United States Patent	12390263
Kind Code	B2
Date of Patent	August 19, 2025
Inventor(s)	Jarrard; Jerry

System and method for controlling power based on impedance detection, such as controlling power to tissue treatment devices

Abstract

A system and method of controlling the application of energy to tissue using measurements of impedance are described. The impedance, correlated to the temperature, may be set at a desired level, such as a percentage of initial impedance. The set impedance may be a function of the initial impedance, the size and spacing of the electrodes, the size of a targeted passageway, and so on. The set impedance may then be entered into a PID algorithm or other control loop algorithm in order to extract a power to be applied to a treatment device.

Inventors: **Jarrard; Jerry (San Jose, CA)**

Applicant: **Boston Scientific Scimed, Inc.** (Maple Grove, MN)

Family ID: **1000008765171**

Assignee: **Boston Scientific Scimed, Inc. (Maple Grove, MN)**

Appl. No.: **18/057863**

Filed: **November 22, 2022**

Prior Publication Data

Document Identifier	Publication Date
US 20230098737 A1	Mar. 30, 2023

Related U.S. Application Data

continuation parent-doc US 16364518 20190326 US 11534229 child-doc US 18057863
continuation parent-doc US 14799346 20150714 US 10278765 20190507 child-doc US 16364518
continuation parent-doc US 12179301 20080724 US 9108052 20150818 child-doc US 14799346
us-provisional-application US 60951655 20070724

Publication Classification

Int. Cl.: **A61B18/12** (20060101); **A61B18/14** (20060101); **A61N1/32** (20060101); **A61N1/36** (20060101); A61B18/00 (20060101)

U.S. Cl.:

CPC **A61B18/1233** (20130101); **A61B18/1206** (20130101); **A61B18/14** (20130101); **A61B18/1492** (20130101); **A61N1/32** (20130101); **A61N1/36128** (20130101); A61B2018/00214 (20130101); A61B2018/00267 (20130101); A61B2018/00541 (20130101); A61B2018/00577 (20130101); A61B2018/00595 (20130101); A61B2018/00642 (20130101); A61B2018/00702 (20130101); A61B2018/00791 (20130101); A61B2018/00875 (20130101); A61B2018/00898 (20130101); A61N1/36146 (20130101)

Field of Classification Search

CPC: A61B (18/1233); A61B (18/1206); A61B (18/14); A61B (18/1492); A61B (2018/00898); A61B (2018/00214); A61B (2018/00875); A61N (1/32); A61N (1/36128); A61N (1/36146)

References Cited

U.S. PATENT DOCUMENTS

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
4739759	12/1987	Rexroth et al.	N/A	N/A
4907589	12/1989	Cosman	N/A	N/A
5425023	12/1994	Haraguchi et al.	N/A	N/A
5496312	12/1995	Klicek	N/A	N/A
5540681	12/1995	Strul et al.	N/A	N/A
5562721	12/1995	Marchlinski et al.	N/A	N/A
5688267	12/1996	Panescu et al.	N/A	N/A
5702386	12/1996	Stern et al.	N/A	N/A
5735846	12/1997	Panescu et al.	N/A	N/A
5743903	12/1997	Stern et al.	N/A	N/A
5782827	12/1997	Gough et al.	N/A	N/A
5837001	12/1997	Mackey	N/A	N/A
5931835	12/1998	Mackey	N/A	N/A
5957961	12/1998	Maguire et al.	N/A	N/A
6033399	12/1999	Gines	N/A	N/A
6063078	12/1999	Wittkampf	N/A	N/A
6071281	12/1999	Burnside et al.	N/A	N/A
6092528	12/1999	Edwards	N/A	N/A
6104954	12/1999	Blunsden	N/A	N/A
6123702	12/1999	Swanson et al.	N/A	N/A
6183468	12/2000	Swanson et al.	N/A	N/A
6245065	12/2000	Panescu et al.	N/A	N/A
6264653	12/2000	Falwell	N/A	N/A
6283987	12/2000	Laird et al.	N/A	N/A

6346104	12/2001	Daly et al.	N/A	N/A
6355031	12/2001	Edwards et al.	N/A	N/A
6411852	12/2001	Danek et al.	N/A	N/A
6423057	12/2001	He	606/49	A61B 18/1206
6458121	12/2001	Rosenstock et al.	N/A	N/A
6488679	12/2001	Swanson et al.	N/A	N/A
6494880	12/2001	Swanson et al.	N/A	N/A
6558378	12/2002	Sherman et al.	N/A	N/A
6575969	12/2002	Rittman, III et al.	N/A	N/A
6588267	12/2002	Bradley	N/A	N/A
6634363	12/2002	Danek et al.	N/A	N/A
6635056	12/2002	Kadhiresan et al.	N/A	N/A
6640119	12/2002	Budd	600/382	A61B 5/6858
6733498	12/2003	Paton et al.	N/A	N/A
6939346	12/2004	Kannenberg et al.	N/A	N/A
7027869	12/2005	Danek et al.	N/A	N/A
7104987	12/2005	Biggs et al.	N/A	N/A
7131445	12/2005	Amoah	N/A	N/A
7160296	12/2006	Pearson et al.	N/A	N/A
7367972	12/2007	Francischelli et al.	N/A	N/A
11534229	12/2021	Jarrard	N/A	A61N 1/36128
2003/0050631	12/2002	Mody et al.	N/A	N/A
2003/0069570	12/2002	Witzel et al.	N/A	N/A
2003/0093069	12/2002	Panescu et al.	N/A	N/A
2003/0130711	12/2002	Pearson et al.	N/A	N/A
2003/0153905	12/2002	Edwards et al.	N/A	N/A
2003/0187430	12/2002	Vorisek	N/A	N/A
2003/0199863	12/2002	Swanson et al.	N/A	N/A
2003/0236455	12/2002	Swanson et al.	N/A	N/A
2004/0010289	12/2003	Biggs et al.	N/A	N/A
2004/0015162	12/2003	Mcgaffigan	N/A	N/A
2004/0031494	12/2003	Danek	128/898	A61B 18/00
2004/0153056	12/2003	Muller et al.	N/A	N/A
2005/0010270	12/2004	Laufer	N/A	N/A
2005/0096644	12/2004	Hall et al.	N/A	N/A
2005/0101948	12/2004	Harano et al.	N/A	N/A
2005/0137662	12/2004	Morris et al.	N/A	N/A
2005/0177210	12/2004	Leung et al.	N/A	N/A
2005/0193279	12/2004	Daners	N/A	N/A
2005/0251128	12/2004	Amoah	N/A	N/A
2006/0079887	12/2005	Buysse et al.	N/A	N/A
2006/0106375	12/2005	Werneth et al.	N/A	N/A
2006/0142801	12/2005	Demarais et al.	N/A	N/A
2006/0247726	12/2005	Biggs et al.	N/A	N/A
2006/0247727	12/2005	Biggs et al.	N/A	N/A
2006/0247746	12/2005	Danek	607/115	A61N 1/403
2007/0074719	12/2006	Danek et al.	N/A	N/A

2007/0106292	12/2006	Kaplan et al.	N/A	N/A
2007/0118184	12/2006	Danek et al.	N/A	N/A
2008/0097424	12/2007	Wizeman et al.	N/A	N/A
2008/0103407	12/2007	Bolea et al.	N/A	N/A

FOREIGN PATENT DOCUMENTS

Patent No.	Application Date	Country	CPC
908713	12/1998	EP	N/A
59167707	12/1983	JP	N/A
2001037776	12/2000	JP	N/A
2002065691	12/2001	JP	N/A
2002541905	12/2001	JP	N/A
2004516867	12/2003	JP	N/A
2008526463	12/2007	JP	N/A
WO-9424949	12/1993	WO	N/A
WO-1999003413	12/1998	WO	N/A
WO-2006078863	12/2005	WO	N/A

OTHER PUBLICATIONS

Cantwell C. P., et al., “MRI MRI Features after Radiofrequency Ablation of Osteoid Osteoma with Cooled Probes and Impedance-Control Energy Delivery,” American Journal of Roentgenology, 2006, vol. 186 (5), pp. 1220-1227. cited by applicant

Cantwell C. P., et al., “Radiofrequency Ablation of Bone with Cooled Probes and Impedance Control Energy Delivery in a Pig Model: MR Imaging Features,” Journal of Vascular and Interventional Radiology, 2007, vol. 18 (8), pp. 1011-1020. cited by applicant

Co-pending U.S. Appl. No. 11/777,225, filed Jul. 12, 2007. cited by applicant

Goldberg S. N., et al., “Percutaneous Radiofrequency Tissue Ablation: Optimization of Pulsed-Radiofrequency Technique to Increase Coagulation Necrosis,” Journal of Vascular and Interventional Radiology, 1999, vol. 10 (7), pp. 907-916. cited by applicant

International Search Report and Written Opinion dated Nov. 7, 2008 for International Application No. PCT/US2008/071037, 7 pages. cited by applicant

Lee J. M., et al., “Radiofrequency Thermal Ablation in Canine Femur: Evaluation of Coagulation Necrosis Reproducibility and MRI-Histopathologic Correlation,” American Journal of Roentgenology, 2005, vol. 185 (3), pp. 661-667. cited by applicant

Strickberger S. A., et al., “Relation between Impedance and Temperature during Radiofrequency Ablation of Accessory Pathways,” American Heart Journal, 1995, vol. 130 (5), pp. 1026-1030. cited by applicant

Thiagalingam A., et al., “Impedance and Temperature Monitoring Improve the Safety of Closed-Loop Irrigated-Tip Radiofrequency Ablation,” Journal of Cardiovascular Electrophysiology, 2007, vol. 18 (3), pp. 318-325. cited by applicant

---

Primary Examiner: Bays; Pamela M.

Attorney, Agent or Firm: Bookoff McAndrews PLLC

Background/Summary

CROSS-REFERENCE TO RELATED APPLICATION (1) This application is a continuation of U.S. patent application Ser. No. 16/364,518, filed Mar. 26, 2019, now U.S. Pat. No. 11,534,229, which is a continuation of U.S. patent application Ser. No. 14/799,346, filed Jul. 14, 2015, now U.S. Pat. No. 10,278,765, which is a continuation of U.S. patent application Ser. No. 12/179,301, filed Jul. 24, 2008, now U.S. Pat. No. 9,108,052, which claims priority under 35 U.S.C. 119 (e) to U.S. Provisional Application No. 60/951,655, filed Jul. 24, 2007, the disclosure of each of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

(1) The present application relates generally to medical treatment devices, such as devices that treat lung diseases by applying energy to airways to reduce the resistance to airflow in the airways.

BACKGROUND

(2) Asthma is a disease that makes it difficult to breathe and in many cases can be debilitating. Asthma is generally manifested by (i) bronchoconstriction, (ii) excessive mucus production, and/or (iii) inflammation and swelling of airways that cause widespread but variable airflow obstructions. Asthma can be a chronic disorder often characterized by persistent airway inflammation, but asthma can be further characterized by acute episodes of additional airway narrowing via contraction of hyper-responsive airway smooth muscle tissue.

(3) Conventional pharmacological approaches for managing asthma include: (i) administering anti-inflammatoires and long-acting bronchodilators for long-term control, and/or (ii) administering short-acting bronchodilators for management of acute episodes. Both of these pharmacological approaches generally require repeated use of the prescribed drugs at regular intervals throughout long periods of time. However, high doses of corticosteroid anti-inflammatory drugs can have serious side effects that require careful management, and some patients are resistant to steroid treatment even at high doses. As such, effective patient compliance with pharmacologic management and avoiding stimuli that triggers asthma are common barriers to successfully managing asthma.

(4) Asthmatx, Inc. has developed new asthma treatments that involve applying energy to alter properties of the smooth muscle tissue or other tissue (e.g., nerves, mucus glands, epithelium, blood vessels, etc.) of airways in a lung of a patient. Several embodiments of methods and apparatus related to such treatments are disclosed in commonly-assigned U.S. Pat. Nos. 6,411,852, 6,634,363, 7,027,869, and 7,104,987; and U.S. Published Application Nos. US2005/0010270 and US2006/0247746, all of which are incorporated by reference herein in their entirety.

(5) Many embodiments of the foregoing asthma treatments that apply energy to tissue of the airways use catheters that can be passed (e.g., navigated) through the tortuous passageways defined by the lung airways. FIG. **1**, for example, illustrates a bronchial tree **90** in which the various bronchioles **92** decrease in size and have many branches **96** as they extend from the right and left bronchi **94**. Accordingly, the treatment devices should be configured to treat airways of varying sizes as well as function properly when repeatedly deployed after navigating through the tortuous anatomy.

(6) It is also desirable to control the amount and rate of energy delivered to the treatment site. For example, the energy delivery devices for delivering radio frequency (RF) energy to tissue in the lung airways disclosed in the commonly-assigned patents and applications incorporated by reference above have been controlled by measuring the temperature of one of the electrodes during energy delivery. Other types of treatment devices that deliver RF energy for other applications outside of the lung airways, such as ablation and cauterization devices, have controlled the delivery of energy to cardiac and vasculature tissue based on measuring factors other than temperature. For example, ablation and cauterization devices have monitored impedance during a procedure and terminated energy deliver when a sharp increase in the impedance is measured. This sharp increase may correlate with a desired end result, such as tissue desiccation or protein denaturation. As such,

existing ablation and cauterization systems may terminate energy delivery based on a direct relationship between an increase in impedance and an increase in temperature.

Description

BRIEF DESCRIPTION OF THE DRAWINGS

(1) The following drawings should be read with reference to the detailed description. Like numbers in different drawings refer to like elements. The drawings, which are not necessarily to scale, illustratively depict embodiments of the disclosure and are not intended to limit the scope of the disclosure.

(2) FIG. **1** is an illustration of the airways within a human lung.

(3) FIG. **2**A is a schematic view illustrating a system for delivery of energy according to some embodiments.

(4) FIGS. **2**B and **2**C are side views in partial cross-section illustrating a portion of a treatment device for supplying energy to tissue within the body.

(5) FIG. **3** is a flow diagram illustrating a routine for controlling the power during treatment using impedance measurements.

(6) FIG. **4** is a block diagram illustrating a system for controlling the power during treatment using impedance measurements.

(7) FIG. **5** is a schematic view illustrating an example electrode configuration of a treatment device in a passageway.

(8) FIG. **6** is a block diagram illustrating an example proportional integral derivative (PID) algorithm for use in calculating applied power.

(9) FIG. **7** is a chart illustrating a function of temperature and impedance versus time during treatment.

(10) FIG. **8** is a chart further illustrating a correlation between temperature and impedance in more detail.

DETAILED DESCRIPTION

(11) Overview

(12) Devices, systems, and methods for controlling the treatment of internal tissue using measured impedance of an energy delivery device and/or targeted tissue are described. In some examples, the system controls power to the energy delivery device based on the measured impedance. The system may determine a desired or set impedance level related to parameters of the treatment site and/or of the energy delivery device, measure a current or present impedance level during or prior to energy delivery to the treatment site, and control the power to maintain the temperature or other parameter of the treatment site based on the two impedances.

(13) Several of the details set forth below are provided to describe the following examples and methods in a manner sufficient to enable a person skilled in the relevant art to practice, make and use them. Several of the details and advantages described below, however, may not be necessary to practice certain embodiments and methods of the technology. Additionally, the technology may include other examples and methods that are within the scope of the claims but are not described in detail.

(14) The particular features, structures, routines, steps, or characteristics may be combined in any suitable manner in one or more examples of the technology. The headings provided herein are for convenience only and are not intended to limit or interpret the scope or meaning of the claimed technology.

(15) In some examples, the system provides closed loop power control of energy delivery devices based on impedance feedback. By monitoring impedance at low non-ablative temperatures (e.g., temperatures below tissue desiccation or protein denaturation temperatures), several embodiments

of the system may enable the simplification of devices used in the treatment systems and/or may result in more stable or consistent treatment delivery. At short treatment times and/or low power and temperature levels, impedance may inversely correlate to temperature because electrical conductivity of the tissue increases because of increased mobility of charge carriers within the tissue. The impedance accordingly decreases with increases in temperature in such circumstances (impedance=1/conductivity). This inverse correlation of temperature and impedance enables the system to (a) measure the impedance of the system using electrodes of an energy delivery device that provide energy to target tissue in order to receive feedback about the temperature or other parameters of the target tissue, and (b) adjust power to the energy delivery device accordingly.
(16) In some cases, for example, measuring impedance may eliminate the need to measure temperature during the delivery of radio frequency or other energy to tissue, and thus several embodiments of the system may utilize catheters without thermocouples or other temperature measurement components. As a result, several embodiments of treatment devices may be small, simple, and relatively less expensive to manufacture. Additionally, controlling power by measuring impedance may enable the system to more accurately or holistically assess the state of the tissue around the passageway because measuring impedance may result in less temperature variability in the tissue versus measuring temperature at only a single location in the passageway. This may result in a more accurate treatment and/or in more consistent energy delivery between applications because impedance monitoring may be less susceptible to variation than temperature monitoring within a treatment location or between treatment locations.
(17) Embodiments of a Treatment System
(18) Specific details of several embodiments of treatment systems and methods for delivering energy to passageways in a patient are described. Although many of the embodiments are described below with respect to delivering RF energy to airways in a lung of a patient to treat asthma, other embodiments that deliver other energy modalities to lung airways or other types of passageways or tissues (e.g., blood vessel, skin, etc.) for treating other indications may be within the scope of the invention. For example, other types of energy modalities can include thermal (resistive and/or infrared), microwave, laser, ultrasonic (e.g., HIFU), cryo-ablation, radiation, or other modalities. Moreover, several other embodiments of the invention can have different configurations, components, or procedures than those described in this section.
(19) FIG. **2**A is a schematic view illustrating a system **100** for delivering energy to passageways in a patient having a power/control unit **110** and an energy delivery device **120** in accordance with an embodiment of the disclosure. The power/control unit **110** can include an energy generator **111** (e.g., power supply), a controller **112** having a processor **113**, and a user interface **114**. The energy generator **111** and controller **112** can provide RF energy to the energy delivery device **120**, but in other embodiments the energy generator **111** and controller **112** can provide other energy modalities. The controller **112** can contain safety algorithms and other control algorithms that control (i) the power output to the energy delivery device **120** and (ii) the indicators **118**, **119**, **121**, **122** of the user interface **114**. The power/control unit **110** can further include one or more connections **123**, **124**, **125** for an optional return electrode **115** for monopolar RF configurations, an optional switch **116** (e.g., an actuation pedal) for directing the controller **112** to cause the energy generator **111** to provide energy, and a conductive line **117** and connector **126** coupled to the energy delivery device **120**. It will be appreciated that the depictions herein are for illustrative purposes only and do not necessarily reflect the actual shape, size, or dimensions of the system or device.
(20) The energy delivery device **120** is an example of a treatment device for treating asthma or other indications associated with passageways in a human. The embodiment of the energy delivery device **120** illustrated in FIG. **2**A includes an elongated body **130** with a distal portion **132** and a proximal portion **134**, an energy delivery unit **140** at the distal portion **132**, and a handle **150** at the proximal portion **134**. The length of the elongated body **130** should be sufficient to access the target tissue in airways of the lung or other passageways targeted for treatment. For example, the length

of the elongated body **130** can be from approximately 0.5-8 feet to allow passage through a bronchoscope and reach targeted airways deep within the lungs. The elongated body **130** can also be configured to treat airways as small as 3 mm in diameter, but the elongated body **130** is not limited to treating airways of any particular size such that airways smaller or larger than 3 mm may be treated. Typically, the delivery unit **140** expands/contracts to variable sizes to treat airways between 3-10 mm.

(21) Several embodiments of the elongated body **130** are flexible catheters configured to slide through the working lumen of an access device (e.g., bronchoscope). The elongated body **130** can also include a plurality of markers **136** at the distal section **132** to position the energy delivery unit **140** relative to an access device (not shown in FIG. **2**A) and a proximal marker(s) **127** so as to assist in expedient positioning of the energy delivery unit **140** out of the distal end of the access device. Specific embodiments of elongated bodies with markers suitable for use in the system **100** are described in U.S. patent application Ser. No. 11/777,225 and in U.S. patent application Ser. No. 11/551,639 and in U.S. Published Application No. US2007/0106292A1, all of which are incorporated herein by reference in their entirety.

(22) The energy delivery unit **140** can have at least one energy delivery element, such as an electrode **142**, configured to deliver energy to the tissue of an airway or other passageway in the patient. FIG. **2**B is a partial cross-sectional view showing an embodiment of the energy delivery unit **140** in greater detail. In this embodiment, the energy delivery unit **140** includes four electrodes **142**, a proximal sleeve **138***a* and a proximal alignment extrusion or retainer **144***a* fixed to the elongated body **130** and attached to the proximal ends of the electrodes **142**, and a distal sleeve **138***b* and a distal alignment extrusion or retainer **144***b* attached to the distal ends of the electrodes **142**. The energy delivery device **120** can also include a wire **146** attached to the distal retainer **144***b* at the distal sleeve **138***b* and configured to move through a lumen **147** of the elongated body **130** and the proximal retainer **144***a*.

(23) The example of the energy delivery unit **140** illustrated in FIG. **2**B is a “basket-type” configuration in which the electrodes **142** move outwardly (arrows O) as the wire **146** moves proximally (arrow P) relative to the elongated body **130**. The electrodes **142** can move inwardly (arrows I) by releasing the wire **146** such that a spring or other resilient element in the handle **150**, and/or the spring force of the electrodes **142**, drives the wire **146** distally. The outward/inward movement of the electrodes **142** is useful when the device is operated intralumenally or in airways in the lungs because the energy delivery unit **140** can be advanced through a working lumen **181** of an access device **180** while the electrodes **142** are in a low-profile configuration, and then the electrodes **142** can repeatedly be moved outwardly according to the varying sizes of the passageways. Visualization of this may be facilitated by an imaging lumen **128** and/or light optical fiber lumens **129** of the access device **180** (or optical chip(s) or fiber(s) mounted at the distal end of the access device). In this illustration, the pull wire **146** may also comprise a conductive wire between the electrodes **142** and the energy supply **111**.

(24) FIG. **2**C is an exploded view illustrating a portion of one electrode **142** in greater detail. The electrode **142** has an outer insulating material or coating **143** at proximal and distal ends so as to define a non-insulated, active central portion **145** of the electrode **142** which delivers controlled energy to the tissue walls. Specific embodiments of suitable electrode configurations are disclosed in U.S. Publication No. US2007/0118184, which is incorporated herein by reference in its entirety. Further embodiments of suitable electrodes and retainers for preventing electrode inversions and limiting basket expansions are disclosed in U.S. Publication No. US2007/0106292. The system **100** may deliver energy to target sites via the energy delivery device **120** in a variety of treatment patterns. Further details with respect to other designs and types of treatment devices, examples of energy, and/or examples of treatment patterns may be found in commonly-assigned U.S. Pat. No. 6,411,852.

(25) Referring back to FIG. **2**A, the illustrated example of the handle **150** is configured so that a

single operator can hold an access device (e.g., a bronchoscope) in one hand (e.g., a first hand) and use the other hand (e.g., a second hand) to (i) advance the elongated body **130** through a working lumen of the access device until the energy delivery unit **140** projects beyond the distal end of the access device and is positioned at a desired target site and (ii) pull the wire **146** (FIG. **2**B) to move the electrodes **142** outwardly until they contact the sidewall of an airway passage while the catheter is held in place relative to the access device with the same second hand. The same operator can also operate the switch **116** of the power/control unit **110** such that the entire procedure can be performed by a single person.

(26) In one embodiment, the handle **150** has a first portion **151** and a second portion **152** rotatably coupled to the first portion **151** by a joint **153**. The first portion **151** and/or the second portion **152** are one example of an actuator for manipulating the electrodes **142**. The first and second portions **151**-**152** can be configured to form a grip **154** and a head **156** located at an upper portion of the grip **154**. The head **156**, for example, can project outwardly from the grip such that a portion of the grip **154** is narrower than the head **156**. In the specific embodiment illustrated in FIG. **2**A, the first portion **151** has a first curved surface **161** with a first neck portion **163** and a first collar portion **165**, and the second portion **152** has a second curved surface **162** with a second neck portion **164** and a second collar portion **166**. The first and second curved surfaces **161**-**162** can be configured such that they are arranged to define a hyperbolic-like shaped grip when viewed from a side elevation.

(27) In several embodiments of the system, the controller **112** includes a processor that is generally configured to accept information from the system **100** and system components, and process the information according to various algorithms to produce control signals for controlling the energy generator. The processor may also accept information from the system and system components, process the information according to various algorithms, and produce information signals. The information signals may be directed to the visual indicators, a digital display or an audio tone generator of the user interface to inform the user of the system status, component status, procedure status, or any other useful information that is being monitored by the system. The processor of the controller **112** may be a digital IC processor, analog processor or any other suitable logic or control system that carries out the control algorithms.

(28) Several embodiments of the system **100** shown in FIGS. **2**A and **2**B can be controlled by measuring the impedance before, during and/or after delivering energy to the tissue of the passages. The following discussion provides a brief, general description of a suitable environment in which the control of the system **100** may be implemented. Although not required, aspects of the system and various components (such as the controller **112**) are described in the general context of computer-executable instructions, such as routines executed by a general-purpose computer (e.g., personal computer, laptop, mobile device, hand-held computer, etc.). Those skilled in the relevant art will appreciate that the system may be practiced with other communications, data processing, or computer system configurations, including Internet appliances, other handheld devices (including personal digital assistants (PDAs)), embedded computers, multi-processor systems, microprocessor-based or programmable consumer electronics, network PCs, mini-computers, mainframe computers, and the like. The terms “computer” and the like are generally used interchangeably and refer to any of the above devices and systems, as well as any data processor. For example, an exemplary computing system may include a processor, input devices, data storage devices, such as hard disks or removable media, display devices, and/or output devices. Additionally, the system **100** may connect to various networked environments via a network connection or a wireless transceiver.

(29) Aspects of the system may be embodied in a special purpose computer or data processor that is specifically programmed, configured, or constructed to perform one or more of the computer-executable instructions explained in detail herein. Aspects of the system may also be practiced in distributed computing environments where tasks or modules are performed by remote processing

devices, which are linked through a communication network. In a distributed computing environment, program modules may be located in both local and remote memory storage devices.
(30) Aspects of the system may be stored or distributed on computer-readable media, including magnetically or optically readable computer disks, as microcode on semiconductor memory, nanotechnology memory, organic or optical memory, or other portable data storage media. Indeed, computer-implemented instructions, data structures, screen displays, and other data under aspects of the system may be distributed over the Internet or over other networks (including wireless networks), on a propagated signal on a propagation medium (e.g., an electromagnetic wave(s), a sound wave, etc.) over a period of time, or may be provided on any analog or digital network (packet switched, circuit switched, or other scheme). Those skilled in the relevant art will recognize that portions of the technology reside on a server computer, while corresponding portions reside on a client computer.
(31) Monitoring and Controlling Power to the Energy Delivery Device
(32) Several embodiments of the controller **112** perform closed loop control of the energy delivery based on the measurement of impedance of targeted tissue sites. For example, the system may measure the impedance, determine an impedance level that corresponds to a desired temperature, and supply power to an energy delivery device until the impedance level is reached. The system may also supply power to the energy delivery device to maintain a desired level of energy at the target site based on impedance measurements. In several embodiments, the system controls the power output to maintain the impedance at a level that is less than an initial or base level when power is not applied to the electrodes or at time to when power is first applied to a target tissue (e.g., the beginning of the first pulse). The impedance is initially inversely related to the temperature of the tissue before the tissue begins to ablate or cauterize. As such, the impedance initially drops during the initial portion of the treatment cycle and continues to fluctuate inversely relative to the tissue temperature. The controller **112** can accurately adjust the power output based on the impedance measurements to maintain the impedance, and thus the temperature, in a desired non-ablative range.
(33) FIG. **3** illustrates a flow diagram of an embodiment of a routine **300** for controlling the power during treatment based on impedance measurements that includes determining an initial impedance of a targeted area (block **310**). For example, the system can determine the initial impedance based on an initial measurement of voltage and current at body temperature of the targeted site or of the energy delivery device. Alternatively, the system may transmit a test or pre-treatment low energy pulse (i.e., that does not heat tissue; non-therapeutic) at the targeted site to determine the initial impedance value.
(34) The routine **300** further includes determining a desired or set impedance that correlates to a desired treatment temperature or temperature range (block **320**). In some cases, the system determines the set impedance as a percentage of the initial impedance determined in block **310**. Alternatively, the system may determine the set impedance based on parameters of the targeted site (e.g., size of the passageway, initial temperature of the passageway, mucus or moisture content of the passageway, or other physiologic factors), parameters of the energy delivery device (e.g., configuration or geometry of the electrodes, such as expanded, contracted, spacing, length, width, thickness, radius), the desired temperature range, parameters of a test or pre-treatment pulse and/or other parameters associated with the effect of energy on the tissue (e.g., bipolar or monopolar energy delivery). These parameters may be automatically detected from the initial impedance value or may be measured (e.g., a device mounted sensor, a non-contact infrared sensor, or a standard thermometer to measure an initial temperature of the passageway). The routine **300** can also include applying the set impedance to an algorithm, such as a PID algorithm, to determine the power to be applied to an energy delivery device (block **330**). Further details with respect to the PID algorithm will be discussed herein.
(35) The routine **300** may also include measuring current or present impedance values during

treatment and applying the measured impedance values to the algorithm to control the power needed to achieve, return to, or maintain the desired impedance and/or temperature. For example, during treatment the system may identify a present impedance level as being higher that the set impedance level, and use both the present and set impedance levels as inputs into the PID algorithm to determine the power output to the electrodes. Thus, several embodiments of the system at least periodically monitor the current or present impedance values to deliver the desired amount of energy to the tissue. The routine **300** can then continue by delivering energy to the tissue (block **340**) via the energy delivery device in a manner that maintains a desired temperature at the tissue.

(36) In some examples the system may periodically or continuously perform some or all of routine **300**. For example, the system may continuously determine the set impedance during a treatment, and adjust power levels based on any changes in the set impedance. The system may periodically determine the set impedance, and may adjust power levels based on a set impedance change being above a certain threshold change. Alternatively, in some examples the system recalculates the set impedance between treatments. For example, after a treatment at a first targeted site, the system may move to a second targeted site, calculate a new set impedance, and adjust the applied power accordingly.

(37) FIG. **4** illustrates a block diagram of an embodiment of the controller **112** maintaining the power during treatment based on impedance measurements. The controller **112** includes a processor **410**, a storage component **420** such as a memory, a control component **430**, a power supply **440**, an input component **450**, and an output component **460**. The control component **430** may contain a routine, algorithm, executable script, or other data structure or program module capable of monitoring impedance and performing actions (e.g., reducing or increasing the power to an energy delivery device) based on reaching or maintaining desired impedance levels, and hence, desired temperature levels. For example, the control component **430** may perform a process of controlling the output of power from an energy source **111** to an energy delivery device. The controller **112** may be configured to deliver energy in either monopolar or bipolar operation.

(38) Calculation of Set Impedance

(39) As described herein, the system may determine the set impedance using parameters related to a target site, energy delivery device, temperature, or other aspects of the treatment. FIG. **5** schematically illustrates an example of an electrode implementation in an airway **500**. The airway **500** has an internal passageway **505**, and a plurality of electrodes **510** are spaced around the passageway **505**. The electrodes **510** directly affect discrete target sites **520**, **522**, **524**, **526** on the target area around the passageway **505**. In this example, the spacing of the electrodes **510** and the size (e.g., diameter) of the passageway **505** determine a length L between the discrete sites, and the length L can influence the set impedance based on the initial impedance. For example, a shorter length L leads to a higher percentage change between the initial impedance and the set impedance because the distance between adjacent heated target sites is small and the heated sites may be a greater factor in determining the set impedance. With larger lengths L the effect of the heated sites on the set impedance may be lesser. Accordingly, a set impedance value may decrease as an airway diameter decreases and increase as an airway diameter increases.

(40) The system may empirically determine the set impedance by modeling the size and/or configuration of the electrodes, the size of the passageway, or other aspects related to the target site or the energy delivery device as described above. Additionally, the system may adjust the set impedance based on measuring a time rate of change of the initial impedance, or may adjust the set impedance based on other factors. For example, the system may determine the set impedance by first determining an initial impedance by measuring the initial impedance when applying minimal energy, and comparing the electrode configuration with the initial impedance to arrive at the set impedance. In some cases, the system may review historical or patient information related to a similar electrode size and/or configuration, and use this information when determining the set

impedance.
(41) Alternatively, the system may determine the set impedance based on one or more parameters of a pre-treatment low energy pulse, such as a test pulse. The system may calculate the set impedance (Z.sub.s) from one or more parameters of a test pulse, including: (a) the initial pulse impedance (Z.sub.o), (b) the average pulse impedance (Z.sub.avg), (c) the ending pulse impedance (Z.sub.end), (d) the slope of a pulse impedance curve (the rate of change of the pulse impedance) (Z.sub.slope), and (e) the pulse energy, and one or more constants (k.sub.1-6). The test pulse may be in an energy range from about 0.01 to about 1 joule, having a current pulse amplitude in a range from about 0.01 to about 500 milliamps and a pulse duration in a range from about 0.01 to about 500 milliseconds. A constant current pulse is utilized for ease of interpreting impedance changes. For a short duration pulse, the temperature and impedance change at the electrode/tissue interface are proportional to the I2R heating of adjacent tissue where I is the current amplitude of the pulse and R is the resistance of the adjacent tissue. Pulse amplitude and duration may be set to achieve about a 10% change in impedance from start to end of the test pulse. For example, a typical setting for the test pulse may be 0.5 joules at 100 milliamps for 300 milliseconds, where Z.sub.s= (k.sub.1*Z.sub.o)+(k.sub.2*Z.sub.avg)+(k.sub.3*Z.sub.end)+(k.sub.4*Z.sub.slope)+k.sub.5. Values for the one or more constants may be determined by making a straight line fit of test pulse impedance measurements to steady-state impedance using data taken under temperature control. It will be appreciated however that any number of variations of the test pulse parameters may be utilized to determine the set impedance.
(42) Determination of Power Using Set Impedance
(43) The system may determine the power to output to an energy delivery device using a PID algorithm, such as an algorithm having one or more variable gain factors. Referring to FIG. **6**, a block diagram illustrating an example of a PID algorithm **600** for use in calculating applied power is shown. For example, the control component **430** (FIG. **4**) may be a PID controller that receives impedance value(s) as set points **610**. The PID controller, can correct for errors between the set point and an output value **670**, such as a voltage or current, to apply to an energy delivery device by performing three corrections including: (a) a proportional correction **630** that determines a reaction to current error; (b) an integral correction **640** that determines a reaction based on recent error; and (c) a derivative correction **650** that determines a reaction based on the rate of change of the error. The algorithm sums the three corrections **660** to output the power value **670**. Additionally, the system may recalculate using output values using block **620** in order to continuously update and correct for errors. It will be appreciated that a pre-treatment or test pulse, as describe above, may be added to this impedance control algorithm to determine the set impedance.
(44) In this example, the proportional gain (alpha), the integral gain (beta), and derivative gain (gamma) are constants that may be set based on the method involved, the applied temperature, the type of electrodes, parameters of the targeted site, or other factors. The system uses the algorithm **600** to tune the output value to a desired value. For example, the PID controller can overshoot the desired set impedance before reaching the set impedance. Suitable methods for determining the PID coefficients include empirical methods, the Ziegler-Nichols method, the Cohen-Coon method and software implemented models (e.g., finite element analysis).
(45) As described above, several embodiments employ the three parameter controller of FIG. **6**. Using a variable gain factor (G) to adaptively control RF energy delivery enables the system to treat a wide range of tissue types including lung tissue bronchus, bronchioles and other airway passages. The variable gain factor scales the coefficients (alpha, beta, and gamma; each a function of the three PID parameters) based on, for example, the temperature response to energy input during the initial temperature ramp up. Examples of PID parameters are presented herein, expressed in alpha-beta-gamma space, for the energy delivering device and/or controller. These settings and timings may be based on testing in various lung tissues using an energy delivering apparatus as described above. In some cases, the system changes the relative weights of alpha, beta,

and gamma, depending upon monitored temperature and/or impedance response working in either PID or Alpha-Beta-Gamma coordinate space beyond just scaling the alpha-beta-gamma coefficients with a variable gain factor. This can be done by individually adjusting any or all of the alpha, beta, or gamma constants.

(46) In one example, an error value **625** of the PID algorithm E; is set to equal the difference in set impedance and current impedance (Z.sub.s−Z.sub.i) during treatment. For example, the parameters may be defined by Z.sub.s=0.9Z.sub.0, and E.sub.i=0.9Z.sub.0−Z.sub.1. Thus, the system may equate the set impedance to be a percentage, generally less than 100% and more typically in a range from about 70% to about 90%, of the initial impedance minus an impedance correction using current impedance. The system may then calculate the current impedance (Z.sub.i), in order to provide input into the algorithm. The power can then be found from the value of the Voltage V outputted from the algorithm, as P=IV. In sum, the PID algorithm may be applied to condition the power supply used to control energy used in treatment, among other benefits.

(47) Impedance Correlates to Temperature

(48) As mentioned above, at certain temperatures impedance may be correlated to temperature. For example, at short treatment times (e.g., approximately 10 to 20 seconds or less) and/or low power and temperature levels (e.g., approximately 4 to 40 Watts and approximately 50 to 80 degrees Celsius), impedance may inversely correlate to temperature. As a treatment device heats tissue, electrical conductivity of the tissue increases because of increased mobility of charge carriers within the tissue and impedance decreases (impedance=1/conductivity).

(49) FIG. **7** is a chart **700** illustrating a function of temperature and impedance versus time during treatment of tissue. Referring to the Figure, temperature **710** and impedance **730** vary inversely as a function of time **720**. As shown at about 1.8-2.0 seconds, the temperature curve **715** begins to show similarities to the impedance curve **735**, at about 60-70 degrees (e.g., 65 degrees) Celsius and about 150-160 Ohms. Both curves **715**, **735** remain inversely correlated as time increases to 10 seconds. Thus, FIG. **7** reflects the correlation of impedance and temperature at low temperatures that enables the system to use impedance measurements to control power levels applied to energy delivery devices in a manner that accurately maintains the temperature of the tissue in a desired range (e.g., a constant treatment tissue temperature in a range from 50 to 80 degrees Celsius).

(50) The chart **800** of FIG. **8** shows the portion of the chart **700** between 1.8 and 9.8 seconds in greater detail. Referring to the varying of temperature **710** and impedance **730** versus time **720** at points **840**, **842**, **844**, and **846**, there is a direct and inverse correlation between a peak in impedance and a valley in temperature consistent with how tissue reacts to temperature (at a lower temperature the impedance increases). Thus, FIG. **8** shows a direct and inverse correlation between impedance and temperature.

(51) Controlling power based on impedance enables several embodiments of the system to accurately assess the status of the tissue at several regions around the passageway using a variety of catheter and electrode designs. For example, because the system can measure the impedance directly through the electrodes, it does not need to incorporate a thermocouple or other temperature sensor into a catheter. This may reduce the cost, size, and complexity of the energy delivery device compared to using thermocouples. Additionally, the spacing of electrodes may cause error inducing variations in detected temperature versus the actual temperature of the targeted tissue. For example, measured temperatures at each electrode may vary more than measured impedances. Using impedance, the system is able to reduce these variations and deliver a more stable treatment because impedance values may be averaged across all electrodes (e.g., a weighted average or other non-equal weighting between impedance values).

CONCLUSION

(52) Systems and methods described herein can control the application of energy to tissue using measurements of impedance. The impedance, correlated to the temperature, may be set at a desired level, such as a percentage of initial impedance. The set impedance may be a function of the initial

impedance, the size and spacing of the electrodes, the size of a targeted passageway, and other parameters. The set impedance may then be entered into a PID algorithm or other control loop algorithm in order to extract a power to be applied to the energy delivery device.

(53) Unless the context clearly requires otherwise, throughout the description and the claims, the words “comprise,” “comprising,” and the like are to be construed in an inclusive sense as opposed to an exclusive or exhaustive sense; that is to say, in a sense of “including, but not limited to.” Words using the singular or plural number also include the plural or singular number, respectively. When the claims use the word “or” in reference to a list of two or more items, that word covers all of the following interpretations of the word: any of the items in the list, all of the items in the list, and any combination of the items in the list.

(54) The various examples described above can be combined to provide further examples. All of the U.S. patents, U.S. patent application publications, U.S. patent applications, foreign patents, foreign patent applications and non-patent publications referred to in this specification and/or listed in the Application Data Sheet are incorporated herein by reference, in their entirety. Aspects of the technology may be modified, if necessary, to employ treatment devices with a plurality of treatment units, thermally conductive devices with various configurations, and concepts of the various patents, applications, and publications to provide yet further embodiments of the technology.

(55) These and other changes can be made to the technology in light of the above-detailed description. In general, in the following claims, the terms used should not be construed to limit the technology to the specific examples disclosed in the specification and the claims, but should be construed to include all that operates in accordance with the claims. Accordingly, the technology is not limited by the disclosure, but instead its scope is to be determined entirely by the following claims.

Claims

1. A method for treating a lumen wall, the method comprising: applying energy to the lumen wall via an energy delivery apparatus; delivering a first pulse to the lumen wall; determining at least one initial impedance value using the first pulse; and determining at least one of a plurality of different set impedance values as a function of the at least one initial impedance value, wherein an amount of the energy applied by the energy delivery apparatus is based on one of the plurality of different set impedance values correlated to a measured impedance value; wherein the energy delivery apparatus includes an expandable member movable between a collapsed configuration and an expanded configuration with different expansion levels; wherein each set impedance value of the plurality of different set impedance values corresponds to a different expansion level of the energy delivery apparatus.

2. The method of claim 1, wherein a plurality of energy delivery elements are disposed on the expandable member.

3. The method of claim 1, wherein the plurality of different set impedance values increase as an expansion level of the energy delivery apparatus increases.

4. The method of claim 1, wherein applying energy to the lumen wall causes the lumen wall to reach a temperature in a range of 50° C. to 80° C. for 20 seconds or less.

5. The method of claim 1, wherein the plurality of different set impedance values are in a range of from 70 percent of the at least one initial impedance value to 90 percent of the at least one initial impedance value.

6. The method of claim 1, wherein a lumen defined by the lumen wall is an airway in a lung.

7. The method of claim 6, wherein applying the energy to the lumen wall reduces a resistance of the airway to airflow.

8. The method of claim 6, wherein applying the energy to the lumen wall damages smooth muscle tissue and nerve tissue in the lung.

9. The method of claim 6, wherein applying the energy to the lumen wall damages epithelial tissue in the lung.
10. The method of claim 1, further including applying the energy to the lumen wall until at least one of the plurality of different set impedance values is reached.
11. A method for treating a lumen wall, the method comprising: applying energy to the lumen wall via an energy delivery apparatus based on an impedance value; delivering a first pulse to the lumen wall; determining at least one initial impedance value using the first pulse; and determining at least one of a plurality of different set impedance values as a function of the at least one initial impedance value, wherein an amount of the energy applied by the energy delivery apparatus is based on one of the plurality of different set impedance values correlated to a measured impedance value; wherein the energy delivery apparatus includes an expandable member, wherein the expandable member is movable between a collapsed configuration and an expanded configuration with different expansion levels; wherein the plurality of different set impedance values increase as an expansion level of the energy delivery apparatus increases; measuring a deviation between a measured impedance value and one of the plurality of different set impedance values and adjusting the amount of the energy applied by the energy delivery apparatus to reduce the deviation until at least one of the plurality of different set impedance values is reached.
12. The method of claim 11, further including controlling an output of energy from an energy source to the energy delivery apparatus with a control component, wherein the control component is configured to measure the deviation from one of the plurality of different set impedance values.
13. The method of claim 12, wherein one of the plurality of different set impedance values is a threshold impedance value, and wherein the output of energy is adjusted based on a set impedance value of one of the plurality of set impedance values being above the threshold impedance value.
14. A method for treating a lumen wall, the method comprising: applying energy to the lumen wall via an energy delivery apparatus, wherein the energy delivery apparatus includes an expandable member movable between a collapsed configuration and expanded configurations with different expansion levels; delivering a first pulse to the lumen wall; determining an initial impedance value using the first pulse; determining at least one of a plurality of different set impedance values as a function of the initial impedance value; wherein an amount of the energy applied by the energy delivery apparatus is based on one of the plurality of different set impedance values correlated to a measured impedance value; and reducing or increasing the amount of the energy applied by the energy delivery apparatus after the measured impedance value reaches at least one set impedance value of the plurality of different set impedance values; wherein the plurality of different set impedance values increase as an expansion level of the energy delivery apparatus increases.
15. The method of claim 14, wherein one of the plurality of different set impedance values is a threshold impedance value, and wherein an output of energy is adjusted based on a set impedance value of one of the plurality of set impedance values being above the threshold impedance value.
16. The method of claim 15, further including a control component that controls the output of energy from an energy source to the energy delivery apparatus, wherein the control component is configured to measure deviation from one of the plurality of different set impedance values.