AUTOMATIC REGULATION OF THERAPY BASED ON RADIOMETRY AND TEMPERATURE

~~SYSTEMS AND METHODS FOR TEMPERATURE-CONTROLLED ABLATION USING RADIOMETRIC FEEDBACK IN AN INTERFACE MODULE-BASED SYSTEM~~

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Patent Application No. 13/418,136, filed March 12, 2012 and entitled "Systems and Methods for Temperature-Controlled Ablation Using Radiometric Feedback in an Interface Module-Based System," the entire contents of which are incorporated by reference herein.

FIELD OF THE INVENTION

[0002] This application generally relates to systems and methods for measuring and controlling temperature during tissue ablation.

BACKGROUND OF THE INVENTION

[0003] Tissue ablation may be used to treat a variety of clinical disorders. For example, tissue ablation may be used to treat cardiac arrhythmias by destroying aberrant pathways that would otherwise conduct abnormal electrical signals to the heart muscle. Several ablation techniques have been developed, including cryoablation, microwave ablation, radio frequency (RF) ablation, and high frequency ultrasound ablation. For cardiac applications, such techniques are typically performed by a clinician who introduces a catheter having an ablative tip to the endocardium via the venous vasculature, positions the ablative tip adjacent to what the clinician believes to be an appropriate region of the endocardium based on tactile feedback, mapping electrocardiogram (ECG) signals, anatomy, and/or fluoroscopic imaging, actuates flow of an irrigant to cool the surface of the selected region, and then actuates the ablative tip for a period of time and at a power believed sufficient to destroy tissue in the selected region.

[0004] Although commercially available ablative tips may include thermocouples for providing temperature feedback via a digital display, such thermocouples typically do not provide meaningful temperature feedback during irrigated ablation. For example, the thermocouple only measures surface temperature, whereas the heating or cooling of the tissue that results in tissue ablation may occur at some depth below the tissue surface. Moreover, for

WHAT IS CLAIMED:

1. An interface module for use with an ablation energy generator and an integrated catheter tip (ICT), the ICT including a radiometer, an ablative tip, and a thermocouple, the interface module comprising:

a processor;

a first input/output (I/O) port configured to receive a digital radiometer signal and a digital thermocouple signal from the ICT;

a second I/O port configured to receive ablative energy from the ablation energy generator;

a temperature display;

a patient relay in communication with the first I/O port, the second I/O port, and the processor;

a non-transitory computer-readable medium storing operation parameters for the radiometer and for the thermocouple, and further storing instructions for causing the processor to execute the steps of:

(a) calculating a temperature adjacent to the ICT based on the digital radiometer signal, the digital thermocouple signal, and the operation parameters;

(b) causing the temperature display to display the calculated temperature; and

(c) closing the patient relay such that the patient relay passes ablative energy received on the second I/O port to the first I/O port; and

a temperature control subsystem configured to regulate the power of the ablative energy based on the calculated temperature.

2. The interface module of claim 1, wherein the ablation energy generator comprises a power control, and wherein the temperature control subsystem comprises:

a processor;

a power control interface configured to be operatively coupled to the power control of the ablation energy generator; and

a memory storing a setpoint and instructions for causing the processor to execute the steps of:

(a) comparing the calculated temperature to the setpoint,

(b) if the calculated temperature is below the setpoint, increasing the ablation energy power with the power control interface; and

(c) if the calculated temperature is above the setpoint, reducing the ablation energy power with the power control interface.

3. The interface module of claim 2, wherein the power control of the ablation energy generator comprises a knob, and wherein the power control interface comprises a stepper motor configured to mechanically turn the knob.

4. The interface module of claim 2, wherein the power control interface is configured to allow a clinician to manually adjust the ablation energy power.

5. The interface module of claim 1, further comprising a load relay and a dummy load, and

wherein the computer-readable medium further stores a safety cutoff temperature and instructions for causing the processor to execute the steps of:

(d) comparing the calculated temperature to the safety cutoff temperature while the patient relay is closed; and

(e) if the calculated temperature exceeds the safety cutoff temperature, opening the patient relay and closing the load relay such that the load relay passes ablative energy received on the second I/O port to the dummy load.

6. The interface module of claim 1, wherein the instructions cause the processor to maintain the patient relay in a normally closed state and to open the patient relay upon detection of an unsafe condition.

7. The interface module of claim 1, wherein the computer-readable medium further stores instructions for causing the processor to execute the steps of:

(d) initially calculating a temperature adjacent to the ICT based on the digital thermocouple and the operation parameters but not the digital radiometer signal;

(e) causing the temperature display to display the initially calculated temperature; and

(f) if the temperature calculated in step (d) is in the range of 35°C to 39°C and if the second I/O port is receiving ablative energy from the ablation energy generator, then executing steps (a)-(c).

8. The interface module of claim 1, further comprising a third I/O port configured to receive a signal from an indifferent electrode and a fourth I/O port configured to provide the signal from the indifferent electrode to the ablation energy generator.

9. The interface module of claim 1, wherein the ablative energy is selected from the group consisting of RF energy, microwave energy, cryoablation energy, and high frequency ultrasound energy.

10. The interface module of claim 1, wherein the ablative energy is RF energy.

11. A method of using an interface module with an ablation energy generator and an integrated catheter tip (ICT), the ICT including a radiometer, an ablative tip, and a thermocouple, the method of using the interface module comprising the steps of:

(a) receiving at a first I/O port of the interface module a digital radiometer signal and a digital thermocouple signal from the ICT;

(b) receiving at a second I/O port of the interface module ablative energy from the ablation energy generator;

(c) calculating at the interface module a temperature adjacent to the ICT based on the digital radiometer signal, the digital thermocouple signal, and the operation parameters;

(d) displaying on a temperature display of the interface module the calculated temperature;

(e) passing ablative energy received on the second I/O port to the first I/O port by closing a patient relay of the ablation module; and

(f) automatically regulating the power of the ablative energy based on the calculated temperature.

12. The method of claim 11, wherein the ablation energy generator comprises a power control, the method further comprising the steps of:

(g) operatively coupling a power control interface to the power control of the ablation energy generator;

(h) storing a setpoint;

(i) comparing the calculated temperature to the setpoint;

(j) if the calculated temperature is below the setpoint, increasing the ablation energy power with the power control interface; and

(k) if the calculated temperature is above the setpoint, reducing the ablation energy power with the power control interface.

13. The method of claim 12, wherein the power control of the ablation energy generator comprises a knob, wherein the power control interface comprises a stepper motor, and wherein steps (j) and (k) comprise mechanically turning the knob with a stepper motor.

14. The method of claim 12, wherein the power control interface is configured to allow a clinician to manually adjust the ablation energy power.

15. The method of claim 11, further comprising the steps of:

(g) storing at the interface module a safety cutoff temperature;

(h) at the interface module, comparing the calculated temperature to the safety cutoff temperature while the patient relay is closed; and

(i) if the calculated temperature exceeds the safety cutoff temperature, opening the patient relay and closing a load relay of the ablation module such that the load relay passes ablative energy received on the second I/O port to a dummy load of the ablation module.

16. The method of claim 11, wherein the patient relay is maintained in a normally closed state and opened upon detection of an unsafe condition.

17. The method of claim 11, further comprising the steps of:

(g) initially calculating at the interface module a temperature adjacent to the ICT based on the digital thermocouple and the operation parameters but not the digital radiometer signal;

(h) displaying on the temperature display the initially calculated temperature; and

(i) if the temperature calculated in step (f) is in the range of 35°C to 39°C and if the second I/O port is receiving ablative energy from the ablation energy generator, then performing steps (c)-(e).

18. The method of claim 11, further comprising the steps of:

(f) receiving at a third I/O port of the ablation energy generator a signal from an indifferent electrode; and

(g) providing at a fourth I/O port the signal from the indifferent electrode to the ablation energy generator.

19. The method of claim 11, wherein the ablative energy is selected from the group consisting of RF energy, microwave energy, cryoablation energy, and high frequency ultrasound energy.

20. The method of claim 11, wherein the ablative energy is RF energy.

WHAT IS CLAIMED:

1. An ablation system for regulating delivery of ablative energy to targeted tissue of a subject, comprising:

an ablation energy source configured to generate ablative energy to be delivered to targeted tissue via an ablation member;

a processor;

wherein the processor is configured to calculate a temperature of the targeted tissue of the subject at a depth relative to a surface of the targeted tissue based on, at least in part, a signal generated by a radiometer and a signal generated by a temperature-measurement device; and

wherein the system is configured to automatically regulate operation of the ablation member to deliver the ablative energy based upon at least the calculated temperature.

2. A system according to Claim 1, wherein the temperature-measurement device comprises a thermocouple.

3. A system according to Claim 1 or 2, wherein the ablation member is positioned along a tip of a catheter, the tip being positioned along a distal end of the catheter.

4. A system according to Claim 3, wherein the temperature-measurement device is located along the tip of the catheter.

5. A system according to Claim 3 or 4, wherein the radiometer is located along the tip of the catheter.

6. A system according to any one of Claims 3 to 5,

wherein the catheter comprises a fluid passage, and wherein the tip of the catheter comprises at least one irrigation fluid port, the at least one irrigation fluid port being in fluid communication with the fluid passage of the catheter; and

wherein the fluid passage of the catheter is configured to be placed in fluid communication with an irrigation pump, the irrigation pump being configured to selectively deliver irrigation fluid through the fluid passage of the catheter and the at least one irrigation fluid port of the tip of the catheter.

7. A system according to any one of the preceding claims, wherein the ablation member comprises a radiofrequency electrode.

8. A system according to any one of Claims 1 to 6, wherein the ablation member comprises one of a microwave ablation member, a cryoablation member and an ultrasound ablation member.

9. A system according to any one of the preceding claims, further comprising a non-transitory computer-readable medium configured to store operation parameters for the radiometer and the temperature-measurement device.

10. A system according to any one of the preceding claims, wherein the system is operatively coupled to an electrophysiology monitoring system.

11. A system according to any one of the preceding claims, wherein the system additionally comprises at least one electrocardiogram electrode.

12. A system according to any one of the preceding claims, wherein the system is configured to automatically regulate the operation of the ablation member to maintain the calculated temperature of the targeted tissue within a target temperature setpoint or range.

13. An ablation system for regulating delivery of ablative energy to targeted tissue of a subject, comprising:

a catheter comprising a proximal end and a distal end;

a catheter tip located along the distal end of the catheter, the catheter tip comprising an ablation member and a temperature-measurement device;

a radiometer;

wherein the ablation member is configured to emit energy to targeted tissue of the subject; and

a processor configured to calculate a temperature of the targeted tissue of the subject at a depth relative to a surface of the targeted tissue based on, at least in part, a signal generated by the radiometer, a signal generated by the temperature-measurement device and operation parameters stored on a computer-readable medium;

wherein the system is configured to automatically regulate operation of the ablation member based upon at least the calculated temperature.

14. A system according to Claim 13, wherein the temperature-measurement device comprises a thermocouple.

15. A system according to Claim 13 or 14, wherein the system is configured to automatically regulate the operation of the ablation member to maintain the calculated temperature of the targeted tissue within a target temperature setpoint or range.

16. A system according to any one of Claims 13 to 15, further comprising an irrigation system comprising a pump in fluid communication with a fluid passage of the catheter, wherein the irrigation system is configured to selectively deliver an irrigation fluid through the fluid passage of the catheter and at least one irrigation fluid port of the catheter tip in fluid communication with the fluid passage of the catheter during use.

17. A system according to any one of Claims 13 to 16, wherein the ablation member comprises a radiofrequency electrode.

18. A system according to any one of Claims 13 to 16, wherein the ablation member comprises one of a microwave ablation member, a cryoablation member and an ultrasound ablation member.

19. A system according to any one of Claims 13 to 18, further comprising a temperature display for displaying the calculated temperature.

20. A system according to any one of Claims 13 to 19, wherein the integrated catheter tip additionally comprises at least one electrocardiogram electrode.

21. A system according to any one of Claims 13 to 20, wherein the system is operatively coupled to an electrophysiology monitoring system.

22. A system according to any one of Claims 13 to 21, further comprising a generator for providing power to the ablation member.

23. A system according to any one of Claims 13 to 22, wherein the catheter is steerable.

24. A system according to any one of Claims 13 to 23, wherein the radiometer is positioned along the catheter tip.

25. A method of determining a temperature of a tissue, comprising:

receiving a signal generated by a radiometer, an antenna of the radiometer being configured to receive energy emitted by a tissue of a subject;

receiving a signal generated by a temperature-measurement device configured to detect a temperature along a portion of a catheter;

determining a temperature of the tissue at a depth relative to a surface of said tissue based on, at least in part, the signal generated by the radiometer and the signal generated by the temperature-measurement device; and

automatically regulating operation of a radiofrequency electrode based, at least in part, on the determined temperature.

26. A method according to Claim 25, wherein the temperature-measurement device comprises a thermocouple.

27. A method according to Claim 25 or 26, further comprising delivering an irrigation fluid to a fluid passage of the catheter and through at least one irrigation fluid port of the catheter.

28. A method according to any one of Claims 25 to 27, further comprising monitoring electrical activity of the subject using at least one electrocardiogram electrode.

29. A method of determining a temperature of tissue, comprising:

receiving signals generated by a radiometer and a temperature-measurement device, said temperature-measurement device being configured to detect a temperature along said temperature-measurement device;

determining a temperature of the tissue at a depth relative to a surface of said tissue based on, at least in part, the signal generated by the radiometer and the signal generated by the temperature-measurement device; and

automatically regulating operation of an ablation member based, at least in part, on the determined temperature.

30. A method according to Claim 29, wherein the temperature-measurement device comprises a thermocouple.

31. A method according to Claim 29 or 30, wherein the ablation member comprises a radiofrequency electrode.

32. A method according to Claim 29 or 30, wherein the ablation member comprises one of a microwave ablation member, a cryoablation member and an ultrasound ablation member.

33. A method according to any one of Claims 29 to 32, wherein the radiometer and the temperature-measurement device are located along a tip of a catheter.

34. A method according to Claim 33, further comprising delivering an irrigation fluid to a fluid passage of a catheter and through at least one irrigation fluid port of the catheter, wherein the ablation member is positioned along the catheter.

35. A method according to any one of Claims 29 to 34, further comprising monitoring electrical activity of a subject using at least one electrocardiogram electrode.

36. A method according to any one of Claims 29 to 35, wherein automatically regulating operation of an ablation member comprises regulating a power of the ablation member.

37. A method according to any one of Claims 29 to 36, wherein automatically regulating the operation of an ablation member comprises regulating the operation of the ablation member to maintain the determined temperature of the tissue within a target temperature setpoint or range.

38. A method according to any one of Claims 29 to 37, further comprising displaying the determined temperature on a display.

39. An ablation system for regulating delivery of ablative energy to targeted tissue of a subject, comprising:

an ablation energy source configured to generate ablative energy to be delivered to targeted tissue via an ablation member; and

a processor;

wherein the processor is configured to calculate a temperature of the targeted tissue of the subject at a depth relative to a surface of the targeted tissue based on, at least in part, a signal generated by a radiometer and a signal generated by a temperature-measurement device; and

wherein the calculated temperature is used to regulate delivery of ablative energy to targeted tissue.

40. A system according to Claim 39, wherein the temperature-measurement device comprises a thermocouple.

41. An ablation system according to Claim 39 or 40, wherein the ablation member is positioned along a distal end of a catheter, said distal end of the catheter further comprising the temperature-measurement device

42. A system according to Claim 41, wherein the radiometer is located along the distal end of the catheter.

43. A system according to Claim 41 or 42, wherein the catheter comprises a fluid passage extending at least partially from a proximal end to the distal end of the catheter, the catheter comprising at least one irrigation fluid port, wherein the at least one irrigation fluid port is in fluid communication with the fluid passage of the catheter, and wherein the fluid passage of the catheter is configured to be placed in fluid communication with an irrigation pump, the irrigation pump being configured to selectively deliver irrigation fluid through the fluid passage of the catheter and through the at least one irrigation fluid port of the catheter.

44. A system according to any one of Claims 39 to 43, wherein the ablation member comprises a radiofrequency electrode.

45. A system according to any one of Claims 39 to 43, wherein the ablation member comprises one of a microwave ablation member, a cryoablation member and an ultrasound ablation member.

46. A system according to any one of Claims 39 to 45, further comprising a non-transitory computer-readable medium configured to store operation parameters for the radiometer and the temperature-measurement device.

47. A system according to any one of Claims 39 to 46, wherein the processor is configured to selectively activate and deactivate the ablation member.

48. A system according to any one of Claims 39 to 47, wherein the system is operatively coupled to an electrophysiology monitoring system, and wherein the system additionally comprises at least one electrocardiogram electrode.

49. A system according to any one of Claims 39 to 48, further comprising a temperature display for displaying the calculated temperature.

50. An ablation system for regulating delivery of ablative energy to targeted tissue of a subject, comprising:

an ablation energy source for activating an ablation member, the ablation member configured to deliver ablative energy to targeted tissue when activated; and

a radiometer;

wherein the system is configured to calculate a temperature of the targeted tissue of the subject at a depth relative to a surface of the targeted tissue based on, at least in part, a signal generated by the radiometer and a signal generated by a temperature-measurement device.

51. A system according to Claim 50, wherein the temperature-measurement device comprises a thermocouple.

52. An ablation system according to Claim 50 or 51, wherein the ablation member is positioned along a distal end of a catheter, said distal end of the catheter further comprising the temperature-measurement device.

53. A system according to Claim 52, wherein the radiometer is located along the distal end of the catheter.

54. A system according to Claim 52 or 53, wherein the catheter comprises a fluid passage extending at least partially from a proximal end to the distal end of the catheter, the catheter comprising at least one irrigation fluid port, wherein the at least one irrigation fluid port is in fluid communication with the fluid passage of the catheter, and wherein the fluid passage of the catheter is configured to be placed in fluid communication with an irrigation pump, the irrigation pump being configured to selectively deliver irrigation fluid through the fluid passage of the catheter and through the at least one irrigation fluid port of the catheter.

55. A system according to any one of Claims 50 to 54, wherein the ablation member comprises a radiofrequency electrode.

56. A system according to any one of Claims 50 to 54, wherein the ablation member comprises one of a microwave ablation member, a cryoablation member and an ultrasound ablation member.

57. A system according to any one of Claims 50 to 56, further comprising a non-transitory computer-readable medium configured to store operation parameters for the radiometer and the temperature-measurement device.

58. A system according to any one of Claims 50 to 57, wherein the system is operatively coupled to an electrophysiology monitoring system, and wherein the system additionally comprises at least one electrocardiogram electrode.

59. A system according to any one of Claims 50 to 58, further comprising a temperature display for displaying the calculated temperature.

60. A method of determining a temperature of a tissue of a subject, comprising:

receiving a signal generated by a radiometer, an antenna of the radiometer being configured to receive energy emitted by tissue;

receiving a signal generated by a temperature-measurement device configured to detect a temperature along a portion of a catheter; and

determining a temperature of the tissue at a depth relative to a surface of said tissue based on, at least in part, the signal generated by the radiometer and the signal generated by the temperature-measurement device.

61. A method according to Claim 60, wherein the temperature-measurement device comprises a thermocouple.

62. A method according to Claim 60 or 61, further comprising delivering an irrigation fluid to a fluid passage of the catheter and through at least one irrigation fluid port of the catheter.

63. A method according to any one of Claims 60 to 62, further comprising monitoring electrical activity of a subject using at least one electrocardiogram electrode.

64. A method according to any one of Claims 60 to 63, further comprising displaying the determined temperature of the tissue on a display.

65. A method according to any one of Claims 60 to 64, wherein determining the temperature is additionally based on, at least in part, operation parameters for the radiometer and the temperature-measurement device, wherein the operation parameters for the radiometer comprise a slope and an offset describing a temperature response of the radiometer, and wherein the operation parameters for the temperature-measurement device comprise a slope and an offset describing a temperature response of the temperature-measurement device.