
- if the filtered ECG signal is no greater than TT, incrementing a counter, but if greater than TT, setting the counter to zero; and
- comparing the counter to a predetermined refractory count RC and, if the count is equal to RC, outputting an R-wave trigger.

94. The method of claim 93 wherein TT is determined by applying the following computation:

$$TT = TT_p + c_2(ST - TT_p),$$

where TT_p is the previous value of TT, c_2 is a constant, and ST is a fraction (c_1) of the maximum value of the filtered ECG signal during a previous predetermined time period (t_m).

95. The method of claim 94 wherein, if no R-wave trigger has occurred for a predetermined dropout period (t_D), TT is set to ST.

96. The method of claim 95 wherein c_1 is about 0.5, c_2 is about 0.25, t_m is about 2 seconds, RC corresponds to a time period of about 90 milliseconds, and t_D is about 5 seconds.

97. The method of claim 95 wherein t_D is within the range of about 2 to 10 seconds.

98. The method of claim 95 wherein c_1 is within the range of about 0.4 to 0.7.

99. The method of claim 95 wherein c_2 is within the range of about 0.15 to 0.8.

100. The method of claim 95 wherein t_m is at least about 1.5 seconds.

101. The method of claim 95 wherein the refractory count RC corresponds to a period within the range of about 30 to 250 milliseconds.

102. The method of claim 92 wherein the subset of 2D images is further selected by respiration gating from a respiration signal from the living body.

103. The method of claim 92 wherein the ECG signal comprises a plurality of ECG channel signals and the R-wave gating is generated by a composite R-wave gate driven by a plurality of channel R-wave gates each operating on a distinct ECG channel signal.

104. The method of claim 103 wherein each of the plurality of channel R-wave gates has an output signal which is an input to a trigger-window filter, and a trigger output of the composite R-wave gate is triggered by an output signal from any one of the channel R-wave gates, all output signals for the other channel R-wave gates not triggering the composite R-wave gate for a predetermined time period after the composite R-wave gate is triggered.

105. The method of claim 104 wherein the channel R-wave gate output signal triggering the composite R-wave gate is the first-received channel R-wave output signal after the predetermined time period has ended.

106. The method of claim 103 wherein each of the plurality of channel R-wave gates has an output signal, and each output signal is an input to an OR-gate the output of which is the output of the composite R-wave gate.

107. The method of claim 106 wherein each channel R-wave gate output signal includes a single pulse of predetermined duration for each R-wave detected by its corresponding channel R-wave gate, and the composite R-wave gate output is triggered by the leading edge of the OR-gate output.

108. The method of claim 103 wherein each channel R-wave gate performs the steps of:

- acquiring its corresponding ECG channel signal from the living body;
- digitizing its ECG channel signal into a corresponding digital ECG channel signal;
- filtering its corresponding digital ECG channel signal with a bandpass filter and applying an absolute value filter thereto to create a corresponding filtered ECG channel signal;
- for each sequential value of its corresponding filtered ECG channel signal, comparing the filtered signal to an ECG tracking threshold (TT),
  - applying the computation $TT = TT_p + c_2(ST - TT_p)$ where TT_p is the previous value of TT, c_2 is a constant, and ST is a fraction (c_1) of the maximum value of its corresponding filtered ECG channel signal during a previous predetermined time period (t_m);
  - if the corresponding filtered ECG signal is no greater than TT, incrementing a corresponding counter but if greater than TT, setting its corresponding counter to zero; and
  - if no channel R-wave trigger has occurred for a predetermined dropout period (t_D), then setting TT to ST; and
- comparing its corresponding counter value to a predetermined refractory count RC and, if its corresponding counter value is equal to RC, outputting a channel R-wave trigger.

109. The method of claim 108 wherein each of the plurality of channel R-wave gates has the same settings for c_1, c_2, t_m, t_D, and RC.

110. The method of claim 108 wherein each of the plurality of channel R-wave gates has an output signal, and each output signal is an input to an OR-gate the output of which is the output of the composite R-wave gate.

111. The method of claim 110 wherein each channel R-wave gate output signal includes a single pulse of predetermined duration for each R-wave detected by its corresponding channel R-wave gate, and the composite R-wave gate output is triggered by the leading edge of the OR-gate output.

112. The method of claim 92 wherein the R-wave gating is by an R-wave gating process having a threshold to which the ECG signal is compared and the threshold is independent of levels of the ECG signal at which previous R-wave triggers occurred.

113. The method of claim 57 further including the steps of capturing, detecting, applying geometric calculations, applying corrections, and calculating 3D position and orientation multiple times with the medical object in a single position and averaging the calculated 3D position and orientation data, thereby to enhance accuracy of the determination.

114. The method of claim 1 further including the steps of capturing, detecting, applying geometric calculations, applying corrections, and calculating 3D position and orientation multiple times with the medical object in a single position and averaging the calculated 3D position and orientation data, thereby to enhance accuracy of the determination.

Claims

1. A method for automatically determining the 3D position and orientation of a radio-opaque medical object in a living body using single-plane fluoroscopy comprising:
capturing (37) a stream of digitized 2D images from a single-plane fluoroscope (10);
detecting (24) the image of the medical object in a subset of the digital 2D images;
applying (29) pixel-level geometric calculations to measure the medical-object image;
applying (31) conical projection and radial elongation corrections to the image measurements; and
calculating (33) the 3D position and orientation of the medical object from the corrected 2D image measurements.

2. The method of claim 1 further comprising initialization steps (21) before the detecting step (24), the initialization steps (21) determining (39) the effective dimensions of the medical-object image and setting (41A,41B) medical-object image size-limit criteria.

3. The method of claim 2 wherein, with respect to each 2D image in the subset, the detecting step (24) includes:
applying (133) a threshold filter to the 2D image;
forming (135) clusters of image pixels;
evaluating (137) each of the clusters against the medical-object image size-limit criteria; and
selecting the cluster that contains the image of the medical object.

4. The method of claims 3 wherein the step (31) of applying measurement corrections includes correcting (185) medical-object image measurements for out-of-plane angle.

5. The method of claim 3 wherein the measuring step includes computing center (141), longitudinal midline (143) and bounding-box data of the selected cluster (145).

6. The method of claim 5 wherein the measuring step further includes applying the center, midline and bounding-box data to the unfiltered 2D image, expanding (147) the bounding box area around the medical-object image, and up-sampling (151) such 2D image.

7. The method of claim 6 wherein the measuring step further includes forming (151) a plurality of cross-sectional image profiles perpendicular to the midline and identifying (153) medical-object image edges substantially parallel to the midline.

8. The method of claim 7 wherein the up-sampling (151) is performed only along each cross-sectional image profile perpendicular to the midline.

9. The method of claim 8 wherein identifying medical-object image edges includes selecting (177) edge points on each profile at a fixed percentage (221) of profile intensity range.

10. The method of claim 9 wherein the profile intensity range of a profile is the difference between the maximum and minimum intensity values (169) for such profile.

11. The method of claim 7 wherein the measuring step further includes evaluating (137) the measured cluster against the medical-object image size-limit criteria and computing (178) the least-squares-fit representations of the edges substantially parallel to the midline.

12. The method of claim 11 wherein the measuring step further includes forming (179) a plurality of cross-sectional image profiles parallel to the midline, identifying (153) medical-object image edges substantially perpendicular to the midline, and computing (178) least-squares-fit representations of the edges substantially perpendicular to the midline.

13. The method of claim 12 wherein the up-sampling (179) is performed along each cross-sectional image profiles parallel to the midline.

14. The method of claim 7 wherein the measuring step further includes recomputing (155) the midline based on the identified medical-object image edges, reforming (157) the cross-sectional image profiles perpendicular to the recomputed midline, and re-identifying (153) medical-object image edges.

15. The method of claim 14 wherein:
the up-sampling (157) is performed only along each reformed cross-sectional image profile perpendicular to the recomputed midline; and
the measuring step further includes:
computing (178) the least-squares-fit representations of the edges substantially parallel to the midline;
forming (179) a plurality of cross-sectional image profiles parallel to the midline;
identifying (153) medical-object edges substantially perpendicular to the midline; and
computing (178) least-squares-fit representations of the edges substantially perpendicular to the midline.

16. The method of claims 12 or 15 wherein the measuring step further includes recomputing the medical-object image center based on the least-squares-fit edges and determining medical-object image width, length and keystoning (185) in the 2D image.

17. The method of claim 1 wherein the subset of 2D images is selected by respiration gating from a respiration signal (47) from the living body.

18. The method of claim 1 further including:
creating a 3D map (36) of an anatomical structure within the living body;
displaying the 3D map on a display device (35); and
displaying the 3D position and orientation on the display device (35).

19. The method of claim 1 wherein the subset of 2D images is selected by R-wave gating (50) of an ECG signal from the living body.

20. The method of claim 1 further including the steps of capturing, detecting, applying geometric calculations, applying corrections, and calculating 3D position and orientation multiple times with the medical object in a single position and averaging the calculated 3D position and orientation data, thereby to enhance accuracy of the determination.