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(54) **METHODS OF DETERMINING TISSUE CONTACT BASED ON RADIOMETRIC SIGNALS**

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(58) **Field of Classification Search**
None
See application file for complete search history.

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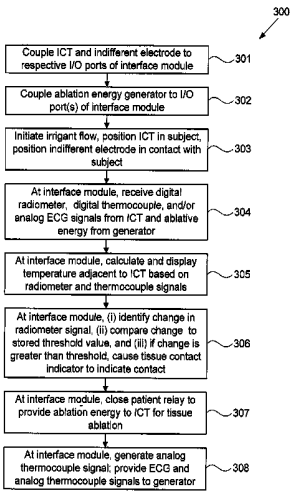
(57) **ABSTRACT**

Methods and systems are provided for detecting tissue contact prior to and/or during energy delivery to tissue. For example, the methods may include calculating temperature and detecting tissue contact based on signal(s) received from a radiometer. The radiometer may provide information about whether a treatment device is in contact with the tissue, and thus provide feedback to assist a clinician in properly contacting and treating the tissue.

20 Claims, 16 Drawing Sheets



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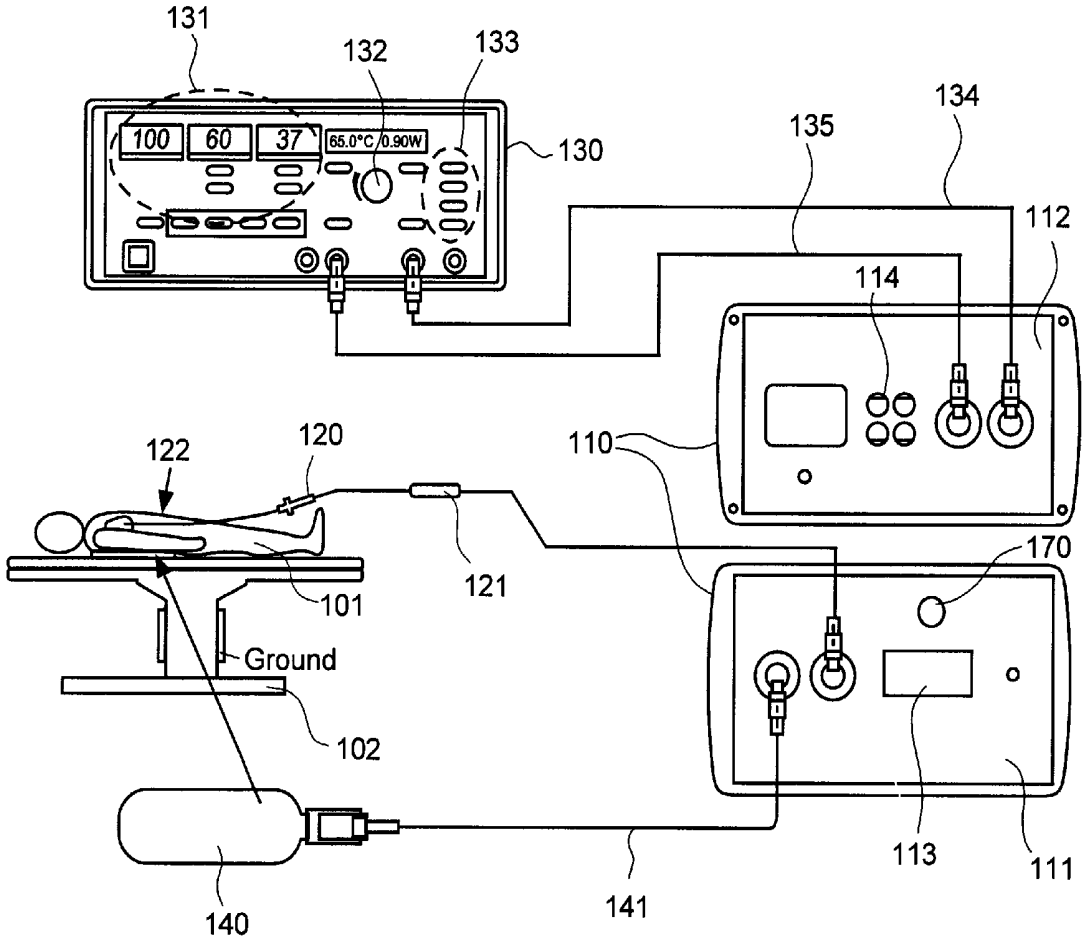
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60
37
65.0°C 0.90W
110
120
122
121
101
170
Ground
102
113
111
140
141

FIG. 1A

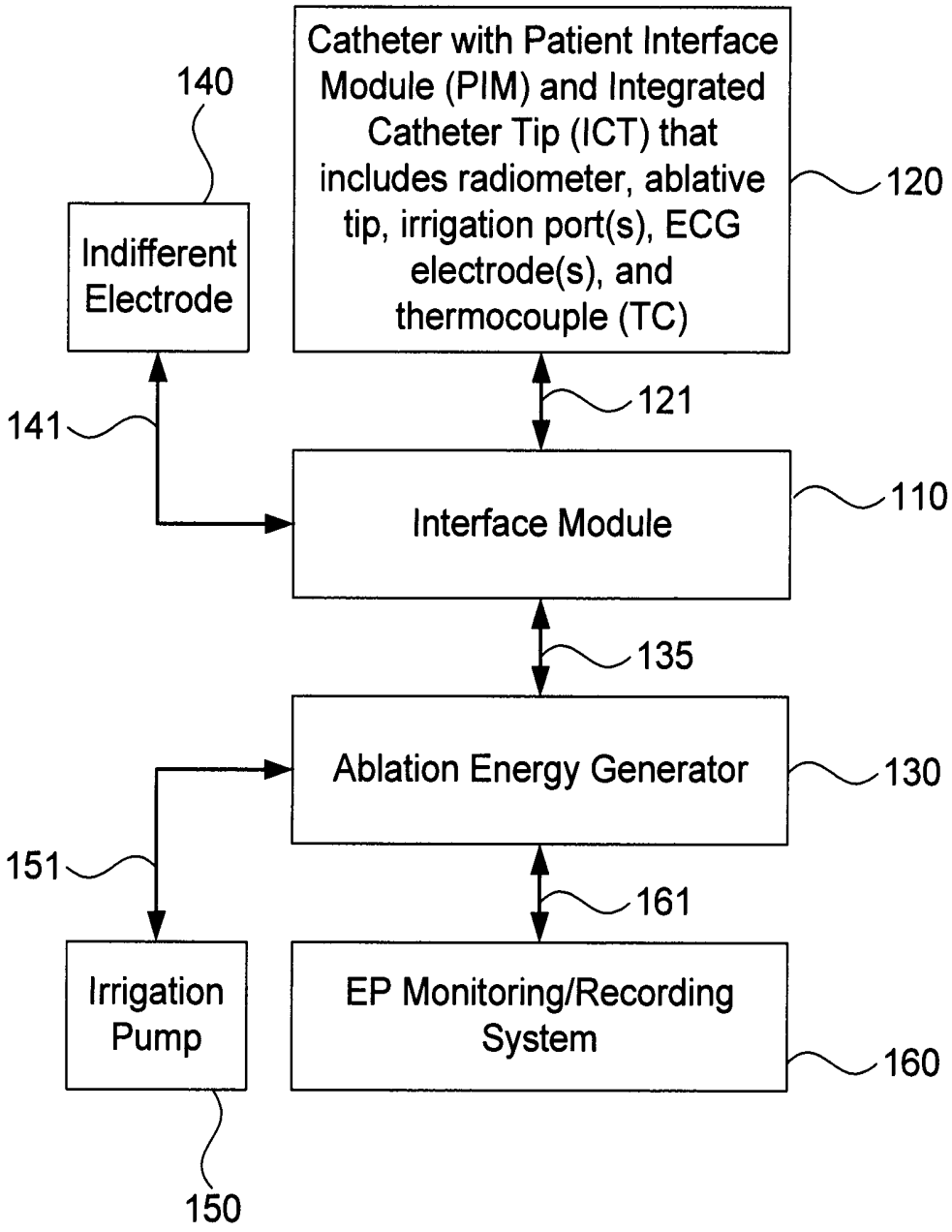
Catheter with Patient Interface Module (PIM) and Integrated Catheter Tip (ICT) that includes radiometer, ablative tip, irrigation port(s), ECG electrode(s), and thermocouple (TC)
120
140
Indifferent Electrode
121
141
Interface Module
110
135
Ablation Energy Generator
130
151
161
Irrigation Pump
EP Monitoring/Recording System
160
150

FIG. 1B

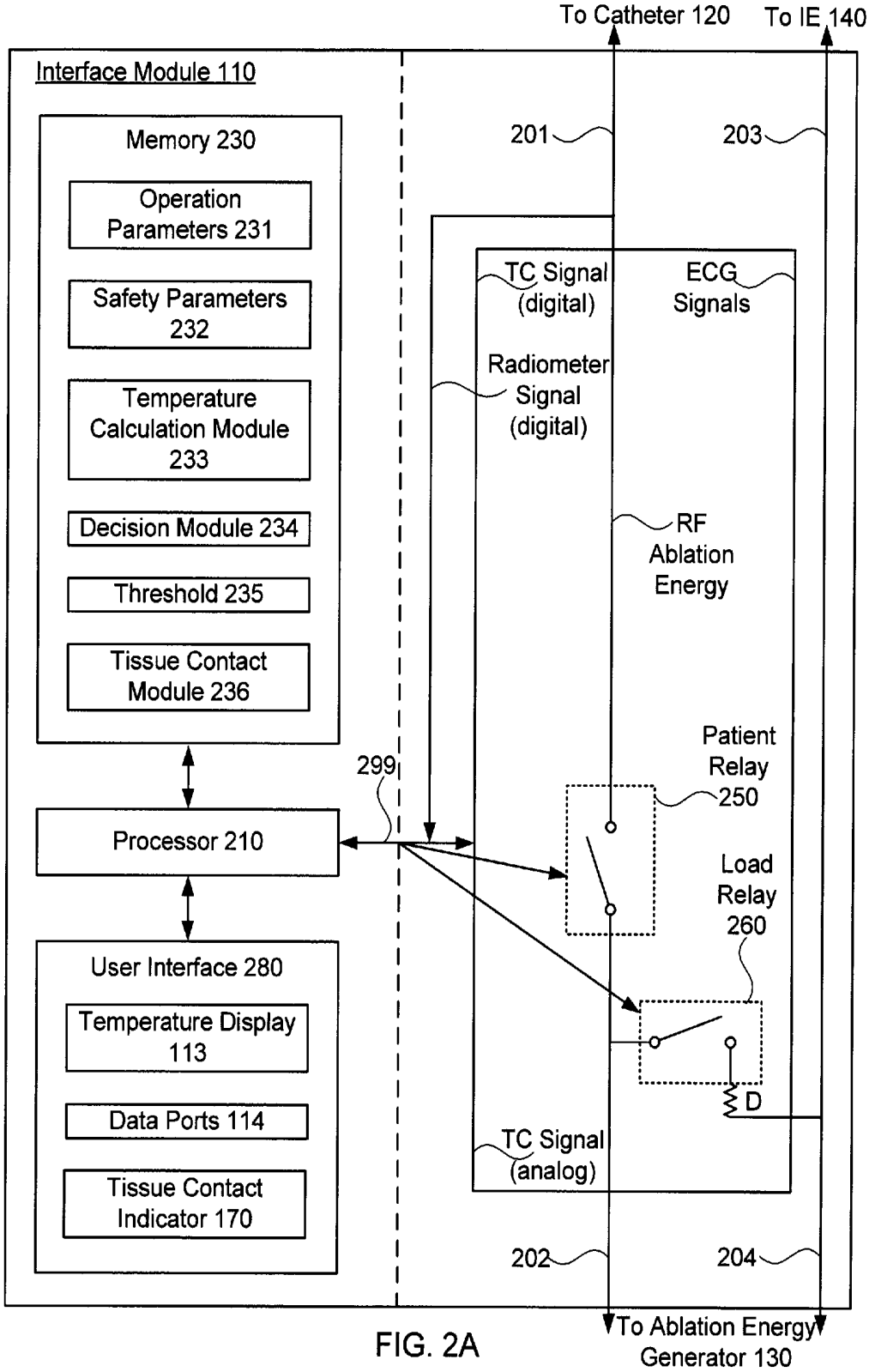
To Catheter 120
To IE 140
Interface Module 110
Memory 230
Operation Parameters 231
Safety Parameters 232
Temperature Calculation Module 233
Decision Module 234
Threshold 235
Tissue Contact Module 236
Processor 210
User Interface 280
Temperature Display 113
Data Ports 114
Tissue Contact Indicator 170
201
203
TC Signal (digital)
ECG Signals
Radiometer Signal (digital)
RF Ablation Energy
299
Patient Relay 250
Load Relay 260
D
TC Signal (analog)
202
204
To Ablation Energy Generator 130

FIG. 2A

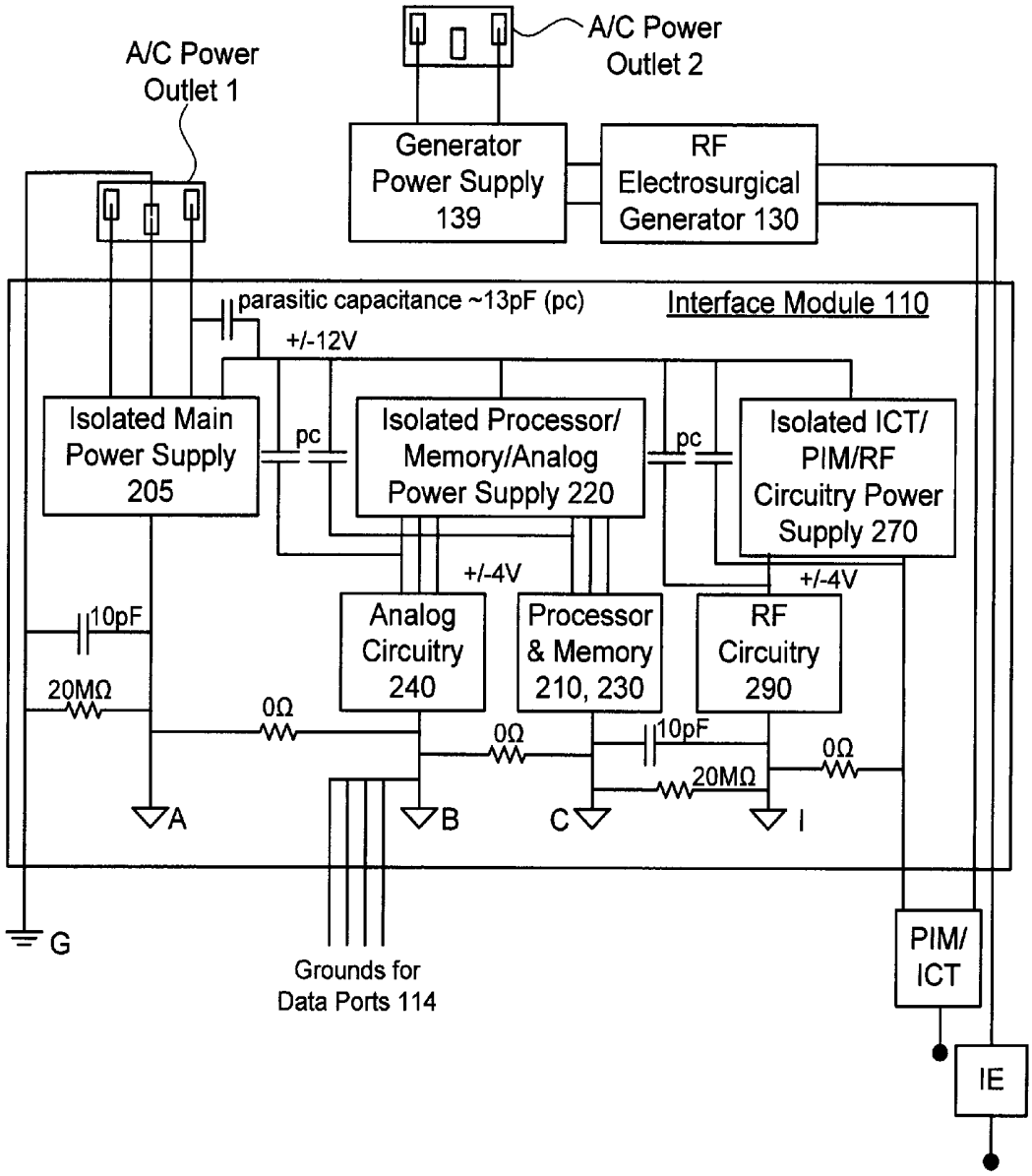
A/C Power Outlet 1
A/C Power Outlet 2
Generator Power Supply 139
RF Electrosurgical Generator 130
parasitic capacitance ~13pF (pc)
Interface Module 110
+/-12V
Isolated Main Power Supply 205
pc
Isolated Processor/ Memory/Analog Power Supply 220
pc
Isolated ICT/ PIM/RF Circuitry Power Supply 270
+/-4V
+/-4V
10pF
20MΩ
Analog Circuitry 240
Processor & Memory 210, 230
RF Circuitry 290
0Ω
0Ω
10pF
20MΩ
0Ω
A
B
C
I
G
Grounds for Data Ports 114
PIM/ ICT
IE

FIG. 2B

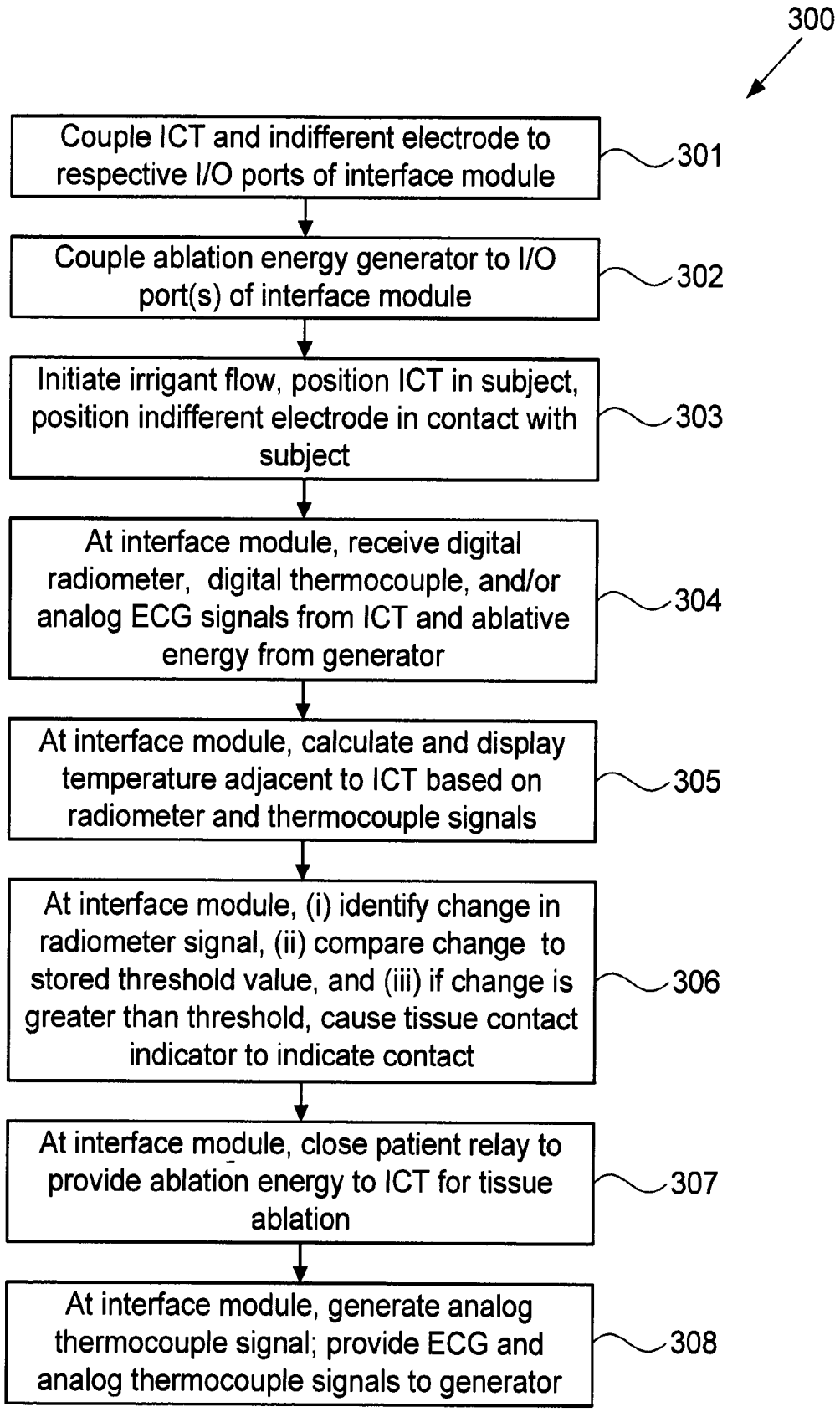
300
Couple ICT and indifferent electrode to respective I/O ports of interface module
301
Couple ablation energy generator to I/O port(s) of interface module
302
Initiate irrigant flow, position ICT in subject, position indifferent electrode in contact with subject
303
At interface module, receive digital radiometer, digital thermocouple, and/or analog ECG signals from ICT and ablative energy from generator
304
At interface module, calculate and display temperature adjacent to ICT based on radiometer and thermocouple signals
305
At interface module, (i) identify change in radiometer signal, (ii) compare change to stored threshold value, and (iii) if change is greater than threshold, cause tissue contact indicator to indicate contact
306
At interface module, close patient relay to provide ablation energy to ICT for tissue ablation
307
At interface module, generate analog thermocouple signal; provide ECG and analog thermocouple signals to generator
308

FIG. 3A

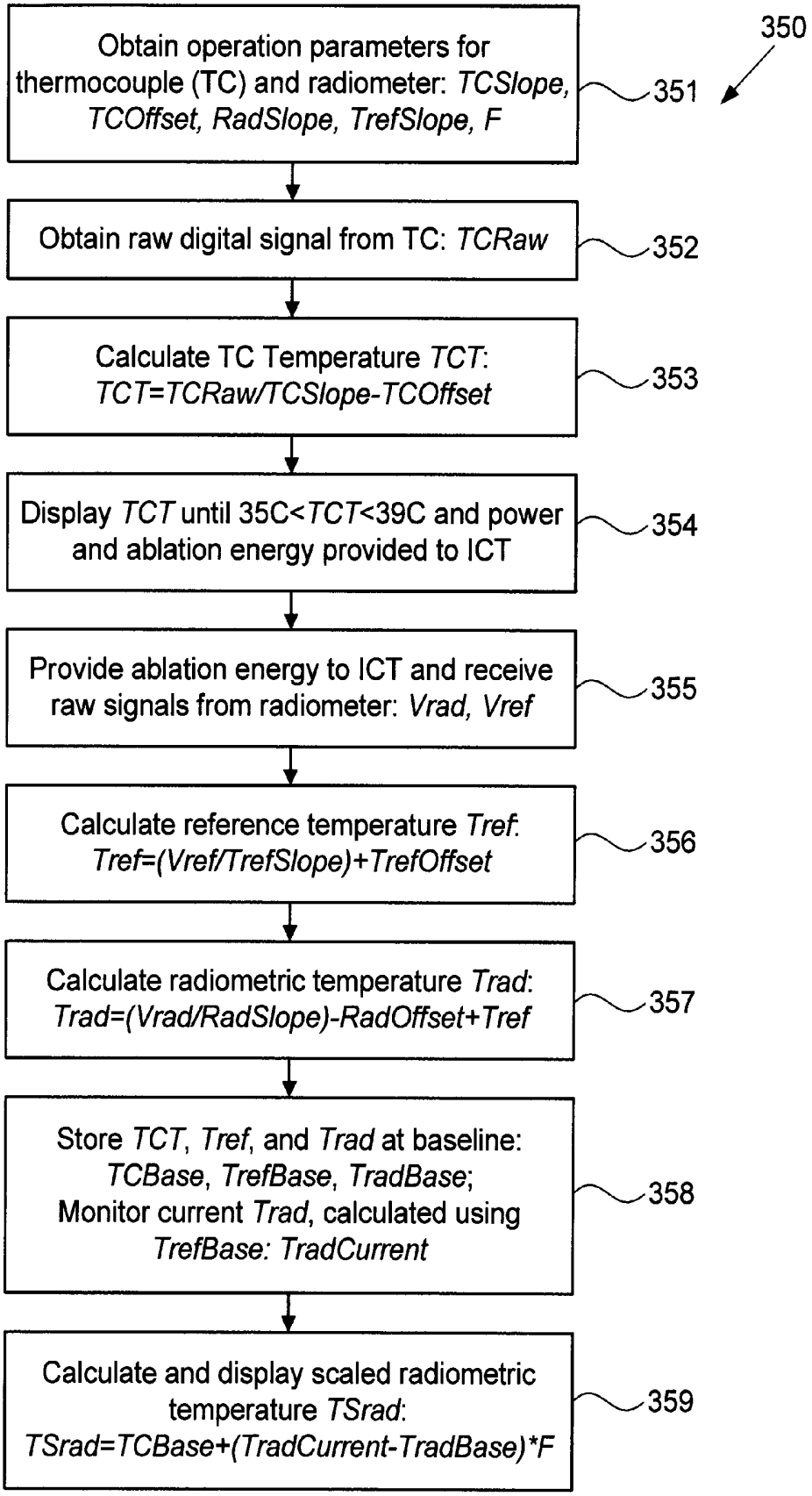
350
Obtain operation parameters for thermocouple (TC) and radiometer: TCSlope, TCOffset, RadSlope, TrefSlope, F
351
Obtain raw digital signal from TC: TCRaw
352
Calculate TC Temperature TCT: TCT=TCRaw/TCSlope-TCOffset
353
Display TCT until 35C<TCT<39C and power and ablation energy provided to ICT
354
Provide ablation energy to ICT and receive raw signals from radiometer: Vrad, Vref
355
Calculate reference temperature Tref: Tref=(Vref/TrefSlope)+TrefOffset
356
Calculate radiometric temperature Trad: Trad=(Vrad/RadSlope)-RadOffset+Tref
357
Store TCT, Tref, and Trad at baseline: TCBase, TrefBase, TradBase; Monitor current Trad, calculated using TrefBase: TradCurrent
358
Calculate and display scaled radiometric temperature TSrad: TSrad=TCBase+(TradCurrent-TradBase)*F
359

FIG. 3B

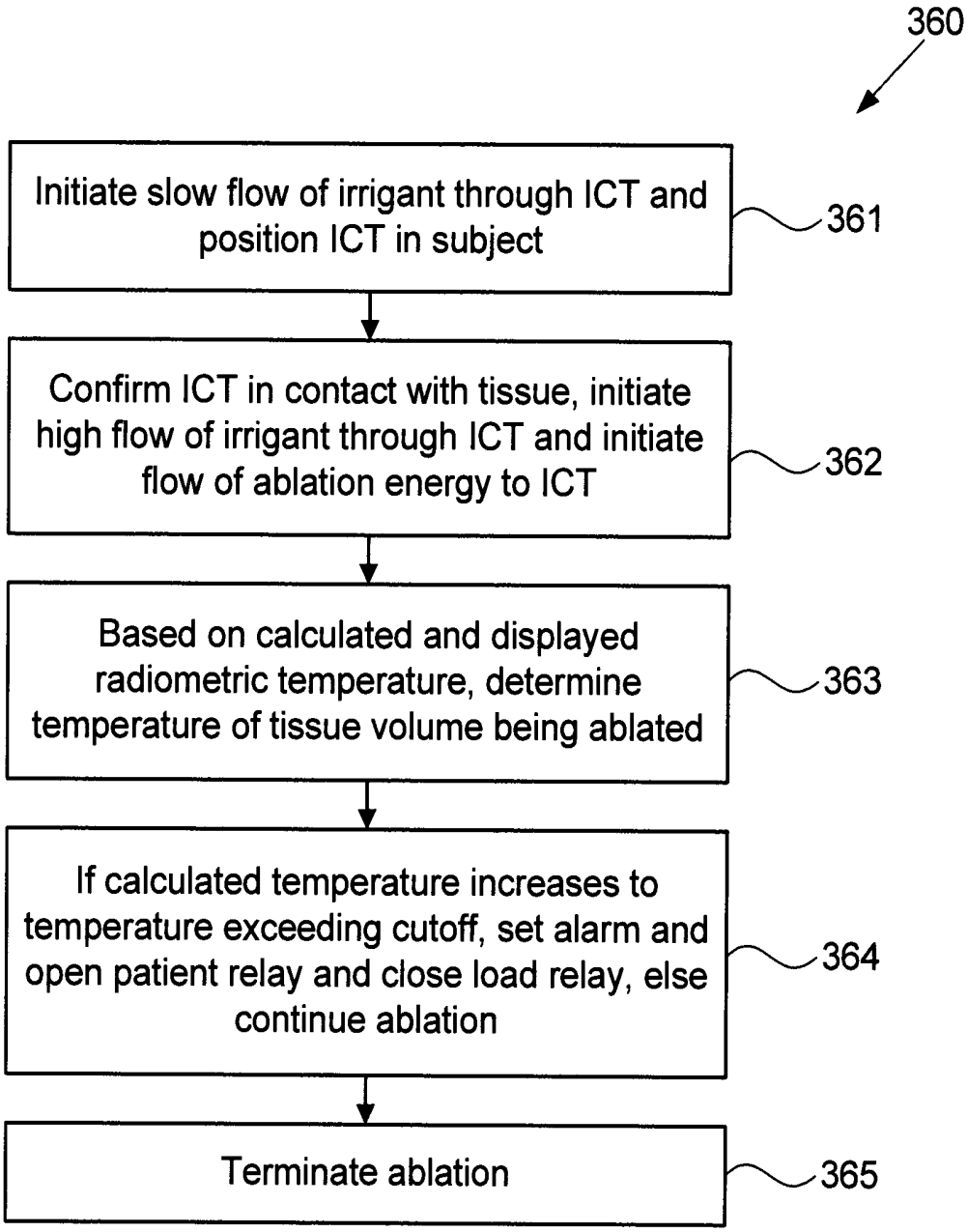
360
Initiate slow flow of irrigant through ICT and position ICT in subject
361
Confirm ICT in contact with tissue, initiate high flow of irrigant through ICT and initiate flow of ablation energy to ICT
362
Based on calculated and displayed radiometric temperature, determine temperature of tissue volume being ablated
363
If calculated temperature increases to temperature exceeding cutoff, set alarm and open patient relay and close load relay, else continue ablation
364
Terminate ablation
365

FIG. 3C

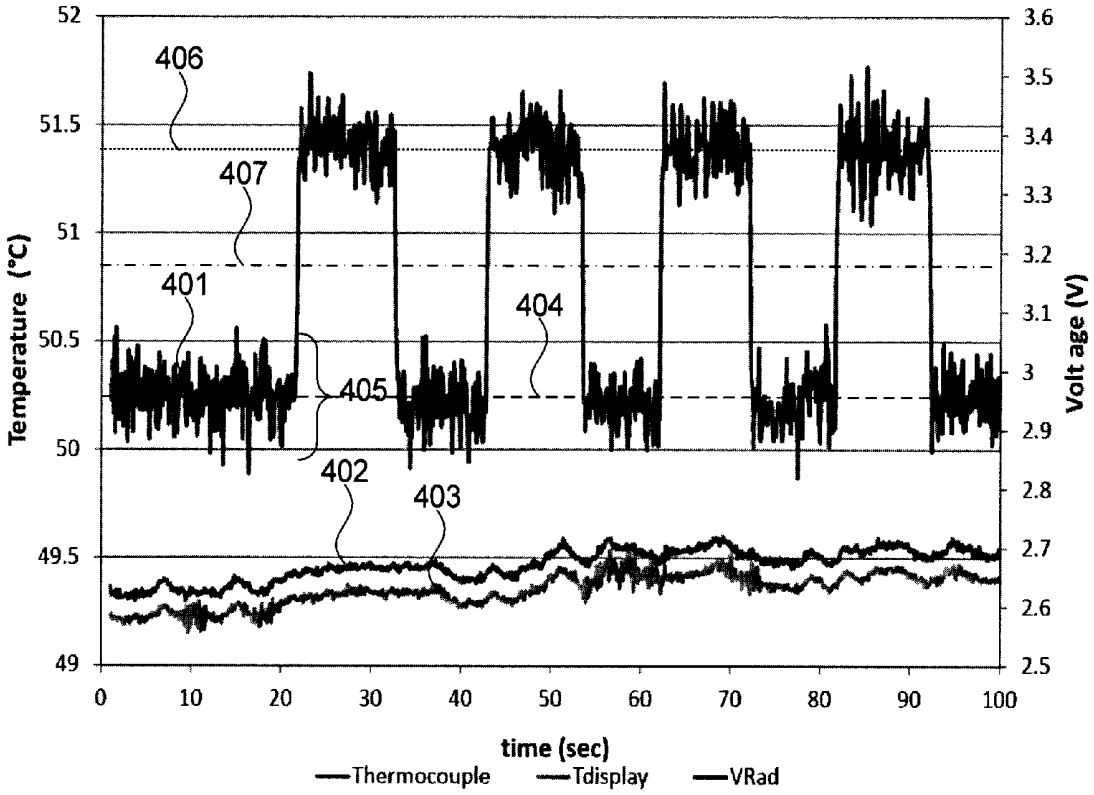
406
407
401
404
405
402
403
Temperature (°C)
Volt age (V)
time (sec)
Thermocouple
Tdisplay
VRad

FIG. 4A

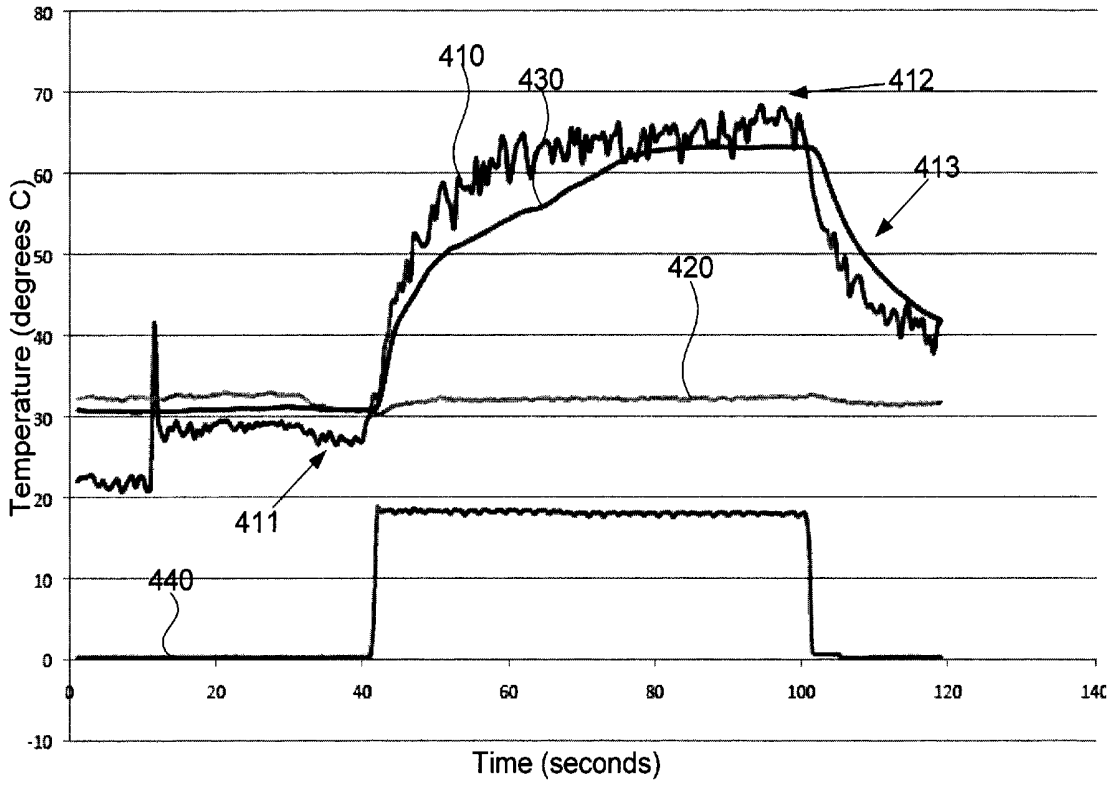
80
70
60
50
40
30
20
10
0
-10
0
20
40
60
80
100
120
140
Temperature (degrees C)
Time (seconds)
410
430
412
413
420
411
440

FIG. 4B

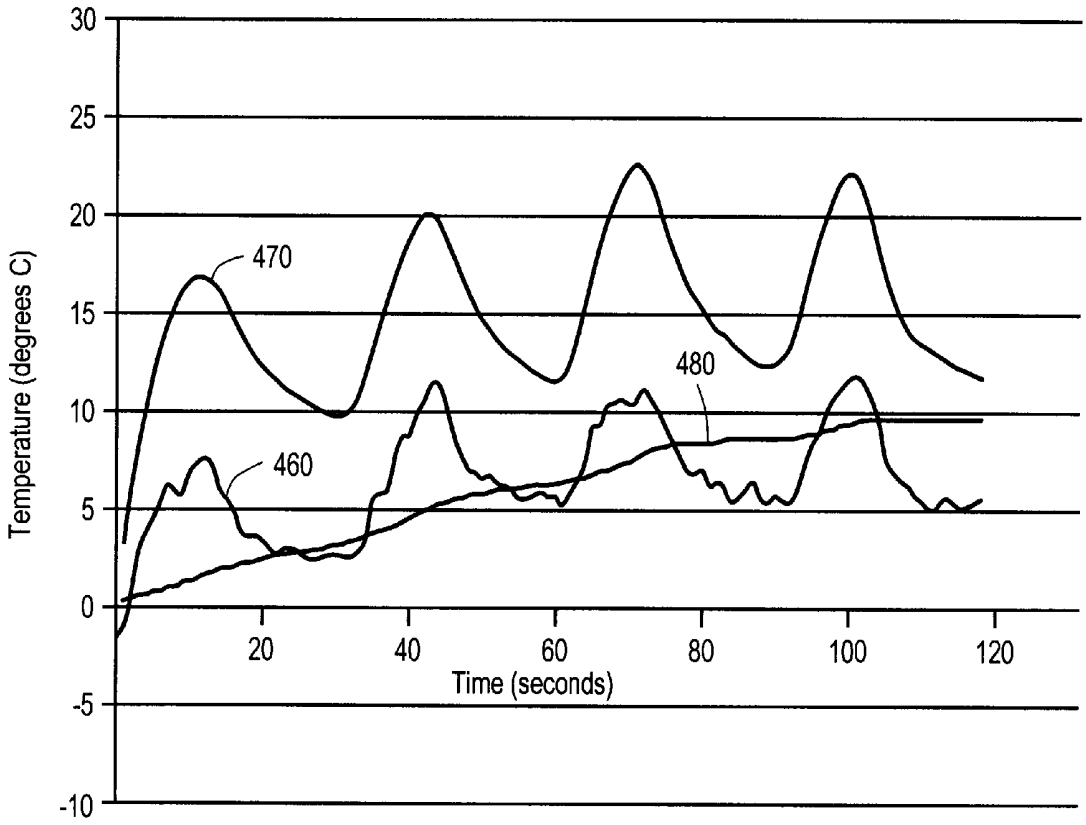
30
25
20
15
10
5
0
-5
-10
Temperature (degrees C)
20
40
60
80
100
120
Time (seconds)
470
480
460

FIG. 4C

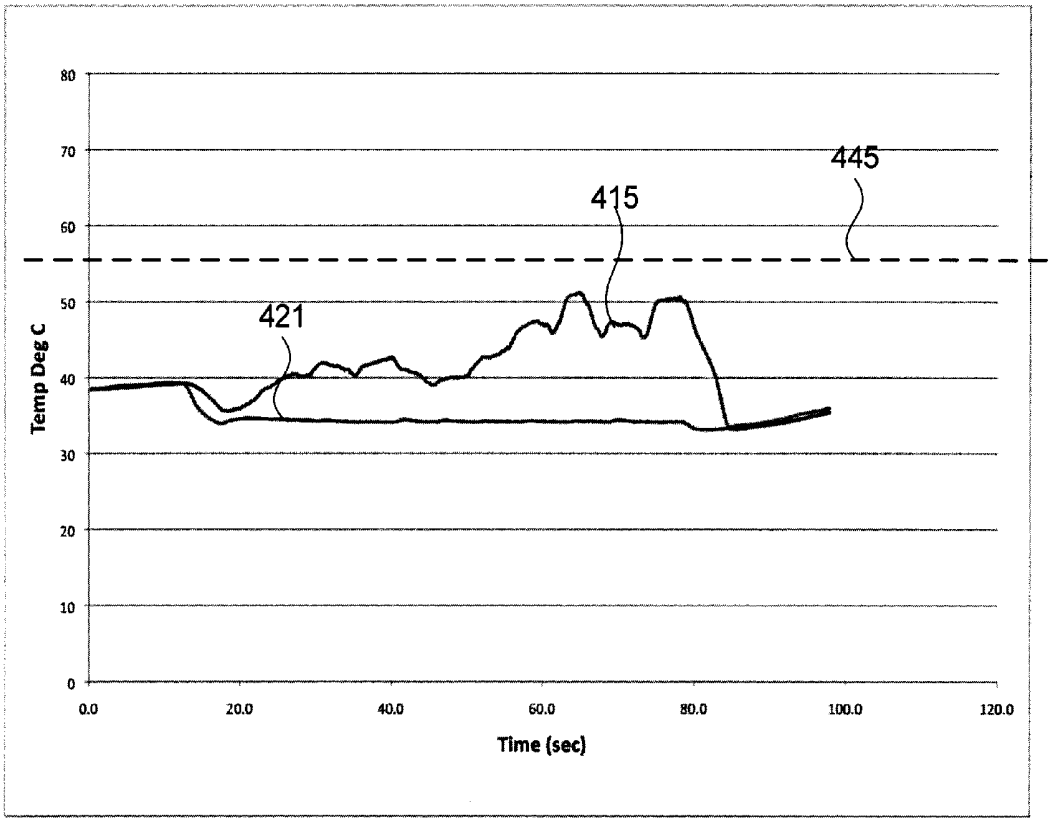
80
70
60
50
40
30
20
10
0
Temp Deg C
0.0
20.0
40.0
60.0
80.0
100.0
120.0
Time (sec)
445
415
421

FIG. 4D

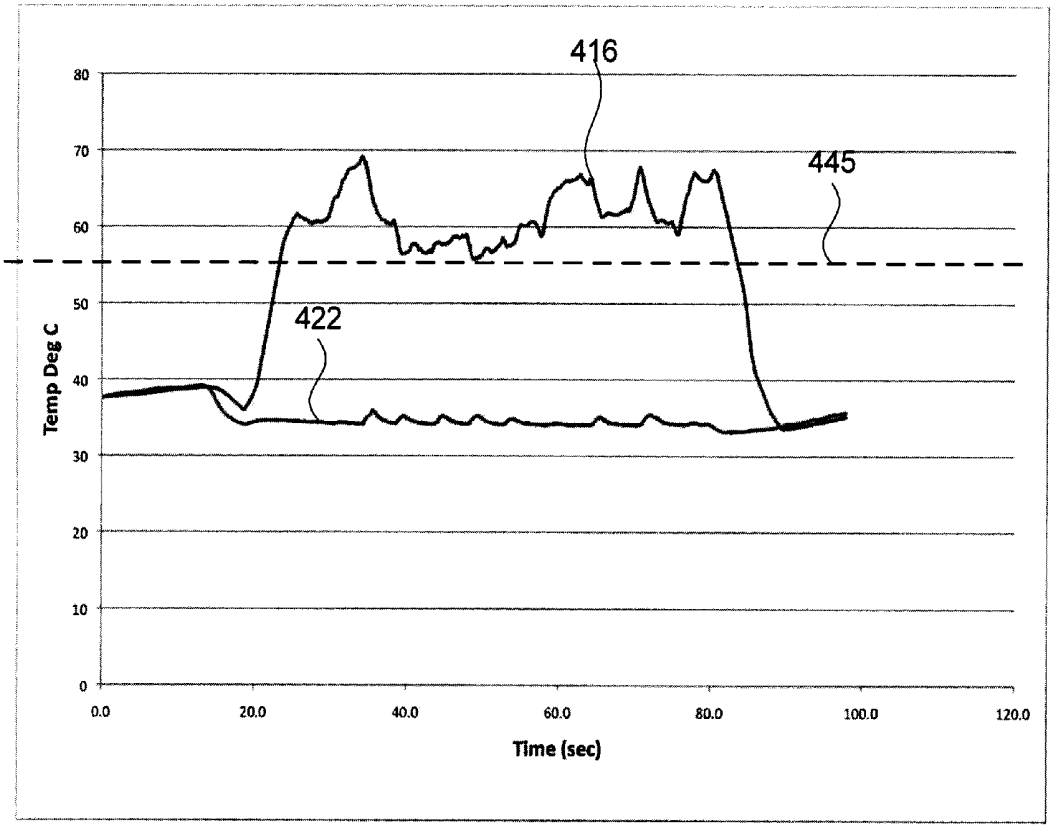
416
445
422
Temp Deg C
80
70
60
50
40
30
20
10
0
0.0
20.0
40.0
60.0
80.0
100.0
120.0
Time (sec)

FIG. 4E

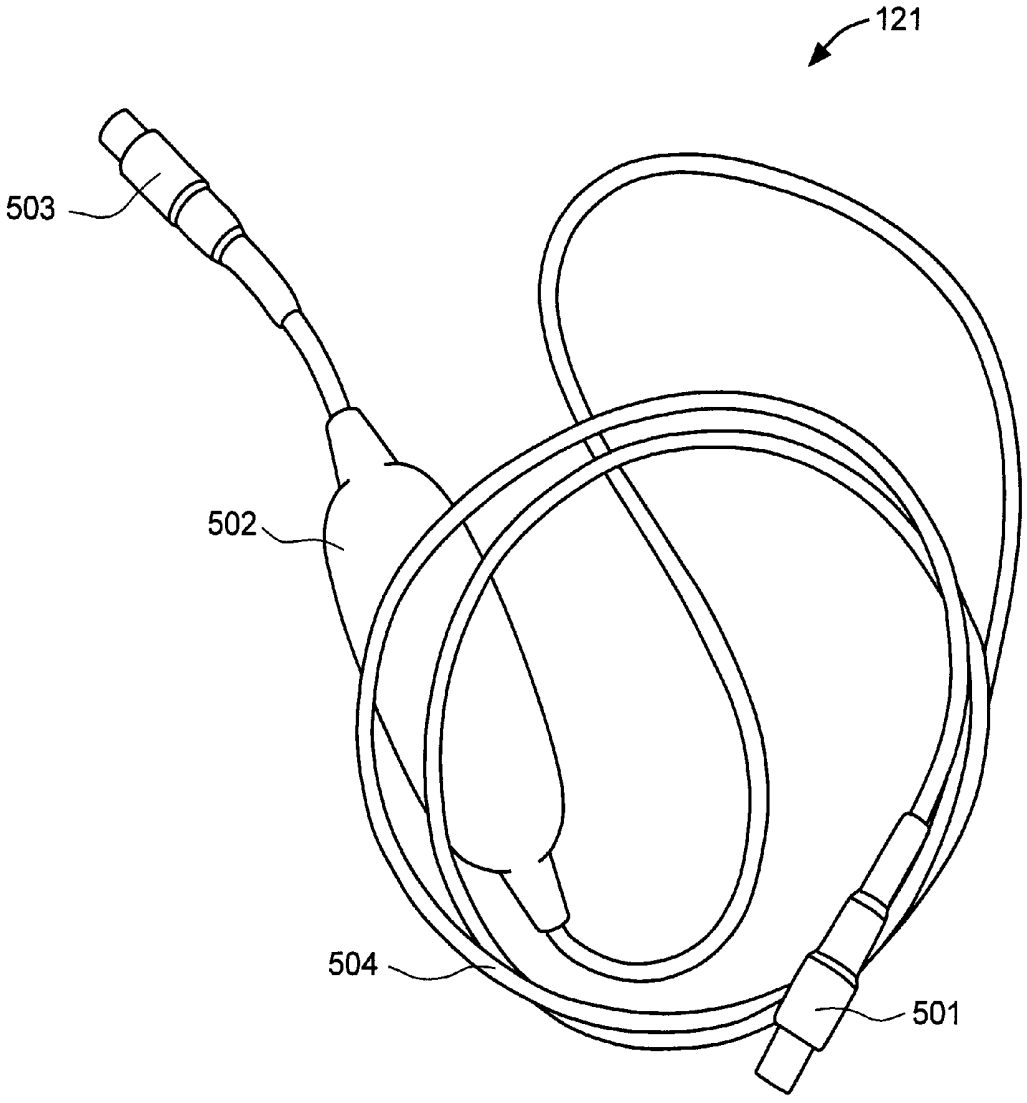

FIG. 5A

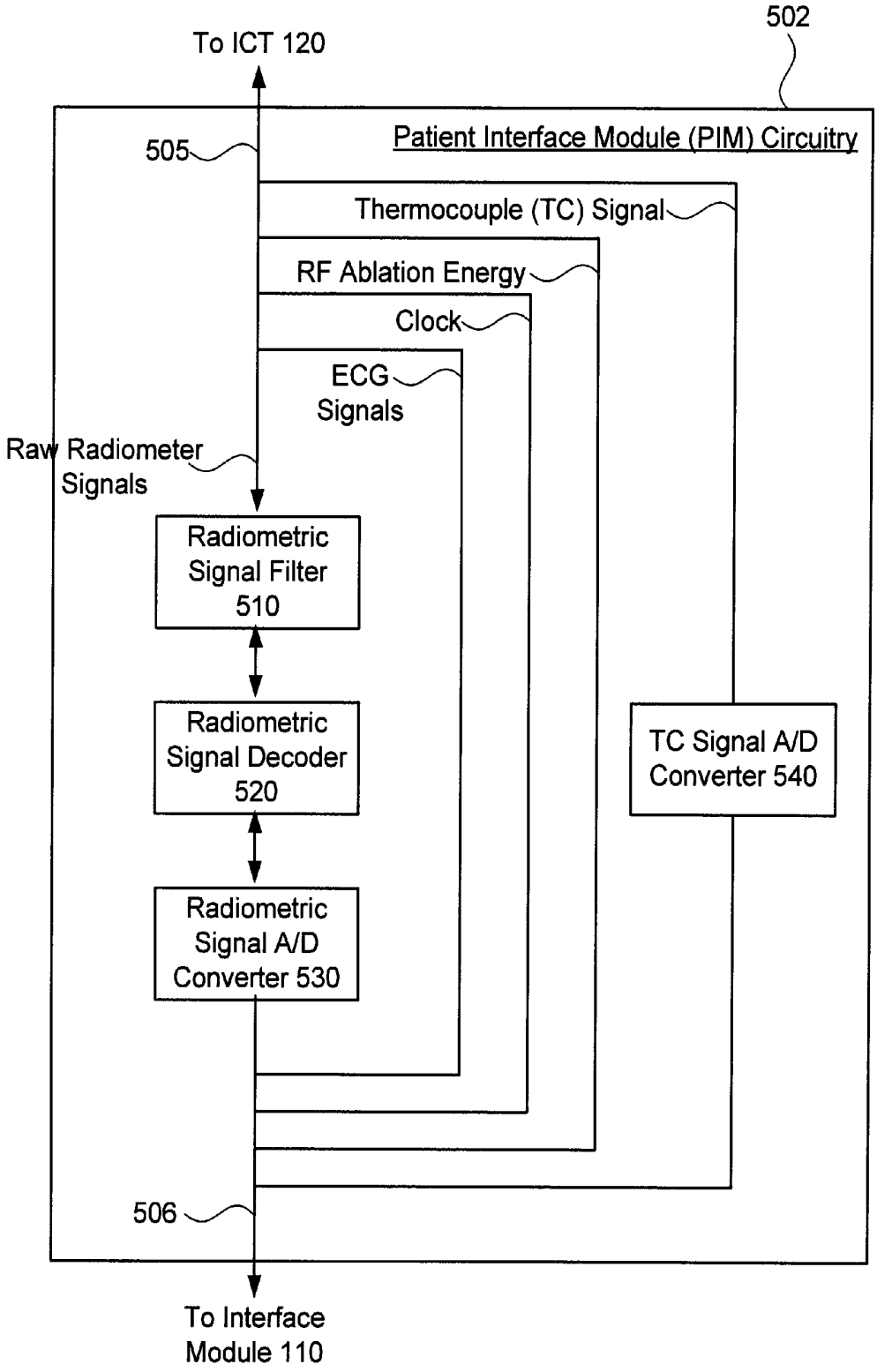
502
To ICT 120
Patient Interface Module (PIM) Circuitry
505
Thermocouple (TC) Signal
RF Ablation Energy
Clock
ECG Signals
Raw Radiometer Signals
Radiometric Signal Filter 510
Radiometric Signal Decoder 520
Radiometric Signal A/D Converter 530
TC Signal A/D Converter 540
506
To Interface Module 110

FIG. 5B

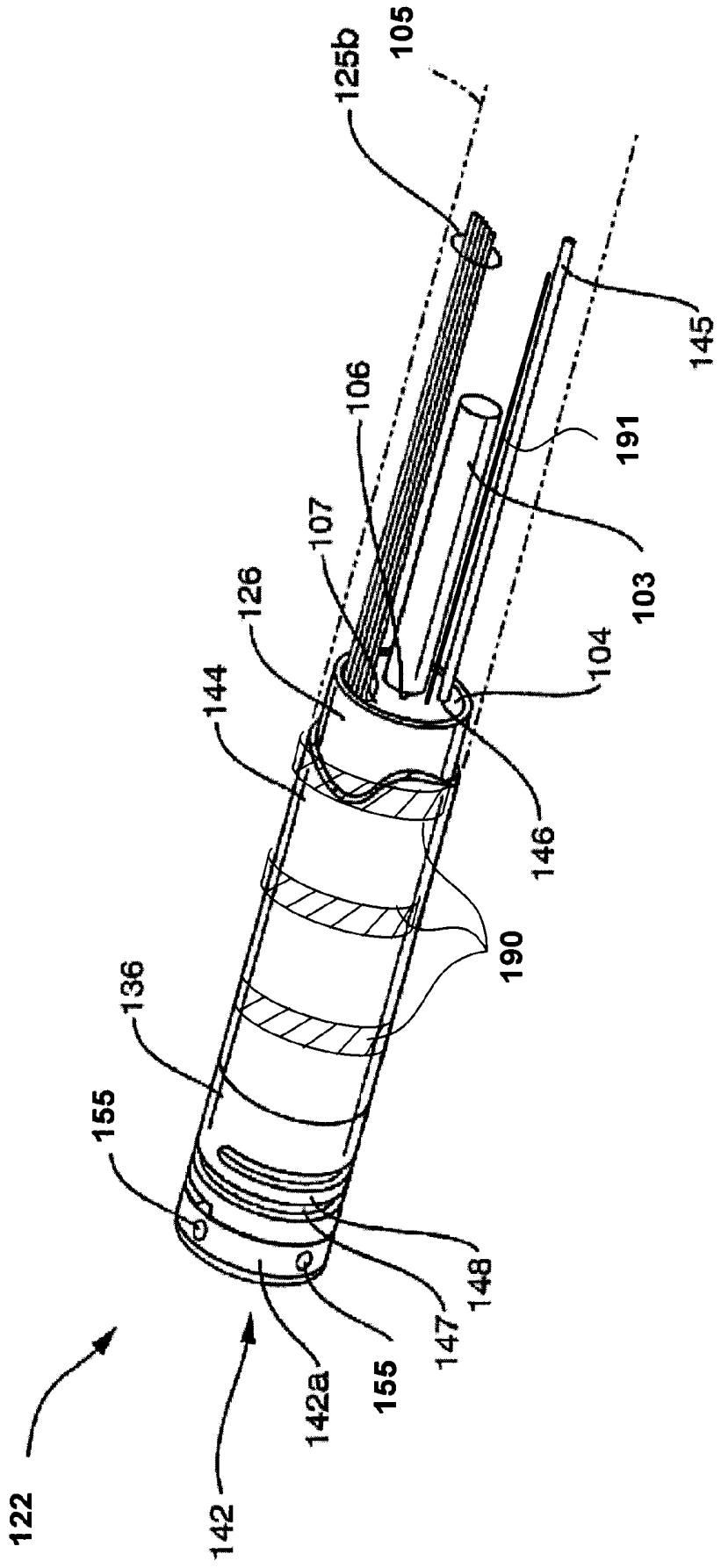
122
142
142a
155
147
148
155
136
190
146
144
126
104
103
107
106
191
145
125b
105

FIG. 6A

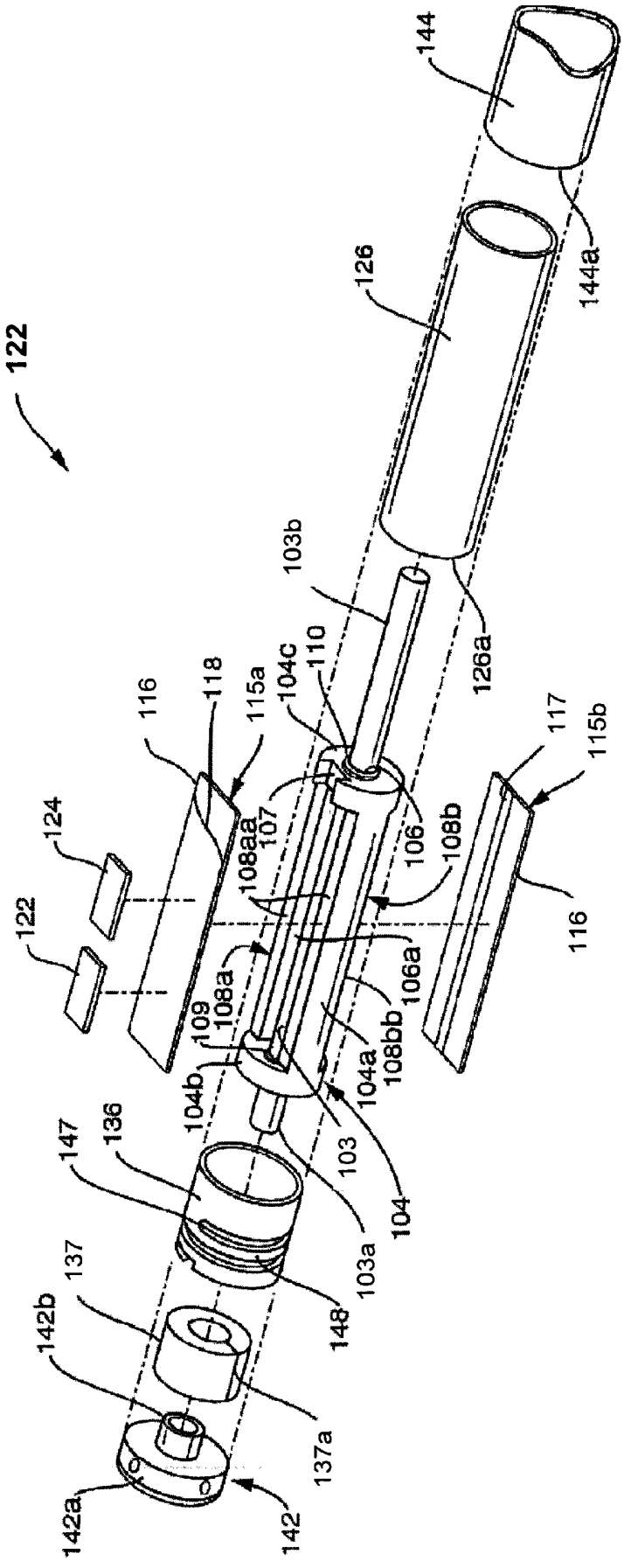
122
144
144a
126
126a
103b
110
104c
115a
118
116
117
115b
124
122
107
108aa
106
108b
116
109
108a
106a
108bb
104a
104b
103
104
147
136
103a
137
148
142b
137a
142a
142

FIG. 6B

METHODS OF DETERMINING TISSUE CONTACT BASED ON RADIOMETRIC SIGNALS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation application of U.S. patent application Ser. No. 13/486,889, filed on Jun. 1, 2012, the entirety of which is hereby incorporated by reference herein.

FIELD

This application generally relates to systems and methods for measuring temperature and detecting tissue contact prior to and during tissue ablation.

BACKGROUND

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.

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 procedures in which the surface of the tissue is cooled with an irrigant, the thermocouple will measure the temperature of the irrigant, thus further obscuring any useful information about the temperature of the tissue, particularly at depth. As such, the clinician has no useful feedback regarding the temperature of the tissue as it is being ablated or whether the time period of the ablation is sufficient.

Moreover, during an ablation procedure it is important that the clinician position the ablative tip directly against the cardiac surface (e.g., makes good contact) before activating the ablation energy source and attempting to ablate the tissue. If the clinician does not have good tissue contact, ablation energy may heat the blood instead of the tissue, leading to the formation of an edema, e.g., a fluid-filled pocket or blister on the tissue surface. Such an edema may inhibit adequate destruction of aberrant nerve pathways in the tissue. For example, edemas may physically interfere with the clinician's ability to contact a desired region of tissue with the ablative tip, and thus may interfere with destruction of a desired nerve pathway. Additionally, partial lesions or lesions in undesired locations have been found after the clinician completes the procedure and the edema dissipates. Formation of such partial or undesired lesions are thought to be caused by reduced contact between the ablative tip and the tissue, resulting in a tissue temperature insufficient to cause tissue necrosis. Edemas and partially formed lesions also may make it more difficult to create an effective lesion in the future, for example during a touch-up ablation within the same procedure or later on during a secondary procedure.

Accordingly, it may only be revealed after the procedure is completed—for example, if the patient continues to experience cardiac arrhythmias—that the targeted aberrant pathway was not adequately interrupted. In such a circumstance, the clinician may not know whether the procedure failed because the incorrect region of tissue was ablated, because the ablative tip was not actuated for a sufficient period of time to destroy the aberrant pathway, because the ablative tip was not touching or not sufficiently touching the tissue, because the power of the ablative energy was insufficient, or some combination of the above. Upon repeating the ablation procedure so as to again attempt to treat the arrhythmia, the clinician may have as little feedback as during the first procedure, and thus potentially may again fail to destroy the aberrant pathway. Additionally, there may be some risk that the clinician would re-treat a previously ablated region of the endocardium and not only ablate the conduction pathway, but damage adjacent tissues.

In some circumstances, to avoid having to repeat the ablation procedure as such, the clinician may ablate a series of regions of the endocardium along which the aberrant pathway is believed to lie, so as to improve the chance of interrupting conduction along that pathway. However, there is again insufficient feedback to assist the clinician in determining whether any of those ablated regions are sufficiently destroyed.

U.S. Pat. No. 4,190,053 to Sterzer describes a hyperthermia treatment apparatus in which a microwave source is used to deposit energy in living tissue to effect hyperthermia. The apparatus includes a radiometer for measuring temperature at depth within the tissue, and includes a controller that feeds back a control signal from the radiometer, corresponding to the measured temperature, to control the application of energy from the microwave source. The apparatus alternates between delivering microwave energy from the microwave source and measuring the radiant energy with the radiometer to measure the temperature. As a consequence of this time division multiplexing of energy application and temperature measurement, temperature values reported by the radiometer are not simultaneous with energy delivery.

U.S. Pat. No. 7,769,469 to Carr et al. describes an integrated heating and sensing catheter apparatus for treating arrhythmias, tumors and the like, having a diplexer that permits near simultaneous heating and temperature measurement. This patent too describes that temperature measured by the radiometer may be used to control the application of energy, e.g., to maintain a selected heating profile.

Despite the promise of precise temperature measurement sensitivity and control offered by the use of radiometry, there have been few successful commercial medical applications of this technology. One drawback of previously-known systems has been an inability to obtain highly reproducible results due to slight variations in the construction of the microwave antenna used in the radiometer, which can lead to significant differences in measured temperature from one catheter to another. Problems also have arisen with respect to orienting the radiometer antenna on the catheter to adequately capture the radiant energy emitted by the tissue, and with respect to shielding high frequency microwave components in the surgical environment so as to prevent interference between the radiometer components and other devices in the surgical field.

Acceptance of microwave-based hyperthermia treatments and temperature measurement techniques also has been impeded by the capital costs associated with implementing radiometric temperature control schemes. Radiofrequency ablation techniques have developed a substantial following in the medical community, even though such systems can have severe limitations, such as the inability to accurately measure tissue temperature at depth, e.g., where irrigation is employed. However, the widespread acceptance of RF ablation systems, extensive knowledge base of the medical community with such systems, and the significant cost required to changeover to, and train for, newer technologies has dramatically retarded the widespread adoption of radiometry.

In view of the foregoing, it would be desirable to provide apparatus and methods that permit radiometric measurement of temperature at depth in tissue, and permit use of such measurements to control the application of ablation energy in an ablation treatment, e.g., a hyperthermia or hypothermia treatment, particularly in which contact between the ablative tip and the tissue readily may be assessed.

It further would be desirable to provide apparatus and methods that employ microwave radiometer components that can be readily constructed and calibrated to provide a high degree of measurement reproducibility and reliability.

It also would be desirable to provide apparatus and methods that permit radiometric temperature measurement and control techniques to be introduced in a manner that is readily accessible to clinicians trained in the use of previously-known RF ablation catheters, with a minimum of retraining, and that provide readily understandable signals to the clinicians as to whether the ablative tip is in contact with tissue.

It still further would be desirable to provide apparatus and methods that permit radiometric temperature measurement and control techniques to be readily employed with previously-known RF electrosurgical generators, thereby reducing the capital costs needed to implement such new techniques.

SUMMARY

In view of the foregoing, it would be desirable to provide apparatus and methods for treating living tissue that employs a radiometer for temperature measurement and control. In accordance with one aspect of the invention, systems and methods are provided for radiometrically measuring temperature and detecting tissue contact prior to and during RF ablation, i.e., calculating temperature and detecting tissue contact based on signal(s) from a radiometer. Unlike standard thermocouple techniques used in existing commercial ablation systems, a radiometer may provide useful information about tissue temperature at depth—where the tissue ablation occurs—and thus provide feedback to the clinician about the extent of tissue damage as the clinician ablates a selected region of the tissue. Additionally, the radiometer may provide useful information about whether an ablative tip is in contact with tissue, and thus provide feedback to assist the clinician in properly contacting and ablating the tissue.

In one embodiment, the present invention comprises an interface module (system) that may be coupled to a previously-known commercially available ablation energy generator, e.g., an electrosurgical generator, thereby enabling radiometric techniques to be employed with reduced capital outlay. In this manner, the conventional electrosurgical generator can be used to supply ablative energy to an "integrated catheter tip" (ICT) that includes an ablative tip, a thermocouple, and a radiometer for detecting the volumetric temperature of tissue subjected to ablation. The interface module is configured to be coupled between the conventional electrosurgical generator and the ICT, and to coordinate signals therebetween. The interface module thereby provides the electrosurgical generator with the information required for operation, transmits ablative energy to the ICT under the control of the clinician, displays via a temperature display the temperature at depth of tissue as it is being ablated, and outputs a visible or audible indication of tissue contact for use by the clinician. The displayed temperature and determination of tissue contact may be calculated based on signal(s) measured by the radiometer using algorithms such as discussed further below.

In an exemplary embodiment, the interface module includes a first input/output (I/O) port that is configured to receive a digital radiometer signal and a digital thermocouple signal from the ICT, and a second I/O port that is configured to receive ablative energy from the electrosurgical generator. The interface module also includes a processor, a patient relay in communication with the processor and the first and second I/O ports, and a persistent computer-readable medium. The computer-readable medium stores operation parameters for the radiometer and the thermocouple, as well as instructions for the processor to use in coordinating operation of the ICT and the electrosurgical generator.

The computer-readable medium preferably stores instructions that cause the processor to execute the step of calculating a temperature adjacent to the ICT based on the digital radiometer signal, the digital thermocouple signal, and the operation parameters. This temperature is expected to provide significantly more accurate information about lesion quality and temperature at depth in the tissue than would a temperature based solely on a thermocouple readout. The computer-readable medium may further store instructions for causing the processor to cause the temperature display to display the calculated temperature, for example so that the clinician may control the time period for ablation responsive to the displayed temperature. The computer-readable medium may further store instructions for causing the processor to close the patient relay, such that the patient relay passes ablative energy received on the second I/O port, from the electrosurgical generator, to the first I/O port, to the ICT. Note that the instructions may cause the processor to maintain the patient relay in a normally closed state, and to open the patient relay upon detection of unsafe conditions.

The computer-readable medium preferably also stores instructions that cause the processor to execute the step of determining whether the ICT is in contact with tissue, based on the digital radiometer signal. For example, because blood and tissue have different dielectric constants, the digital radiometer signal may change when the ICT is brought into or out of contact with the tissue. The instructions may cause the processor to monitor the digital radiometer signal for changes. Any such changes may be compared to a predetermined threshold value (also stored on the computer-readable medium). If the change is determined to be greater than the threshold value, then the processor outputs a signal to an output device that, responsive to the signal, indicates whether the ICT is in contact with tissue. The output device may be, for example, a visual display device that visually represents the tissue contact, e.g., a light that illuminates when there is tissue contact, or an audio device that audibly represents the tissue contact, e.g., a speaker that generates a tone when there is tissue contact. Preferably, the processor determines whether the ICT is in contact with the tissue before passing ablation energy to the ICT.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A is a schematic illustration of a first embodiment of an arrangement including an interface module with tissue

contact indicator according to one aspect of the present invention, including a display of the front and back panels of, and exemplary connections between, the interface module, a previously known ablation energy generator, e.g., electrosurgical generator, and an integrated catheter tip (ICT).

FIG. **1**B is a schematic illustrating exemplary connections to and from the interface module of FIG. **1**A, as well as connections among other components that may be used with the interface module.

FIG. **2**A is a schematic illustrating internal components of the interface module of FIGS. **1**A-**1**B.

FIG. **2**B schematically illustrates additional internal components of the interface module of FIG. **2**A, as well as selected connections to and from the interface module.

FIG. **3**A illustrates steps in a method of using the interface module of FIGS. **1**A-**2**B during tissue ablation.

FIG. **3**B illustrates steps in a method of calculating radiometric temperature using digital signals from a radiometer and a thermocouple and operation parameters.

FIG. **3**C illustrates steps in a method of controlling an ablation procedure using a temperature calculated based on signal(s) from a radiometer using the interface module of FIGS. **1**A-**2**B.

FIG. **4**A illustrates data obtained during an exemplary tissue contact measurement procedure performed using the interface module of FIGS. **1**A-**2**B.

FIGS. **4**B-**4**E illustrate data obtained during exemplary ablation procedures performed using the interface module of FIGS. **1**A-**2**B.

FIG. **5**A illustrates a plan view of an exemplary patient interface module (PIM) associated with an integrated catheter tip (ICT) for use with the interface module of FIGS. **1**A-**2**B.

FIG. **5**B schematically illustrates selected internal components of the PIM of FIG. **5**A, according to some embodiments of the present invention.

FIGS. **6**A-**6**B respectively illustrate perspective and exploded views of an exemplary integrated catheter tip (ICT) for use with the interface module of FIGS. **1**A-**2**B and the PIM of FIGS. **5**A-**5**B, according to some embodiments of the present invention.

DETAILED DESCRIPTION

Embodiments of the present invention provide systems and methods for radiometrically measuring temperature and detecting tissue contact prior to and during ablation, in particular cardiac ablation. As noted above, commercially available systems for cardiac ablation may include thermocouples for measuring temperature, but such thermocouples may not adequately provide the clinician with information about tissue temperature or tissue contact. Thus, the clinician may need to make an "educated guess" about whether an ablative tip is in contact with tissue, as well as whether a given region of tissue has been sufficiently ablated to achieve the desired effect. By comparison, calculating a temperature based on signal(s) from a radiometer is expected to provide accurate information to the clinician about the temperature of tissue at depth, even during an irrigated procedure. Moreover, the signal(s) from the radiometer may be used to determine whether the ablative tip is in sufficient contact with tissue before attempting to ablate the tissue, so as to reduce the likelihood of forming edemas such as described above and improve the likelihood of creating effective transmural lesions. The present invention provides a "retrofit" solution that includes an interface module that works with existing, commercially available ablation energy generators, such as electrosurgical generators. In accordance with one aspect of the present invention, the interface module displays a tissue temperature and provides an indication of tissue contact based on signal(s) measured by a radiometer, that a clinician may use to perform ablation procedures with significantly better accuracy than can be achieved using only a thermocouple for temperature measurement.

First, high level overviews of the interface module, including tissue contact indicator, and connections thereto are provided. Then, further detail on the internal components of the interface module, and exemplary methods of calculating radiometric temperature, determining tissue contact, and controlling an ablation procedure based on same, are provided. Data obtained during experimental procedures also is presented. Lastly, further detail on components that may be used with the interface module is provided.

FIG. **1**A illustrates plan views of front panel **111**, back panel **112**, and connections to and from exemplary interface module **110**, constructed in accordance with the principles of the present invention. As illustrated in FIG. **1**A, front panel **111** of interface module **110** may be connected to a catheter **120** that includes patient interface module (PIM) **121** and integrated catheter tip (ICT) **122**. Catheter **120** optionally is steerable, or may be non-steerable and used in conjunction with a robotic positioning system or a third-party steerable sheath (not shown). ICT **122** is positioned by a clinician (optionally with mechanical assistance such as noted above), during a procedure, within subject **101** lying on grounded table **102**. ICT **122** may include, among other things, an ablative tip, a thermocouple, and a radiometer for detecting the volumetric temperature of tissue subjected to ablation. The ICT **122** optionally includes one or more irrigation ports, which in one embodiment may be connected directly to a commercially available irrigant pump.

In embodiments in which the ablation energy is radiofrequency (RF) energy, the ablative tip may include an irrigated ablation electrode, such as described in greater detail below with reference to FIGS. **6**A-**6**B. ICT **122** further may include one or more electrocardiogram (ECG) electrodes for use in monitoring electrical activity of the heart of subject **101**. Interface module **110** receives signals from the thermocouple, radiometer, and optional ECG electrodes of ICT **122** via PIM **121**. Interface module **110** provides to ICT **122**, via PIM **121**, power for the operation of the PIM and the sensors (thermocouple, radiometer, and ECG electrodes), and ablation energy to be applied to subject **101** via the ablative tip.

Front panel **111** includes tissue contact indicator **170**, which is an output device configured to indicate whether ICT **122** is in contact with tissue, e.g., which interface module **110** determines based on signal(s) from the radiometer as described in greater detail below. Tissue contact indicator **170** may include a visual display device that visually represents interface module **110**'s determination of whether ICT **122** is in contact with tissue. For example, tissue contact indicator **170** may include a light that illuminates when interface module **110** determines that ICT **122** is in contact with tissue, and is dark when interface module **110** determines that ICT **122** is out of contact with tissue. Alternatively, tissue contact indicator **170** may be an audio device that audibly represents interface module **110**'s determination of whether ICT **122** is in contact with tissue. For example, tissue contact indicator **170** may include a speaker that generates a tone when interface module **110** determines that ICT **122** is in contact with tissue, and is silent when interface module **110** determines that ICT **122** is out of contact with tissue. Tissue contact indicator **170** may continuously generate a tone throughout the duration of the contact, and cease generating the tone when contact is lost, so as to facilitate the clinician's ability to

determine whether tissue contact has been lost. Alternatively, tissue contact indicator **170** may generate a brief tone at a first frequency when contact is made, and may generate a second tone at a second frequency when contact is lost. Optionally, tissue contact indicator **170** includes a visual display device and an audio device for providing the clinician with both visible and audible indications of tissue contact.

Back panel **112** of interface module **110** may be connected via connection cable **135** to a commercially available previously-known ablation energy generator **130**, for example an electrosurgical generator **130**, such as a Stockert EP-Shuttle 100 Generator (Stockert GmbH, Freiburg Germany) or Stockert 70 RF Generator (Biosense Webster, Diamond Bar, Calif.). In embodiments where the electrosurgical generator **130** is a Stockert EP-Shuttle or 70 RF Generator, generator **130** includes display device **131** for displaying temperature and the impedance and time associated with application of a dose of RF ablation energy; power control knob **132** for allowing a clinician to manually adjust the power of RF ablative energy delivered to subject **101**; and start/stop/mode input **133** for allowing a clinician to initiate or terminate the delivery of RF ablation energy. Start/stop/mode input **133** also may be configured to control the mode of energy delivery, e.g., whether the energy is to be cut off after a given period of time.

Although generator **130** may be configured to display temperature on display device **131**, that temperature is based on readings from a standard thermocouple. As noted above, however, that reported temperature may be inaccurate while irrigant and ablative energy are being applied to tissue. Interface module **110** provides to generator **130**, via connection cable **135**, a thermocouple signal for use in displaying such a temperature, and signals from the ECG electrodes; and provides via indifferent electrode cable **134** a pass-through connection to indifferent electrode **140**. Interface module **110** receives from generator **130**, via connection cable **135**, RF ablation energy that module **110** controllably provides to ICT **122** for use in ablating tissue of subject **101**.

As will be familiar to those skilled in the art, for a monopolar RF ablation procedure, a clinician may position an indifferent electrode (IE) **140** on the back of subject **101** so as to provide a voltage differential that enables transmission of RF energy into the tissue of the subject. In the illustrated embodiment, IE **140** is connected to interface module **110** via first indifferent electrode cable **141**. Interface module **110** passes through the IE signal to second indifferent electrode cable **134**, which is connected to an indifferent electrode input port on electrosurgical generator **130**. Alternatively, IE **140** may be connected directly to that port of the electrosurgical generator **130** via appropriate cabling (not shown).

It should be understood that electrosurgical generators other than the Stockert EP-Shuttle or 70 RF Generator suitably may be used, e.g., other makes or models of RF electrosurgical generators. Alternatively, generators that produce other types of ablation energy, such as microwave generators, cryosurgical sources, or high frequency ultrasound generators, may be used. Ablation energy generator **130** need not necessarily be commercially available, although as noted above it may be convenient to use one that is. It should also be appreciated that the connections described herein may be provided on any desired face or panel of interface module **110**, and that the functionalities of different connectors and input/output (I/O) ports may be combined or otherwise suitably modified.

Front panel **111** of interface module **110** includes temperature display **113**, e.g., a digital two or three-digit display device configured to display a temperature calculated by a processor internal to interface module **110**, e.g., as described in greater detail below with reference to FIGS. **2**A-**2**B and **3**A. Other types of temperature displays, such multicolor liquid crystal displays (LCDs), alternatively may be used. In one embodiment, the functionalities of temperature display **113** and tissue contact indicator **170** are provided by a single display device configured both to display temperature and to provide an indication of interface module **110**'s determination of whether ICT **122** is in contact with tissue. For example, the background of temperature display **113** may be configured to change from one color to another (e.g., from red to green) when interface module **110** determines that ICT **122** is in contact with tissue. In such an embodiment, a separate, audible tissue contact indicator **170** such as described above optionally may be provided as well. Front panel **111** also includes connectors (not labeled) through which interface module **110** is connected to ICT **122** via PIM **121**, and to IE **140** via indifferent electrode cable **141**.

Back panel **112** of interface module **110** includes connectors (not labeled) through which interface module **110** is connected to electrosurgical generator **130**, via indifferent electrode cable **134** and connection cable **135**. Back panel **112** of interface module **110** also includes data ports **114** configured to output one or more signals to a suitably programmed personal computer or other remote device, for example an EP monitoring/recording system such as the LABSYSTEM™ PRO EP Recording System (C.R. Bard, Inc., Lowell, Mass.). Such signals may, for example, include signals generated by the thermocouple, radiometer, and/or ECG electrodes of the ICT, the tissue temperature calculated by interface module **110**, and the like.

Referring now to FIG. **1**B, exemplary connections to and from interface module **110** of FIG. **1**A, as well as connections among other components, are described. In FIG. **1**B, interface module **110** is in operable communication with catheter **120** having a patient interface module (PIM) **121** and an integrated catheter tip (ICT) **122** that includes a radiometer, ablative tip, a thermocouple (TC), and optionally also includes ECG electrodes and/or irrigation ports(s). Interface module **110** is also in operable communication with electrosurgical generator **130** and indifferent electrode **140**.

Electrosurgical generator **130** optionally is in operable communication with electrophysiology (EP) monitoring/recording system **160** via appropriate cabling **161**, or alternatively via data ports **114** of interface module **110** and appropriate cabling (not shown). EP monitoring/recording system **160** may include, for example, various monitors, processors, and the like that display pertinent information about an ablation procedure to a clinician, such as the subject's heart rate and blood pressure, the temperature recorded by the thermocouple on the catheter tip, the ablation power and time period over which it is applied, fluoroscopic images, and the like. EP monitoring/recording systems are commercially available, e.g., the MEDELEC™ Synergy T-EP—EMG/EP Monitoring System (CareFusion, San Diego, Calif.), or the LABSYSTEM™ PRO EP Recording System (C.R. Bard, Inc., Lowell, Mass.).

If ICT **122** includes irrigation port(s), then one convenient means of providing irrigant to such ports is irrigation pump **140** associated with electrosurgical generator **130**, which pump is in operable communication with the generator and in fluidic communication with the ICT **122** via connector **151**. For example, the Stockert 70 RF Generator is designed for use with a CoolFlow™ Irrigation pump, also manufactured by Biosense Webster. Specifically, the Stockert 70 RF Generator and the CoolFlow™ pump may be connected to one another by a commercially available interface cable, so as to operate

as an integrated system that works in substantially the same way as it would with a standard, commercially available catheter tip. For example, prior to positioning ICT **122** in the body, the clinician instructs the pump to provide a low flow rate of irrigant to the ICT, as it would to a standard catheter tip; the ICT is then positioned in the body. Then, when the clinician presses the "start" button on the face of generator **130**, the generator may instruct pump **150** to provide a high flow rate of irrigant for a predetermined period (e.g., 5 seconds) before providing RF ablation energy, again as it would for a standard catheter tip. After the RF ablation energy application is terminated, then pump **150** returns to a low flow rate until the clinician removes the ICT **122** from the body and manually turns off the pump.

Referring now to FIGS. **2**A-**2**B, further details of internal components of interface module **110** of FIGS. **1**A-**1**B are provided.

FIG. **2**A schematically illustrates internal components of one embodiment of interface module **110**. Interface module **110** includes first, second, third, and fourth ports **201**-**204** by which it communicates with external components. Specifically, first port **201** is an input/output (I/O) port configured to be connected to catheter **120** via PIM **121**, as illustrated in FIG. **1**A. Port **201** receives as input from catheter **120** digital radiometer and digital thermocouple (TC) signals, and optionally ECG signals, generated by ICT **122**, and provides as output to catheter **120** RF ablation energy, as well as power for circuitry within the ICT **122** and the PIM **121**. Second port **202** is also an I/O port, configured to be connected to electrosurgical generator **130** via connection cable **135** illustrated in FIG. **1**A, and receives as input from generator **130** RF ablation energy, and provides as output to generator **130** a reconstituted analog thermocouple (TC) signal and raw ECG signal(s). Third port **203** is an input port configured to be connected to indifferent electrode (IE) **140** via indifferent electrode cable **134** illustrated in FIG. **1**A, and fourth port **204** is an output port configured to be connected to generator **130** via indifferent electrode cable **141** illustrated in FIG. **1**A. As shown in FIG. **2**A, interface module **110** acts as a pass-through for the IE signal from IE **140** to generator **130**, and simply receives IE signal on third port **203** and provides the IE signal to generator **130** on fourth port **204**.

Interface module **110** also includes processor **210** coupled to non-volatile (persistent) computer-readable memory **230**, user interface **280**, load relay **260**, and patient relay **250**. Memory **230** stores programming that causes processor **210** to perform steps described further below with respect to FIGS. **3**A-**3**C, thereby controlling the functionality of interface module **110**. Memory **230** also stores parameters used by processor **210**. For example, memory **230** may store a set of operation parameters **231** for the thermocouple and radiometer, as well as a temperature calculation module **233**, that processor **210** uses to calculate the radiometric temperature based on the digital TC and radiometer signals received on first I/O port **201**, as described in greater detail below with respect to FIG. **3**B. The operation parameters **231** may be obtained through calibration, or may be fixed. Memory **230** also stores a set of safety parameters **232** that processor **210** uses to maintain safe conditions during an ablation procedure, as described further below with respect to FIG. **3**C. Memory **230** further stores decision module **234** that processor **210** uses to control the opening and closing of patient relay **250** and load relay **260** based on its determinations of temperature and safety conditions, as described further below with reference to FIGS. **3**A-**3**C. When closed, patient relay **250** passes ablative energy from the second I/O port **202** to the first I/O port **201**. When closed, load relay **260** returns ablative energy to the IE **140** via dummy load D (resistor, e.g., of 120.OMEGA. resistance) and fourth I/O port **204**. Memory **230** further stores predetermined threshold **235** value and tissue contact module **236** that processor **210** uses to determine whether ICT **122** is in contact with tissue, and to provide output indicative of such contact to the clinician, such as described further below with reference to FIG. **3**A.

As illustrated in FIG. **2**A, interface module **110** further includes user interface **280** by which a user may receive information about the temperature adjacent ICT **122** as calculated by processor **210**, as well as other potentially useful information. In the illustrated embodiment, user interface **280** includes digital temperature display **113**, which displays the instantaneous temperature calculated by processor **210**. In other embodiments (not shown), display **113** may be an LCD device that, in addition to displaying the instantaneous temperature calculated by processor **210**, also graphically display changes in the temperature over time for use by the clinician during the ablation procedure. User interface **280** further may include data ports **114**, which may be connected to a computer or EP monitoring/recording system by appropriate cabling as noted above, and which may output digital or analog signals being received or generated by interface module **110**, e.g., radiometer signal(s), a thermocouple signal, and/or the temperature calculated by processor **210**. Preferably, user interface **280** also includes tissue contact indicator **170**, which is configured display the processor **210**'s determination as to whether ICT **122** is in contact with tissue based on predetermined threshold value **235** and tissue contact module **236** stored in memory **230**, e.g., as described in further detail below with reference to FIG. **3**A.

So as to inhibit potential degradations in the performance of processor **210**, memory **230**, or user interface **280** resulting from electrical contact with RF energy, interface module **110** may include opto-electronics **299** that communicate information to and from processor **210**, but that substantially inhibit transmission of RF energy to processor **210**, memory **230**, or user interface **280**. This isolation is designated by the dashed line in FIG. **2**A. For example, opto-electronics **299** may include circuitry that is in operable communication with first I/O port **201** so as to receive the digital TC and radiometer signals from first I/O port **201**, and that converts such digital signals into optical digital signals. Opto-electronics **299** also may include an optical transmitter in operable communication with such circuitry, that transmits those optical digital signals to processor **210** through free space. Opto-electronics **299** further may include an optical receiver in operable communication with processor **210**, that receives such optical digital signals, and circuitry that converts the optical digital signals into digital signals for use by processor **210**. The opto-electronic circuitry in communication with the processor also may be in operable communication with a second optical transmitter, and may receive signals from processor **210** to be transmitted across free space to an optical receiver in communication with the circuitry that receives and processes the digital TC and radiometer signals. For example, processor **210** may transmit to such circuitry, via an optical signal, a signal that causes the circuitry to generate an analog version of the TC signal and to provide that analog signal to the second I/O port. Because opto-electronic circuitry, transmitters, and receivers are known in the art, its specific components are not illustrated in FIG. **2**A.

With respect to FIG. **2**B, additional internal components of interface module **110** of FIG. **2**A are described, as well as selected connections to and from the interface module. FIG. **2**B is an exemplary schematic for a grounding and power supply scheme suitable for using interface module **110** with

an RF electrosurgical generator, e.g., a Stockert EP-Shuttle or 70 RF Generator. Other grounding and power supply schemes suitably may be used with other types, makes, or models of electrosurgical generators, as will be appreciated by those skilled in the art.

As illustrated in FIG. **2**B, interface module **110** includes isolated main power supply **205** that may be connected to standard three-prong A/C power outlet **1**, which is grounded to mains ground G. Interface module **110** also includes several internal grounds, designated A, B, C, and I. Internal ground A is coupled to the external mains ground G via a relatively small capacitance capacitor (e.g., a 10 pF capacitor) and a relatively high resistance resistor (e.g., a 20 NE/resistor) that substantially prevents internal ground A from floating. Internal ground B is coupled to internal ground A via a low resistance pathway (e.g., a pathway or resistor(s) providing less than 1000Ω resistance, e.g., about 0Ω resistance). Similarly, internal ground C is coupled to internal ground B via another low resistance pathway. Internal ground I is an isolated ground that is coupled to internal ground C via a relatively small capacitance capacitor (e.g., a 10 pF capacitor) and a relatively high resistance resistor (e.g., a 20 MΩ resistor) that substantially prevents isolated ground I from floating.

Isolated main power supply **205** is coupled to internal ground A via a low resistance pathway. Isolated main power supply **205** is also coupled to, and provides power (e.g., ±12V) to, one or more internal isolated power supplies that in turn provide power to components internal to interface module **110**. Such components include, but are not limited to components illustrated in FIG. **2**A. For example, interface module **110** may include one or more isolated power supplies **220** that provide power (e.g., ±4V) to processor **210**, memory **230**, and analog circuitry **240**. Analog circuitry **240** may include components of user interface **280**, including temperature display **113** and circuitry that appropriately prepares signals for output on data ports **114**. Data ports **114**, as well as analog circuitry **240**, are coupled to internal ground B via low resistance pathways, while processor and memory **210**, **230** are coupled to internal ground C via low resistance pathways. Interface module also may include one or more isolated power supplies **270** that provide power (e.g., ±4V) to ICT **122**, PIM **121**, and RF circuitry **290**.

RF circuitry **290** may include patient and load relays **250**, **260**, as well as circuitry that receives the radiometer and thermocouple signals and provides such signals to the processor via optoelectronic coupling, and circuitry that generates a clock signal to be provided to the ICT as described further below with reference to FIG. **5**B. RF circuitry **290**, ICT **122**, and PIM **121** are coupled to isolated internal ground I via low resistance pathways.

As shown in FIG. **2**B, power supply **139** of RF electrosurgical generator **130**, which may be external to generator **130** as in FIG. **2**B or may be internal to generator **130**, is connected to standard two- or three-prong A/C power outlet **2**. However, generator power supply **139** is not connected to the ground of the outlet, and thus not connected to the mains ground G, as is the isolated main power supply. Instead, generator power supply **139** and RF electrosurgical generator **130** are grounded to internal isolated ground I of interface module **110** via low resistance pathways between generator **130** and PIM **121** and ICT **122**, and low resistance pathways between PIM **121** and ICT **122** and internal isolated ground I. As such, RF circuitry **290**, PIM **121**, IE **140**, and generator **130** are all "grounded" to an internal isolated ground I that has essentially the same potential as does ICT **122**. Thus, when RF energy is applied to ICT **122** from generator **130** through interface module **110**, the ground of RF circuitry **290**, PIM **121**, ICT **122**, IE **140**, and generator **130** all essentially float with the RF energy amplitude, which may be a sine wave of 50-100V at 500 kHz.

As further illustrated in FIG. **2**B, the ±12V of power that isolated main power supply **205** provides to isolated processor/memory/analog power supply **220** and to isolated ICT/RF power supply **270** may be coupled by parasitic capacitance (pc, approximately 13 pF) to A/C power outlet **1**, as may be the ±4V of power that such power supplies provide to their respective components. Such parasitic coupling will be familiar to those skilled in the art. Note also that the particular resistances, capacitances, and voltages described with reference to FIG. **2**B are purely exemplary and may be suitably varied as appropriate to different configurations.

Referring now to FIG. **3**A, method **300** of using interface module **110** of FIGS. **1**A-**2**B during a tissue ablation procedure is described. The clinician couples the integrated catheter tip (ICT) **122** and indifferent electrode (IE) **140** to respective I/O ports of interface module **110** (step **301**). For example, as shown in FIG. **1**A, ICT **122** may be coupled to a first connector on front panel **111** of interface module **110** via patient interface module (PIM) **121**, and IE **140** may be coupled to a third connector on front panel **111** via indifferent electrode cable **141**. The first connector is in operable communication with first I/O port **201** (see FIG. **2**A) and the third connector is in operable communication with third I/O port **203** (see FIG. **2**A).

In method **300** of FIG. **3**A, the clinician may couple electrosurgical generator **130** to I/O port(s) of interface module **110** (step **302**). For example, as illustrated in FIG. **1**A, electrosurgical generator **130** may be coupled to a second connector on back panel **112** of interface module **110** via connection cable **135**, and also may be coupled to a fourth connector on back panel **112** via indifferent electrode cable **134**. The second connector is in operable communication with second I/O port **202** (see FIG. **2**A), and the fourth connector is in operable communication with fourth I/O port **204** (see FIG. **2**A).

In method **300** of FIG. **3**A, the clinician initiates flow of irrigant, positions ICT **122** within the subject, e.g., in the subject's heart, and positions IE **140** in contact with the subject, e.g., on the subject's back (step **303**). Those skilled in the art will be familiar with methods of appropriately positioning catheter tips relative to the heart of a subject in an ablation procedure, for example via the peripheral arterial or venous vasculature.

In method **300** of FIG. **3**A, interface module **110** receives digital radiometer, digital thermocouple, and/or analog ECG signals from the ICT, and receives ablation energy from generator **130** (step **304**), for example using the connections, ports, and pathways described above with references to FIGS. **1**A-**2**B. Preferably, generator **130** may provide such ablation energy to the interface module responsive to the clinician pressing "start" using inputs **133** on the front face of generator **130** (see FIG. **1**A).

In method **300** of FIG. **3**A, interface module **110** calculates and displays the temperature adjacent to ICT **122**, based on the radiometer and thermocouple signals (step **305**). This calculation may be performed, for example, by processor **210** based on instructions in temperature calculation module **233** stored in memory **230** (see FIG. **2**A). Exemplary methods of performing such a calculation are described in greater detail below with respect to FIG. **3**B.

In method **300** of FIG. **3**A, interface module **110** determines whether ICT **122** is in contact with tissue based on the digital radiometer signal (step **306**). For example, tissue con-

tact module **236** stored in memory **230** may cause processor **210** of interface module **110** first to identify a change in the radiometer signal. Specifically, the magnitude of the radiometer signal is a function of, among other things, the temperature of the material(s) near the radiometer and the dielectric constants of the material(s). Blood and tissue have different dielectric constants from one another. Therefore, as the clinician brings ICT **122** into or out of contact with the tissue, that is, into or out of contact with a material having a different dielectric constant than the blood, the radiometer signal varies correspondingly. If the tissue and the blood are at the same temperature as one another, then any changes to the radiometer signal may be attributed to ICT **122** coming into or out of contact with the tissue. Such changes may be viewed as a change in the magnitude (e.g., voltage) of the radiometer signal over baseline, or as a percent change in the radiometer signal over baseline, in which baseline is the magnitude of the signal when ICT **122** is in the blood and away from the tissue.

Tissue contact module **236** then may cause processor **210** of interface module **110** to compare the change in the radiometer signal to a predetermined threshold value, e.g., predetermined threshold value **235** stored in memory **230**. The predetermined threshold value preferably is selected such that changes in the radiometer signal caused by non-contact sources such as noise fall below the threshold value, while changes in the radiometer caused by tissue contact fall above the threshold value. As such, threshold values may vary from system to system, depending on the particular noise characteristics and sensitivity of the radiometer. For example, at baseline, the radiometer signal may have a noise level of about ±0.1 V. It may be determined via calibration that the radiometer signal increases to about 0.3 V above baseline when ICT **122** is brought into contact with tissue. As such, predetermined threshold value **135** suitably may be set to an intermediate magnitude between the upper end of the noise level and the average value when ICT **122** is in contact with tissue, e.g., a value in the range of about 0.11-0.29 V in the above example, e.g., 0.15 V, 0.2 V, or 0.25 V. Alternatively, the noise level of the radiometer is ±10% of baseline, and it may be determined via calibration that the radiometer signal increases by about 30% when ICT **122** is brought into contact with tissue. As such, predetermined threshold value **135** suitably may be set to an intermediate percentage between the upper end of the noise level and the average value when ICT **122** is in contact with tissue, e.g., in the range of 11-29% in the above example, e.g., 15%, 20%, or 25% in the above example.

If processor **210** of interface module **110** determines that the change in the radiometer signal is greater than stored predetermined threshold value **235**, then the processor causes tissue contact indicator **170** to indicate that there is contact between ICT **122** and the tissue. For example, processor **210** may transmit a signal to tissue contact indicator **170** that indicates that ICT **122** is in contact with tissue. Responsive to the signal, tissue contact indicator **170** generates an appropriate indicator that the clinician may perceive as meaning that ICT **122** has been brought into contact with tissue. For example, tissue contact indicator **170** may include a light that illuminates when there is tissue contact, and/or may include a speaker that generates a tone when there is tissue contact, or otherwise signal contact such as described above with reference to FIG. **1**A.

In method **300** illustrated in FIG. **3**A, interface module **110** also actuates patient relay **250** so as to provide ablation energy to ICT **122** for use in tissue ablation (step **307**). For example, processor **210** may maintain patient relay **250** illustrated in FIG. **2**A in a normally closed state during operation, such that ablation energy flows from electrosurgical generator **130** to ICT **122** through interface module **110** without delay upon the clinician's actuation of the generator, and may open patient relay **250** only upon detection of unsafe conditions such as described below with respect to FIG. **3**C. In an alternative embodiment, processor **210** may maintain patient relay **250** in a normally open state during operation, and may determine based on instructions in decision module **234** and on the temperature calculated in step **305** that it is safe to proceed with the tissue ablation, and then close patient relay so as to pass ablation energy to the ICT. In either case, after a time period defined using input **133** on the front face of generator **130**, the supply of ablation energy ceases or the clinician manually turns off the supply of ablation energy. Preferably, step **307** is executed after step **306**. That is, processor **210** preferably determines that there is tissue contact, and causes tissue contact indicator to provide an indication of such contact to the clinician, before allowing ablation energy to be provided to ICT **122** via patient relay **250**.

Interface module **110** also generates an analog version of the thermocouple signal, and provides the ECG and analog thermocouple signals to generator **130** (step **308**). Preferably, step **308** is performed continuously by the interface module throughout steps **303** through **307**, rather than just at the end of the ablation procedure. For example, as will be familiar to those skilled in the art, the Stockert EP-Shuttle or 70 RF Generator may "expect" certain signals to function properly, e.g., those signals that the generator would receive during a standard ablation procedure that did not include use of interface module **110**. The Stockert EP-Shuttle or 70 RF generator requires as input an analog thermocouple signal, and optionally may accept analog ECG signal(s). The interface module **110** thus may pass through the ECG signal(s) generated by the ICT to the Stockert EP-shuttle or 70 RF generator via second I/O port **202**. However, as described above with reference to FIG. **2**A, interface module **110** receives a digital thermocouple signal from ICT **122**. In its standard configuration, the Stockert EP-Shuttle or 70 RF generator is not configured to receive or interpret a digital thermocouple signal. As such, interface module **110** includes the functionality of reconstituting an analog version of the thermocouple signal, for example using processor **210** and opto-electronics **299**, and providing that analog signal to generator **130** via second I/O port **202**.

Turning to FIG. **3**B, the steps of method **350** of calculating radiometric temperature using digital signals from a radiometer and a thermocouple and operation parameters is described. The steps of the method may be executed by processor **210** based on temperature calculation module **233** stored in memory **230** (see FIG. **2**A). While some of the signals and operation parameters discussed below are particular to a PIM and ICT configured for use with RF ablation energy, other signals and operation parameters may be suitable for use with a PIM and ICT configured for use with other types of ablation energy. Those skilled in the art will be able to modify the systems and methods provided herein for use with other types of ablation energy.

In FIG. **3**B, processor **210** obtains from memory **230** of interface module **110** the operation parameters for the thermocouple (TC) and the radiometer (step **351**). These operation parameters may include, for example, TCSlope, which is the slope of the TC response with respect to temperature; TCOffset, which is the offset of the TC response with respect to temperature; RadSlope, which is the slope of the radiometer response with respect to temperature; TrefSlope, which is the slope of a reference temperature signal generated by the radiometer with respect to temperature; and F, which is a scaling factor.

Processor **210** then obtains via first I/O port **201** and optoelectronics **299** the raw digital signal from the thermocouple, TCRaw (step **352**), and calculates the thermocouple temperature, TCT, based on TCRaw using the following equation (step **353**):

$$TCT = \frac{TCRaw}{TCSlope} - TCOffset$$

Then, processor **210** causes temperature display **113** to display TCT until both of the following conditions are satisfied: TCT is in the range of 35° C. to 39° C., and ablation energy is being provided to the ICT (e.g., until step **307** of FIG. **3**A). There are several reasons to display only the thermocouple temperature TCT, as opposed to the temperature calculated based on signal(s) from the radiometer, until both of these conditions are satisfied. For example, if the temperature TCT measured by the thermocouple is less than 35° C., then based on instructions in decision module **234** the processor **210** interprets that temperature as meaning that ICT **122** is not positioned within a living human body, which would have a temperature of approximately 37° C. If ICT **122** is positioned in the body, power safely may be provided to the radiometer circuitry so as to obtain radiometer signal(s) that processor **210** may use to determine whether ICT **122** is in contact with tissue (e.g., step **306** of FIG. **3**A).

As illustrated in FIG. **3**B, processor **210** then provides ablation energy to ICT **122**, e.g., in accordance with step **307** described above, and receives via second I/O port **202** two raw digital signals from the radiometer: Vrad, which is a voltage generated by the radiometer based on the temperature adjacent the ICT; and Vref, which is a reference voltage generated by the radiometer (step **355**). Note that Vrad and Vref also may be provided from the radiometer at times other than when ablation energy is being provided to ICT **122**, and that Vrad and/or Vref may constitute the radiometer signal(s) used by processor **210** to determine whether ICT **122** is in contact with tissue (e.g., step **306** of FIG. **3**A).

As illustrated in FIG. **3**B, processor **210** calculates the reference temperature Tref based on Vref using the following equation (step **356**):

$$Tref = \frac{Vref}{TrefSlope} + TrefOffset$$

Processor **210** also calculates the radiometric temperature Trad based on Vrad and Tref using the following equation (step **357**):

$$Trad = \frac{Vrad}{RadSlope} - RadOffset + Tref$$

During operation of interface module **110**, processor **210** may continuously calculate TCT, and also may continuously calculate Tref and Trad during times when ablation power is provided to the ICT (which is subject to several conditions discussed further herein). Processor **210** may store in memory **230** these values at specific times and/or continuously, and use the stored values to perform further temperature calculations. For example, processor **210** may store in memory **230** TCT, Tref, and Trad at baseline, as the respective values TCBase, TrefBase, and TradBase. The processor then recalculates the current radiometric temperature TradCurrent based on the current Vrad received on second I/O port **202**, but instead with reference to the baseline reference temperature TrefBase, using the following equation (step **358**):

$$TradCurrent = \frac{Vrad}{RadSlope} - RadOffset + TrefBase$$

Processor **210** then calculates and causes temperature display **113** to display a scaled radiometric temperature TSrad for use by the clinician based on the baseline thermocouple temperature TCBase, the baseline radiometer temperature TradBase, and the current radiometer temperature TradCurrent, using the following equation (step **359**):

$$TSrad = TCBase + (TradCurrent - TradBase) \times F$$

In this manner, interface module **110** displays for the clinician's use a temperature calculated based on signal(s) from the radiometer that is based not only on voltages generated by the radiometer and its internal reference, described further below with reference to FIGS. **6**A-**6**B, but also on temperature measured by the thermocouple.

With respect to FIG. **3**C, method **360** of controlling an ablation procedure based on a temperature calculated based on signal(s) from a radiometer, e.g., as calculated using method **350** of FIG. **3**B, and also based on safety parameters **232** and decision module **234** stored in memory **230** is described.

In method **360** of FIG. **3**C, a slow flow of irrigant is initiated through the ICT and the ICT is then positioned within the subject (step **361**). For example, in embodiments for use with a Stockert 70 RF Generator, the generator may automatically initiate slow irrigant flow to the catheter tip by sending appropriate signals to a CoolFlow irrigant pumping system associated with the generator, responsive to actuation of the generator by the clinician.

After confirming that the ICT is in contact with tissue based on an indication by tissue contact indicator **170** such as described above, the clinician presses a button on the generator to start the flow of ablation energy to the ICT; this may cause the generator to initiate a high flow of irrigant to the ICT and generation of ablation energy following a 5 second delay (step **362**). The interface module passes the ablation energy to the ICT via the patient relay, as described above with respect to step **306** of FIG. **3**A.

Based on the calculated and displayed radiometric temperature (see methods **300** and **350** described above with respect to FIGS. **3**A-**3**B), the clinician determines the temperature of the tissue volume that is being ablated by the ablation energy (step **363**). By comparison, temperature measured by a thermocouple alone would provide little to no useful information during this stage of the procedure.

Interface module **110** may use the calculated radiometric temperature to determine whether the ablation procedure is being performed within safety parameters. For example, processor **210** may obtain safety parameters **232** from memory **230**. Among other things, these safety parameters may include a cutoff temperature above which the ablation procedure is considered to be "unsafe" because it may result in perforation of the cardiac tissue being ablated, with potentially dire consequences. The cutoff temperature may be any suitable temperature below which one or more unsafe conditions may not occur, for example "popping" such as described below with respect to FIGS. **4**D-**4**E, or tissue burning, but at which the tissue still may be sufficiently heated. One example

of a suitable cutoff temperature is 85° C., although higher or lower cutoff temperatures may be used, e.g., 65° C., 70° C., 75° C., 80° C., 90° C., or 95° C. Instructions in decision module **234**, also stored in memory **230**, cause processor **210** to continuously compare the calculated radiometric temperature to the cutoff temperature, and if the radiometric temperature exceeds the cutoff temperature, the processor may set an alarm, open the patient relay, and close the load relay so as to return power to the IE via I/O port **204**, thereby cutting off flow of ablation energy to the ICT (step **364** of FIG. **3**C). Otherwise, the processor may allow the ablation procedure to proceed (step **364**).

The ablation procedure terminates (step **365**), for example, when the clinician presses the appropriate button on generator **130**, or when the generator **130** automatically cuts of ablation energy at the end of a predetermined period of time.

Referring now to FIGS. **4**A-**4**E, illustrative data obtained during experiments using an interface module constructed in accordance with the present invention is described. This data was obtained using an unmodified Stockert EP Shuttle Generator with integrated irrigation pump, and a catheter including the PIM **121** and ICT **122** described further below with reference to FIGS. **5**A-**6**B coupled to interface module **110**.

FIG. **4**A illustrates the change over time in various signals collected during a procedure in which the ablative tip of ICT **122** was immersed into a tank of saline containing a tissue sample that were maintained at a constant temperature of about 49.5° C. and had dielectric constants similar to that of living blood and tissue, respectively. The ablative tip of ICT **122** was manually brought into and out of contact with the tissue several times. Signal **401** illustrated in FIG. **4**A corresponds to radiometer signal Vrad (having units of Volts, right side y-axis of graph) signal **402** corresponds to the thermocouple temperature (having units of ° C., left side y-axis of graph), and signal **403** corresponds to display temperature Tdisplay (also having units of ° C., left side y-axis of graph). Signals **401**, **402**, and **403** were collected without actuating the Stockert EP Shuttle Generator, so that changes in Vrad as ICT **122** was brought into contact with the tissue could be attributed to the difference between the dielectric constants of the saline and the tissue, rather than to changes in temperature.

As can be seen in FIG. **4**A, radiometer signal **401** begins at a baseline **404** around 2.95 V; the particular value of this baseline depends, among other things, on the dielectric constant and temperature of the saline in which ICT **122** is immersed, and the sensitivity of the radiometer. Radiometer signal **401** has a noise level **405** of about ±0.05 V about baseline **404**, which may be attributed to random noise in the radiometer electronics. During the time periods between about 20-32 seconds, 40-52 seconds, 60-72 seconds, and 80-92 seconds, radiometer signal **401** may be seen to rapidly increase from baseline **404** to a higher level **406** around 3.37 V. Because the tissue is at the same temperature as the saline, the change in radiometer signal **401** to level **406** may be attributed to the different dielectric constant of the tissue as compared to the saline. As such, contact between ICT **122** and the tissue in the tank readily may be identified based on changes in radiometer signal from baseline **404** to level **406**. Additionally, based on such observations a predetermined threshold value **407** may be defined that lies between the upper end of noise **405** and level **406** indicative of tissue contact, and that may be stored in memory **230** and used by processor **210** of interface module **110** at a later time to determine whether ICT **122** is in contact with tissue. Thus, in essence, such a procedure calibrates the ICT **122** with regards to tissue contact. Preferably, the temperature and the dielectric constants of the materials used during such a calibration are selected to be relatively similar to those of blood and tissue of a human, so that baseline **404**, level **406**, and predetermined threshold value **407** are based on the expected temperatures and dielectric constants measured by the radiometer during an actual ablation procedure.

FIG. **4**B illustrates the change over time in various signals collected during an ablation procedure in which ICT **122** was placed against exposed thigh tissue of a living dog, and the Stockert EP Shuttle generator actuated so as to apply 20 W of RF energy for 60 seconds. A Luxtron probe was also inserted at a depth of 3 mm into the dog's thigh. Luxtron probes are considered to provide accurate temperature information, but are impractical for normal use in cardiac ablation procedures because such probes cannot be placed in the heart of a living being.

FIG. **4**B illustrates the change over time in various signals collected during the ablation procedure. Signal **410** corresponds to scaled radiometric temperature TSrad; signal **420** corresponds to the thermocouple temperature; signal **430** corresponds to a temperature measured by the Luxtron probe; and signal **440** corresponds to the power generated by the Stockert EP Shuttle Generator.

As can be seen from FIG. **4**B, power signal **440** indicates that RF power was applied to the subject's tissue beginning at a time of about 40 seconds and ending at a time of about 100 seconds. Radiometric temperature signal **410** indicates a sharp rise in temperature beginning at about 40 seconds, from a baseline in region **411** of about 28° C. to a maximum in region **412** of about 67° C., followed by a gradual fall in region **413** beginning around 100 seconds. The features of radiometric temperature signal **410** are similar to those of Luxtron probe signal **430**, which similarly shows a temperature increase beginning around 40 seconds to a maximum value just before 100 seconds, and then a temperature decrease beginning around 100 seconds. This similarity indicates that the radiometric temperature has similar accuracy to that of the Luxtron probe. By comparison, thermocouple signal **420** shows a significantly smaller temperature increase beginning around 40 seconds, followed by a low-level plateau in the 40-100 second region, and then a decrease beginning around 100 seconds. The relatively weak response of the thermocouple, and the relatively strong and accurate response of the Luxtron thermocouple, indicate that an unmodified Stockert EP Shuttle Generator successfully may be retrofit using interface module **110** constructed in accordance with the principles of the present invention to provide a clinician with useful radiometric temperature information for use in an ablation procedure.

FIG. **4**C illustrates signals obtained during a similar experimental procedure, but in which two Luxtron probes were implanted into the animal's tissue, the first at a depth of 3 mm and the second at a depth of 7 mm. The Stockert EP Shuttle generator was activated, and the RF power was manually modulated between 5 and 50 W using the power control knob on the front panel of the generator. In FIG. **4**C, the radiometer signal is designated **460**, the 3 mm Luxtron designated **470**, and the 7 mm Luxtron designated **480**. The radiometer and 3 mm Luxtron signals **460**, **470** may be seen to have relatively similar changes in amplitude to one another resulting from the periodic heating of the tissue by RF energy. The 7 mm Luxtron signal **480** may be seen to have a slight periodicity, but far less modulation than do the radiometer and 3 mm Luxtron signals **460**, **470**. This is because the 7 mm Luxtron is sufficiently deep within the tissue that ablation energy substantially does not directly penetrate at that depth. Instead, the tissue at 7 mm may be seen to slowly warm as a function

of time, as heat deposited in shallower portions of the tissue gradually diffuses to a depth of 7 mm.

A series of cardiac ablation procedures were also performed in living humans using the experimental setup described above with respect to FIGS. **4**B-**4**C, but omitting the Luxtron probes. The humans all suffered from atrial flutter, were scheduled for conventional cardiac ablation procedures for the treatment of same, and consented to the clinician's use of the interface box and ICT during the procedures. The procedures were performed by a clinician who introduced the ICT into the individuals' endocardia using conventional methods. During the procedures, the clinician was not allowed to view the temperature calculated by the interface module. As such, the clinician performed the procedures in the same manner as they would have done with a system including a conventional RF ablation catheter directly connected to a Stockert EP-Shuttle generator. The temperature calculated by the interface module during the various procedures was made available for the clinician to review at a later time. The clinician performed a total of 113 ablation procedures on five humans using the above-noted experimental setup.

FIGS. **4**D-**4**E illustrate data obtained during sequential ablation procedures performed on a single individual using the experimental setup. Specifically, FIG. **4**D illustrates the change over time in the signal **415** corresponding to the scaled radiometric temperature TSrad, as well as the change over time in the signal **421** corresponding to the thermocouple temperature, during the tenth ablation procedure performed on the individual. During the procedure, about 40 W of RF power was applied to the individual's cardiac tissue for 60 seconds (between about 20 seconds and 80 seconds in FIG. **4**D), and the clinician had a target temperature **445** of 55° C. to which it was desired to heat the cardiac tissue so as to sufficiently interrupt an aberrant pathway causing the individual's atrial flutter. It can be seen that the scaled radiometric temperature signal **415**, which was subjected to data smoothing in FIG. **4**D, varied between about 40° C. and 51° C. while RF power was applied. By comparison, as expected, the thermocouple temperature **421** provided essentially no useful information about the tissue temperature during the procedure. Notably, the clinician's target temperature **445** of 55° C. was never reached during the procedure, even though the clinician believed based on his or her perceptions of the procedure that such temperature had been reached. Because the target temperature **445** was not reached, the tissue was insufficiently heated during the procedure to interrupt an aberrant pathway. The failure to reach the target temperature may be attributed to insufficient contact or force between the ablative tip of the ICT and the individual's cardiac tissue, the condition of the cardiac surface, insufficient power, and the like.

FIG. **4**E illustrates the change over time in signal **416** corresponding to TSrad, as well as the change over time in the signal **422** corresponding to the thermocouple temperature, during the eleventh ablation procedure performed on the same individual as in FIG. **4**D. During this procedure, again about 40 W of RF power was applied to the individual's cardiac tissue for 60 seconds (between about 20 seconds and 80 seconds in FIG. **4**E), and the clinician again had a target temperature **445** of 55° C. It can be seen that the scaled radiometric signal **416**, again subject to data smoothing, varied between about 55° C. and 70° C. while RF power was applied, while the thermocouple temperature **421** again provided essentially no useful information. Here, the clinician attributed the higher temperature tissue temperature achieved during the ablation to better contact between the ablative tip of the ICT and the individual's cardiac tissue. However, it can be seen that even while RF power was being applied to the tissue, the temperature varied relatively rapidly over time, e.g., from about 70° C. at about 35 seconds, to about 56° C. at 40 seconds, which may be attributed to variations in the quality of contact between the ICT and the individual's cardiac tissue.

The results of the ablation procedures performed on the five individuals are summarized in the following table:

	Total	% of Total Ablation
Number of patients	5	
Number of ablations	113	
Number of ablations that did not reach target temperature of 55° C.	50	44%
Number of ablations that reached high temperature cutoff of 95° C.	13	12%
Number of pops	3	3%
Number of successful treatments of atrial flutter	5	100%

As can be seen from the above table, 44% of the ablation procedures did not reach the clinician's target tissue temperature of 55° C. As such, it is likely that this percentage of the procedures resulted in insufficient tissue heating to interrupt aberrant pathway(s). However, although many of the ablation procedures failed, the clinician repeated the ablation procedures a sufficient number of times to achieve 100% treatment of the individuals' atrial flutter. It is believed that displaying the calculated temperature to the clinician during ablation procedures would enable the clinician to far more accurately assess the quality of contact between the ablative tip of the ICT and the individual's cardiac tissue, and thus to sufficiently heat the tissue above the target temperature for a desired period of time, and thus reduce the clinicians' need to repeatedly perform numerous ablation procedures on the same subject so as to achieve the desired treatment.

As shown in the above table, 12% of the ablation procedures triggered the high temperature cutoff such as illustrated in FIG. **3**C. Here, the cutoff temperature was defined to be 95° C. However, it was observed that at this cutoff temperature, "pops" formed during three of the ablation procedures. A "pop" occurs when the blood boils because of excessive localized heating caused by ablation energy, which results in formation of a rapidly expanding bubble of hot gas that may cause catastrophic damage to the cardiac tissue. It is believed that a lower cutoff temperature, e.g., 85° C., may inhibit formation of such "pops."

Additional components that may be used in conjunction with interface module **110** of the present invention, e.g., PIM **121** and ICT **122** of catheter **120**, are now briefly described with reference to FIGS. **5**A-**6**B.

In FIG. **5**A, patient interface module (PIM) **121** that may be associated with the integrated catheter tip (ICT) described further below with respect to FIGS. **6**A-**6**B is described. PIM **121** includes interface module connector **501** that may be connected to front panel **111** of interface module **110**, as described with reference to FIG. **1**A; PIM circuitry **502**, which will be described in greater detail below with reference to FIG. **5**B; ICT connector **503** that may be connected to catheter **120**; and PIM cable **504** that extends between interface module connector **501** and PIM circuitry **502**. PIM **121** is preferably, but not necessarily, designed to remain outside the sterile field during the ablation procedure, and optionally is reusable with multiple ICT's.

FIG. **5**B schematically illustrates internal components of PIM circuitry **502**, and includes first I/O port **505** configured to be coupled to catheter **120**, e.g., via ICT connector **503**, and second I/O port **506** configured to be coupled to interface module **110**, e.g., via PIM cable **504** and interface module connector **501**.

PIM circuitry **502** receives on first I/O port **505** an analog thermocouple (TC) signal, raw analog radiometer signals, and analog ECG signals from catheter **120**. PIM circuitry **502** includes TC signal analog-to-digital (A/D) converter **540** that is configured to convert the analog TC signal to a digital TC signal, and provide the digital TC signal to interface module **110** via second I/O port **506**. PIM circuitry **502** includes a series of components configured to convert the raw analog radiometer signals into a usable digital form. For example, PIM circuitry may include radiometric signal filter **510** configured to filter residual RF energy from the raw analog radiometer signals; radiometric signal decoder **520** configured to decode the filtered signals into analog versions of the Vref and Vrad signals mentioned above with reference to FIG. **3**B; and radiometric signal A/D converter **530** configured to convert the analog Vref, Vrad signals into digital Vref, Vrad signals and to provide those digital signals to second I/O port for transmission to interface module **110**. PIM circuitry **502** also passes through the ECG signals to second I/O port **506** for transmission to interface module **110**.

On second I/O port **506**, PIM circuitry **502** receives RF ablation energy from generator **130** (e.g., a Stockert EP-Shuttle or 70 RF Generator) via interface module **110**. PIM circuitry **502** passes that RF ablation energy through to catheter **120** via first I/O port **505**. PIM circuitry **502** also receives on second I/O port **506** a clock signal generated by RF circuitry within interface module **110**, as described further above with reference to FIG. **2**B, and passes through the clock signal to first I/O port **505** for use in controlling microwave circuitry in ICT **122**, as described below.

Referring now to FIGS. **6**A-**6**B, an exemplary integrated catheter tip (ICT) **122** for use with the interface module **110** of FIGS. **1**A-**2**B and the PIM of FIGS. **5**A-**5**B is described. Further detail on components of ICT **122** may be found in U.S. Pat. No. 7,769,469 to Carr, the entire contents of which are incorporated herein by reference, as well as in U.S. Patent Publication No. 2010/0076424, also to Carr ("the Carr publication"), the entire contents of which are incorporated herein by reference. The device described in the aforementioned patent and publication do not include a thermocouple or ECG electrodes, which preferably are included in ICT **122** configured for use with interface module **110**.

As described in the Carr publication and as depicted in FIGS. **6**A-**6**B, ICT **122** includes an inner or center conductor **103** supported by a conductive carrier or insert **104**. Carrier **104** may be formed from a cylindrical metal body having an axial passage **106** that receives conductor **103**. Upper and lower sectors of that body extending inward from the ends may be milled away to expose passage **106** and conductor **103** therein and to form upper and lower substantially parallel flats **108***a* and **108***b*. Flat **108***a* may include coplanar rectangular areas **108***aa* spaced on opposite sides of conductor **103** near the top thereof. Likewise, flat **108***b* may include two coplanar rectangular areas **108***bb* spaced on opposite sides of conductor **103** near the bottom thereof. Thus, carrier **104** may include center segment **104***a* containing the flats and distal and proximal end segments **104***b* and **104***c*, respectively, which remain cylindrical, except that a vertical groove **107** may be formed in proximal segment **104***c*.

Center conductor **103** may be fixed coaxially within passage **106** by means of an electrically insulating collar or bushing **109**, e.g. of PTFE, press fit into passage **106** at distal end segment **104***b* of the carrier and by a weld to the passage wall or by an electrically conductive collar or bushing (not shown) at the carrier proximal segment **104***c*. This causes a short circuit between conductor **103** and carrier **104** at the proximal end of the carrier, while an open circuit may be present therebetween at the distal end of the carrier. In the carrier center segment **104***a*, the walls **106***a* of passage **106** may be spaced from center conductor **103**. This forms a quarter wave stub S, as described in greater detail in U.S. Pat. No. 7,769,469 and U.S. Patent Publication No. 2010/0076424. Conductor **103** includes distal end segment **103***a* which extends beyond the distal end of carrier **104** a selected distance, and a proximal end segment **103***b* which extends from the proximal end of ICT **122** and connects to the center conductor of cable **105** configured to connect to PIM **121**.

As illustrated in FIG. **6**B, mounted to the upper and lower flats **108***a* and **108***b* of carrier **104** is a pair of opposed, parallel, mirror-image, generally rectangular plates **115***a* and **115***b*. Each plate **115***a*, **115***b* may include a thin, e.g. 0.005 in., substrate **116** formed of an electrically insulating material having a high dielectric constant. Printed, plated or otherwise formed on the opposing or facing surfaces of substrates **116** are axially centered, lengthwise conductive strips **117**, preferably 0.013-0.016 mm wide, which extend the entire lengths of substrates **116**. Also, the opposite or away-facing surfaces of substrates **116** are plated with conductive layers **118**, e.g. of gold. The side edges of layers **118** wrap around the side edges of the substrates.

When the ICT is being assembled, plate **115***a* may be seated on the upper flat **108***a* of carrier **104** and the lower plate **115***b* is likewise seated on the lower flat **108***b* so that the center conductor **103** is contacted from above and below by the conductive strips **117** of the upper and lower plates and the layer **118** side edges of those plates contact carrier segment **104***a*. A suitable conductive epoxy or cement may be applied between those contacting surfaces to secure the plates in place.

At least one of the plates, e.g. plate **115***a*, functions also as a support surface for one or more monolithic integrated circuit chips (MMICs), e.g. chips **122** and **124**. The chip(s) may include a coupling capacitor connected by a lead (not shown) to center conductor **103** and the usual components of a radiometer such as a Dicke switch, a noise source to provide a reference temperature, amplifier stages, a band pass filter to establish the radiometer bandwidth, additional gain stages if needed, a detector and buffer amplifier. Due to the relatively small profile of the present ICT **122**, the above circuit components may be arranged in a string of four chips. The chip(s) may be secured to the metal layer **118** of plate **115***a* by a suitable conductive adhesive so that that layer which, as described above, is grounded to the insert **104** may function as a ground plane for those chips. The plates also conduct heat away from the chips to conductor **103** and carrier **104**. Various leads (not shown) connect the chips to each other and other leads **125***b* extend through carrier slot **107** and connect the last chip **124** in the string, i.e. the radiometer output, to corresponding conductors of cable **105** leading to PIM **121**.

A tubular outer conductor **126** may be slid onto carrier **104** from an end thereof so that it snugly engages around the carrier with its proximal and distal ends coinciding with the corresponding ends of the carrier (not shown). The conductor **126** may be fixed in place by a conductive epoxy or cement applied around the carrier segments **104***b* and **104***c*.

ICT **122** also may include an annular dielectric spacer **137**, e.g. of PTFE, which is centered on the distal end of carrier **104** and surrounds the conductor segment **103***a*. The spacer may

have a slit **137***a* enabling it to be engaged around that conductor segment from the side thereof. The spacer **137** may be held in place by a conductive collar **136** which encircles the spacer and is long enough to slidably engage over a distal end segment of outer conductor **126**. The collar **136** may be press fit around that conductor and carrier segment **104***b* to hold it in place and to electrically connect all those elements.

The distal end of the ICT **122** may be closed off by conductive tip **142** which, in axial section, may be T shaped. That is, the tip **142** may have discoid head **142***a* that forms the distal end of the ICT and an axially extending tubular neck **142***b*. The conductor segment **103***a* is sufficiently long to extend beyond the distal end of the spacer **137** into the axial passage in neck **104***b*. The tip may be secured in place by conductive adhesive applied around the distal end of conductor segment **103***a* and at the distal end or edge of collar **136**. When the tip is in place, the conductor segment **103***a* and tip **104** form a radiometric receiving antenna, as described in greater detail in U.S. Pat. No. 7,769,469 and U.S. Patent Publication No. 2010/0076424.

ICT **122** may further include dielectric sheath **144** which may be engaged over the rear end of outer conductor **126** and slid forwardly until its distal end **144***a* is spaced a selected distance behind the distal end of tip **142**. The conductors **103** and **126** of ICT **122** form an RF transmission line terminated by the tip **104**. When the ICT **122** is operative, the transmission line may radiate energy for heating tissue only from the uninsulated segment of the probe between tip **104** and the distal end **144***a* of the sheath **144**. That segment thus constitutes an RF ablation antenna.

The proximal ends of the center conductor segment **103***b*, outer conductor **126** and sheath **144** may be connected, respectively, to the inner and outer conductors and outer sheath of cable **105** that leads to PIM **121**. Alternatively, those elements may be extensions of the corresponding components of cable **105**. In any event, that cable **105** connects the center conductor **103** to the output of a transmitter which transmits a RF heating signal at a selected heating frequency, e.g. 500 GHz, to the RF ablation antenna.

As illustrated in FIG. **6**A, ICT **122** further may include first, second, and third ECG electrodes **190** disposed on the outside of sheath **144**, as well as a thermocouple **191** positioned so as to detect the temperature of blood or tissue in contact with ICT **122**. Signals generated by electrodes **190** and thermocouple **191** may be provided along cable **105** connected to PIM **121**.

If desired, cable **105** further may include probe steering wire **145** whose leading end **145***a* may be secured to the wall of a passage **146** in carrier segment **104***c*.

Preferably, helical through slot **147** is provided in collar **136** as shown in FIGS. **6**A-**6**B. The collar material left between the slot turns essentially forms helical wire **148** that bridges spacer **137**. Wire **148** is found to improve the microwave antenna pattern of the radiometric receiving antenna without materially degrading the RF heating pattern of the RF ablation antenna.

The inner or center conductor **103** may be a solid wire, or preferably is formed as a tube that enables conductor **103** to carry an irrigation fluid or coolant to the interior of probe tip **142** for distribution therefrom through radial passages **155** in tip head **142***a* that communicate with the distal end of the axial passage in tip neck **142***b*.

When plates **115***a* and **115***b* are seated on and secured to the upper and lower flats **108***a* and **108***b*, respectively, of carrier **104**, conductive strips **117**, **117** of those members may be electrically connected to center conductor **103** at the top and bottom thereof so that conductor **103** forms the center conducts for of a slab-type transmission line whose ground plane includes layers **118**, **118**.

When ablation energy is provided to ICT **122**, a microwave field exists within the substrate **116** and is concentrated between the center conductor **103** and layers **118**, **118**. Preferably, as noted here, conductive epoxy is applied between conductor **103** and strips **117** to ensure that no air gaps exist there because such a gap would have a significant effect on the impedance of the transmission line as the highest field parts are closest to conductor **103**.

Plates **115***a*, **115***b* and conductor **103** segment together with carrier **104** form a quarter wave ($\lambda_R/4$) stub S that may be tuned to the frequency of radiometer circuit **124**, e.g. 4 GHz. The quarter wave stub S may be tuned to the center frequency of the radiometer circuit along with components in chips **122**, **124** to form a low pass filter in the signal transmitting path to the RF ablation antenna, while other components of the chips form a high pass or band pass filter in the signal receiving path from the antenna to the radiometer. The combination forms a passive diplexer D which prevents the lower frequency transmitter signals on the signal transmitting path from antenna T from reaching the radiometer, while isolating the path to the transmitter from the higher frequency signals on the signal receiving path from the antenna.

The impedance of the quarter wave stub S depends upon the K value and thickness t of substrates **116** of the two plates **115***a*, **115***b* and the spacing of center conductor **103** from the walls **106***a*, **106***a* of passage **106** in the carrier center segment **104***a*. Because the center conductor **103** is not surrounded by a ceramic sleeve, those walls can be moved closer to the center conductor, enabling accurate tuning of the suspended substrate transmission line impedance while minimizing the overall diameter of the ICT **122**. As noted above, the length of the stub S may also be reduced by making substrate **116** of a dielectric material which has a relatively high K value.

In one working embodiment of the ICT **122**, which is only about 0.43 in. long and about 0.08 in. in diameter, the components of the ICT have the following dimensions:

Component	Dimension (inches)
Conductor 103	0.020 outer diameter 0.016 inner diameter (if hollow)
Substrate 116 (K = 9.8)	0.065 wide; thickness t = 0.005
Strips 117	0.015 wide
Air gap between 103 and each 106a	0.015

Thus, the overall length and diameter of the ICT **122** may be relatively small, which is a useful feature for devices configured for percutaneous use.

While various illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made herein without departing from the invention. For example, although the interface module has primarily been described with reference for use with an RF electrosurgical generator and the PIM and ICT illustrated in FIGS. **5**A-**6**B, it should be understood that the interface module suitably may be adapted for use with other sources of ablation energy and other types of radiometers. Moreover, the radiometer may have components in the ICT and/or the PIM, and need not necessarily be located entirely in the ICT. Furthermore, the functionality of the radiometer, ICT, and/or PIM optionally may be included in the interface module. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

What is claimed is:

1. A method of determining contact between a medical instrument and tissue of a subject, comprising:

determining whether a radiofrequency electrode positioned at a distal end of a catheter is in contact with tissue based on tissue properties determined from a signal generated by a radiometer positioned at the distal end of the catheter before activating the radio frequency electrode; and

causing energy to be delivered to the tissue by activating the radiofrequency electrode after determining that the radiofrequency electrode is in contact with the tissue.

2. The method of claim 1, wherein the tissue properties comprise differences in electrical properties between blood and tissue.

3. The method of claim 1, further comprising generating an output indicating that the radiofrequency electrode is in contact with the tissue.

4. The method of claim 3, further comprising regulating operation of the radiofrequency electrode based on said output.

5. The method of claim 1, further comprising providing a visual or audible confirmation of contact between the radiofrequency electrode and the tissue.

6. The method of claim 1, further comprising monitoring electrical activity using an electrophysiology monitoring system.

7. The method of claim 1, further comprising delivering irrigation fluid to a fluid passage of the catheter and through at least one irrigation fluid port positioned at a tip of the catheter to cool tissue adjacent the radiofrequency electrode.

8. A method of determining contact between a medical instrument and tissue of a subject, comprising:

determining whether an energy delivery member of a medical instrument is in contact with tissue based on tissue properties determined from a signal generated by a radiometer positioned at a distal end of the medical instrument before activating the energy delivery member; and

causing energy to be delivered to the tissue by activating the energy delivery member after determining that the energy delivery member is in contact with the tissue.

9. The method of claim 8, wherein the tissue properties comprise differences in electrical properties between blood and tissue.

10. The method of claim 8, further comprising generating an output indicating that the energy delivery member is in contact with the tissue.

11. The method of claim 10, further comprising regulating operation of the energy delivery member based on said output.

12. The method of claim 8, further comprising providing a visual or audible confirmation of contact between the energy delivery member and the tissue.

13. The method of claim 8, further comprising monitoring electrical activity using an electrophysiology monitoring system.

14. The method of claim 8, further comprising delivering irrigation fluid to a fluid passage of the medical instrument and through at least one irrigation fluid port of the medical instrument to cool tissue adjacent the energy delivery member.

15. The method of claim 8, wherein the energy delivery member comprises one of a radiofrequency electrode, a microwave energy delivery member, and an ultrasound energy delivery member.

16. A method of determining contact between a medical instrument and tissue of a subject, comprising:

determining whether a medical instrument is in contact with tissue based on tissue properties determined from a signal generated by a radiometer carried by the medical instrument; and

generating an output indicating that a portion of the medical instrument is in contact with the tissue, prior to activating an energy delivery member of the medical instrument.

17. The method of claim 16, further comprising activating the energy delivery member of the medical instrument after the output is generated.

18. The method of claim 16, wherein the energy delivery member comprises a radiofrequency electrode, the method further comprising activating the radiofrequency electrode of the medical instrument after the output is generated to deliver energy to the tissue sufficient to ablate the tissue.

19. The method of claim 16, further comprising regulating operation of the medical instrument based on said output.

20. The method of claim 16, further comprising providing a visual or audible confirmation of contact between the portion of the medical instrument and the tissue.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	: 9,014,814 B2
APPLICATION NO.	: 14/274438
DATED	: April 21, 2015
INVENTOR(S)	: John F. McCarthy

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

In Column 1, (page 1, Item (71) Applicant) at Line 2, Change "Menlo Park," to --Santa Clara,--.

Signed and Sealed this

Seventh Day of February, 2017

Michelle K. Lee

Michelle K. Lee

Director of the United States Patent and Trademark Office

专利名称(译)	基于辐射信号确定组织接触的方法		
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申请(专利权)人(译)	高级心脏THERAPUTICS，INC.		
当前申请(专利权)人(译)	高级心脏治疗学，INC. MERIDIAN医疗系统有限责任公司		
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其他公开文献	US20140249521A1		
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摘要(译)

提供了用于在向组织递送能量之前和/或期间检测组织接触的方法和系统。例如，该方法可以包括基于从辐射计接收的信号计算温度和检测组织接触。辐射计可以提供关于治疗装置是否与组织接触的信息，并因此提供反馈以帮助临床医生正确地接触和治疗组织。