



US006542767B1

(12) **United States Patent**
McNichols et al.

(10) **Patent No.:** **US 6,542,767 B1**
(45) **Date of Patent:** **Apr. 1, 2003**

(54) **METHOD AND SYSTEM FOR CONTROLLING HEAT DELIVERY TO A TARGET**

(75) Inventors: **Roger J. McNichols**, Bryan, TX (US); **Ashok Gowda**, College Station, TX (US)

(73) Assignee: **Biotex, Inc.**, Houston, TX (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 266 days.

(21) Appl. No.: **09/710,694**

(22) Filed: **Nov. 8, 2000**

Related U.S. Application Data

(60) Provisional application No. 60/164,416, filed on Nov. 9, 1999.

(51) **Int. Cl.**⁷ **A61B 5/00**; A61N 7/00

(52) **U.S. Cl.** **600/407**; 600/410; 600/549; 600/442; 607/96; 607/100

(58) **Field of Search** 607/96, 100, 102; 600/407, 412, 410, 411, 437, 438, 442, 549

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,515,165 A * 5/1985 Carroll 600/475
4,633,875 A * 1/1987 Turner 607/98
5,501,655 A * 3/1996 Rolt et al. 600/439

FOREIGN PATENT DOCUMENTS

JP 2000-217835 A * 8/2000 A61B/17/32
JP 2001-46523 A * 2/2001 A61N/1/40
WO WO 02/00298 A1 * 1/2002 A61N/7/00

OTHER PUBLICATIONS

Temperature Mapping with MR Imaging of Molecular Diffusion, etc., Feb. 8, 1989.

MR Imaging of Laser-Tissue Interactions, Mar. 29, 1988.

Magnetic Resonance Imaging of the Acute Effects of Interstitial Neodymium, Apr. 22, 1991.

Effects Related to Temperature Changes during MR Imaging, Nov. 6, 1991.

Noninvasive Temperature Imaging Using Diffusion MRI, 1999.

A Precise and Fast Temperature Mapping Using Water Proton Chemical Shift, 1995.

Noninvasive MRI Thermometry with the Proton Resonance Frequency, etc., 1995.

Ex Vivo Tissue-Type Invariability in Proton-Resonance Frequency Shift MR, etc, Date of Publication Unknown.

Motion Corrected Proton-Resonance-Frequency Method for MR-Thermometry, Date of Publication Unknown.

MR Temperature Measurement in Vivo with TMDOTP5-Date of Publication Unknown.

New Techniques for Reducing the Thermochemical Damage in the Course of, 1987.

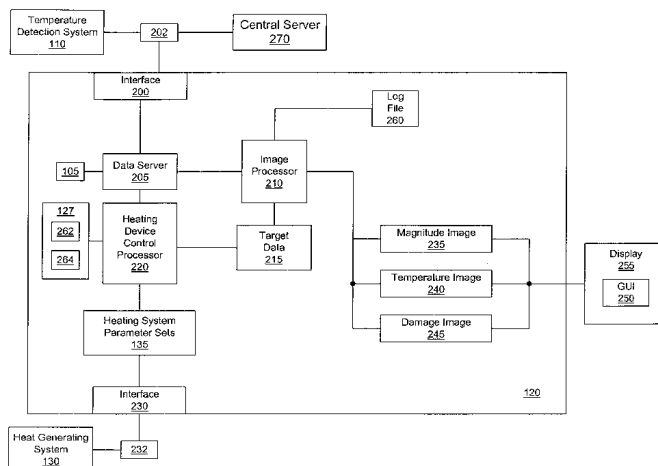
(List continued on next page.)

Primary Examiner—Hieu T. Vo

(57) **ABSTRACT**

A method and system for using real time closed loop feedback to control the delivery of heat energy is disclosed herein. An energy delivery system may be used to deliver heat energy to a target to effect a change in the target. For example, medical professionals use laser energy to irreversibly damage cells found in cancerous tumors without damaging the surrounding healthy cells. The energy delivery system includes a temperature detection system, a data processor, and a heat generating device. The temperature detection system obtains temperature data from a target and transmits the data to the data processor. The data processor may process the temperature data to provide real time feedback control to the heat generating system, as well as display the data as one or more images on a graphical user interface. The heat generating system receives control commands from the data processor and modulates its heat output accordingly.

77 Claims, 8 Drawing Sheets



OTHER PUBLICATIONS

Development of Controlled Nd: YAG Laser for Medical Applications, Date of Publication Unknown.

A Control Method for a Nonlinear Multivariable System: Application, etc., 09/91.

Application of Half-Space Acquisition to Burst SNR Improvement, Date of Publication Unknown.

Fuzzy Logic Hierarchical Controller, etc. Date of Publication Unknown.

Theoretical & Linguistic Aspects of the Fuzzy Logic Controller, Jun. 19, 1978.

Fuzzy Set Theory in Medical Diagnosis, Sep. 19, 1985.

Linguistic Assessment of Structural Damage, Date of Publication Unknown.

Analysis & Synthesis of Fuzzy Linguistic Control Systems, Date of Publication Unknown.

Tissue Precooling for Thermochemical Damage, etc., 1987.

* cited by examiner

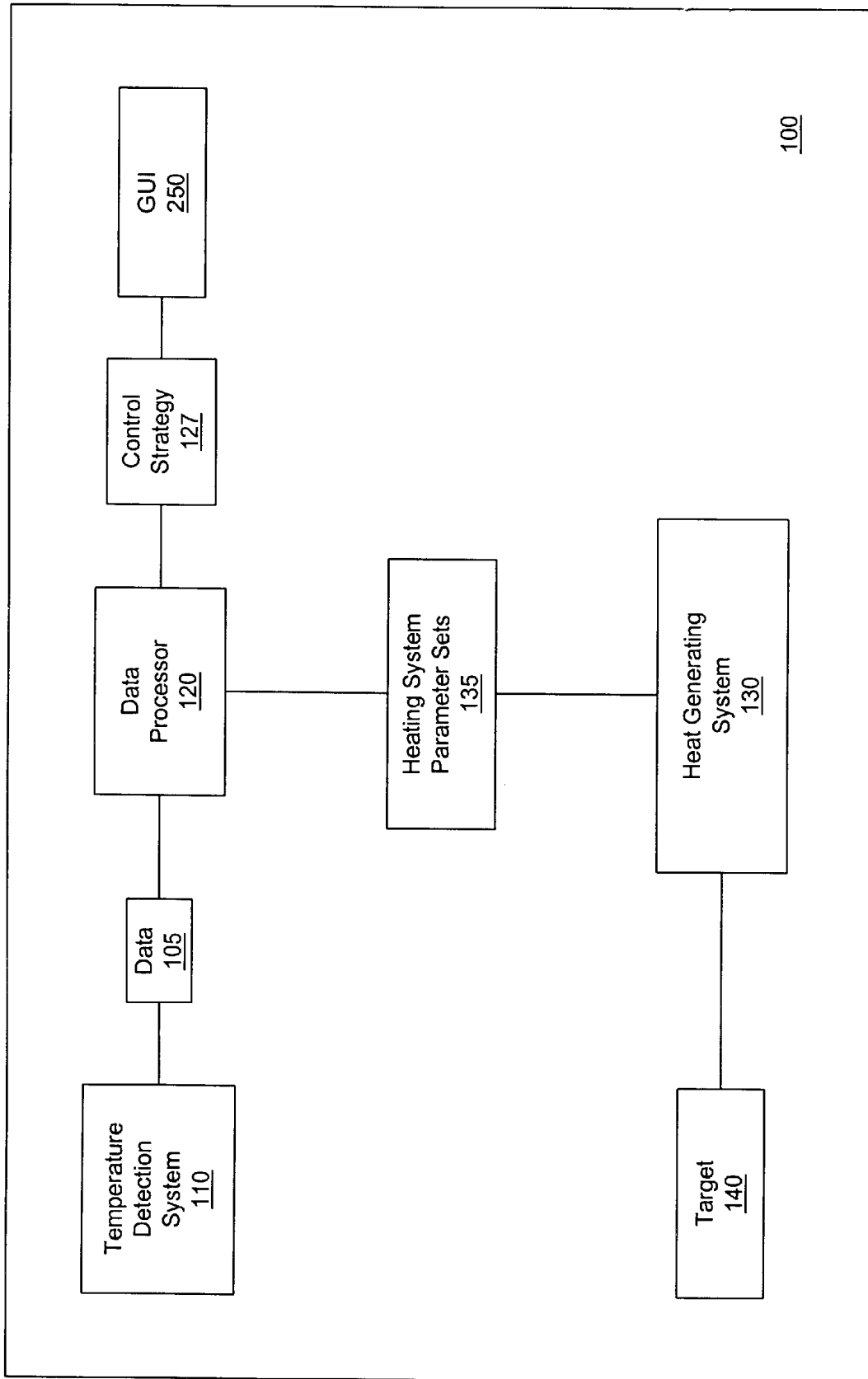


FIG. 1

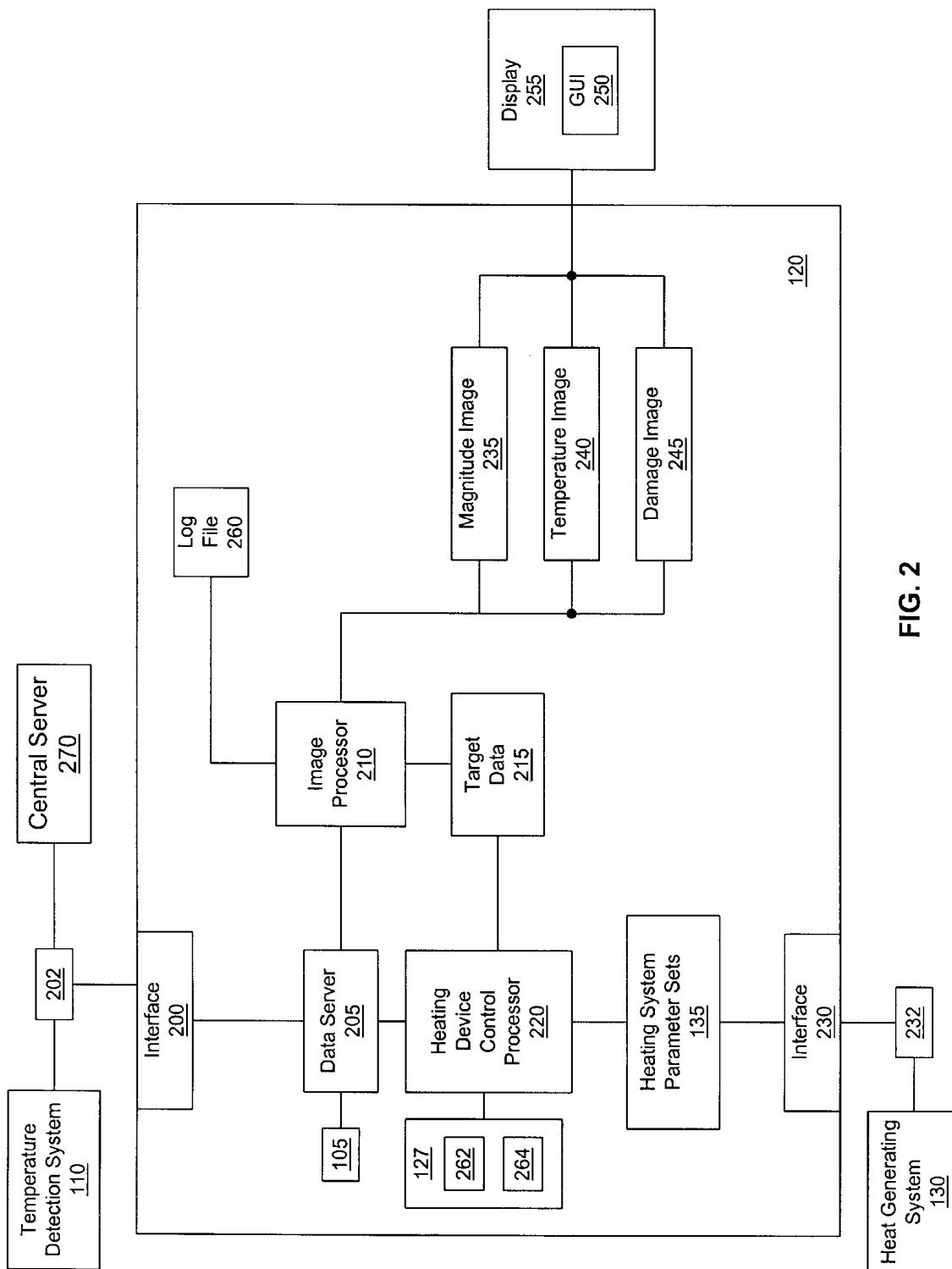


FIG. 2

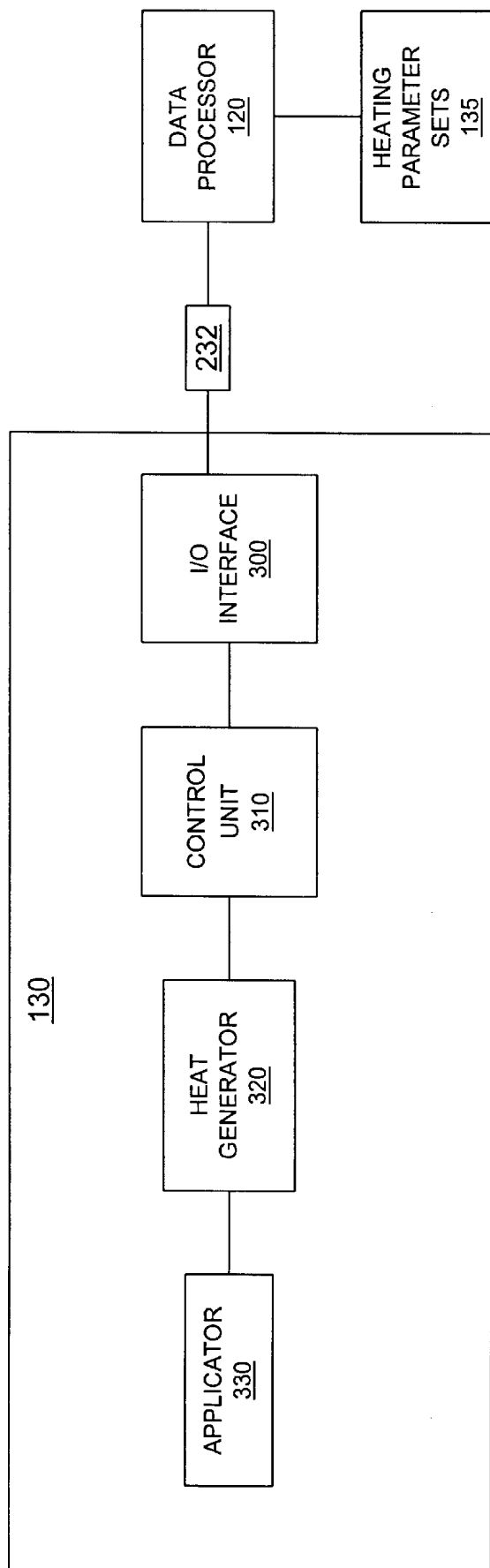


FIG. 3

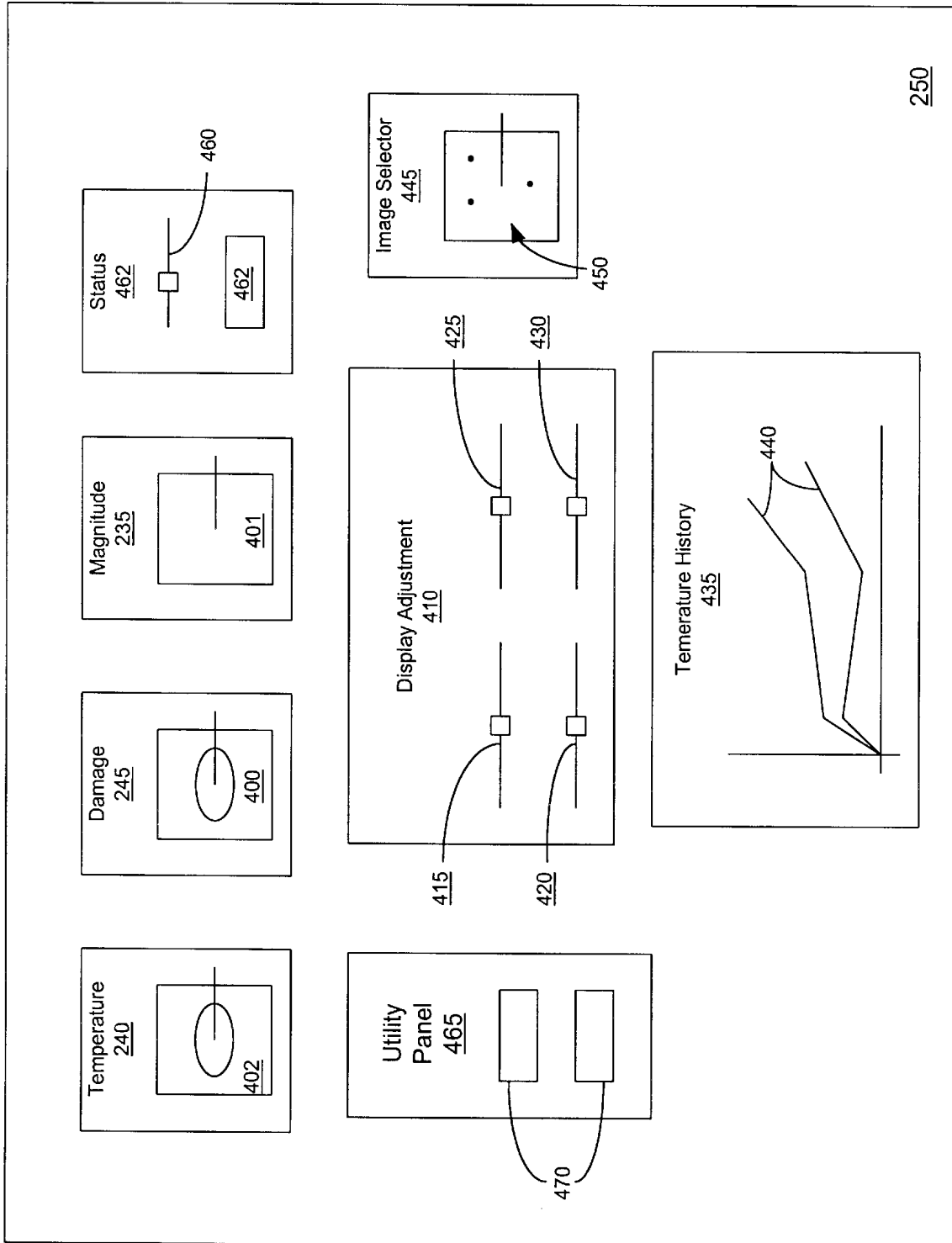


FIG. 4

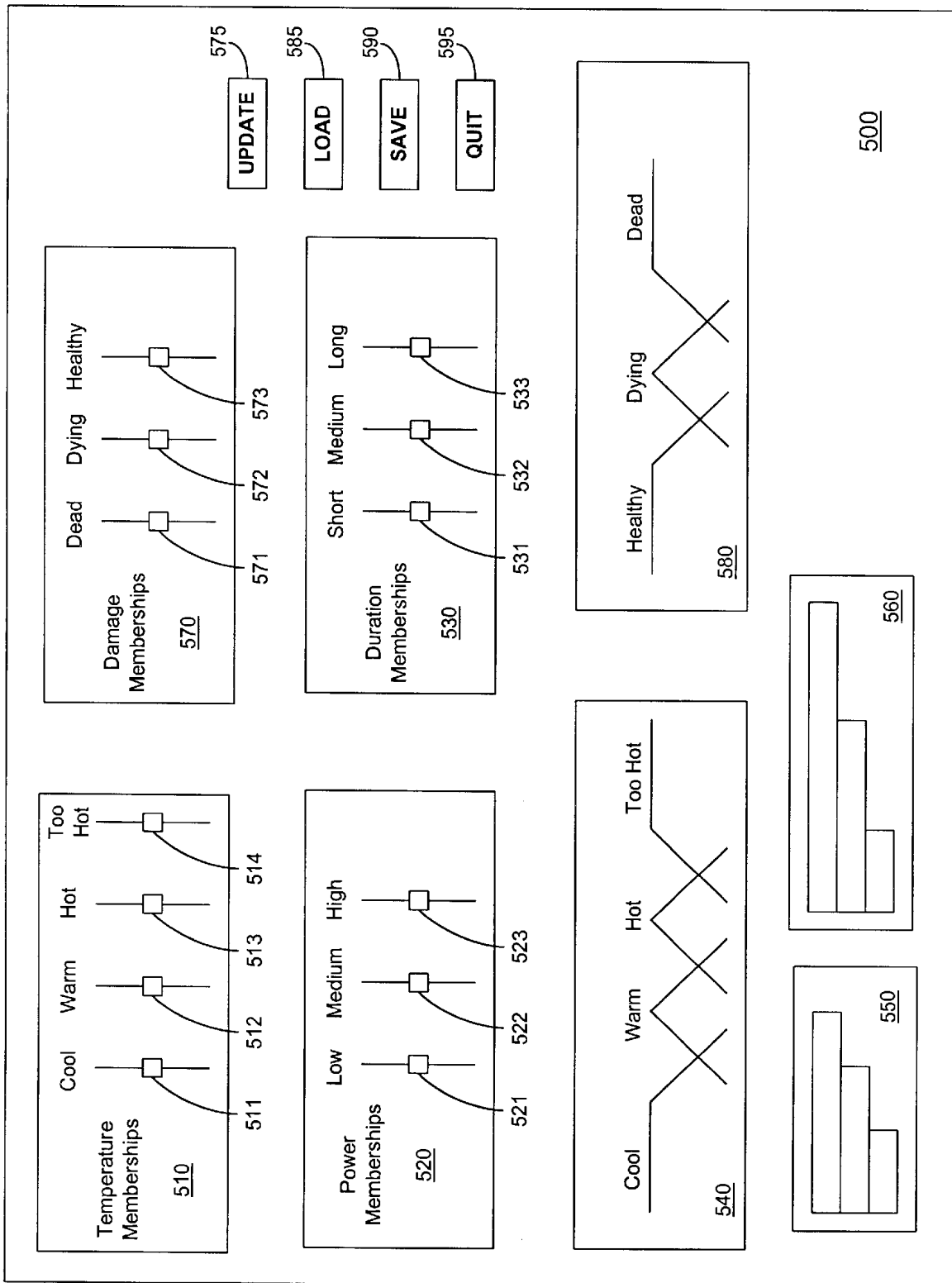


FIG. 5

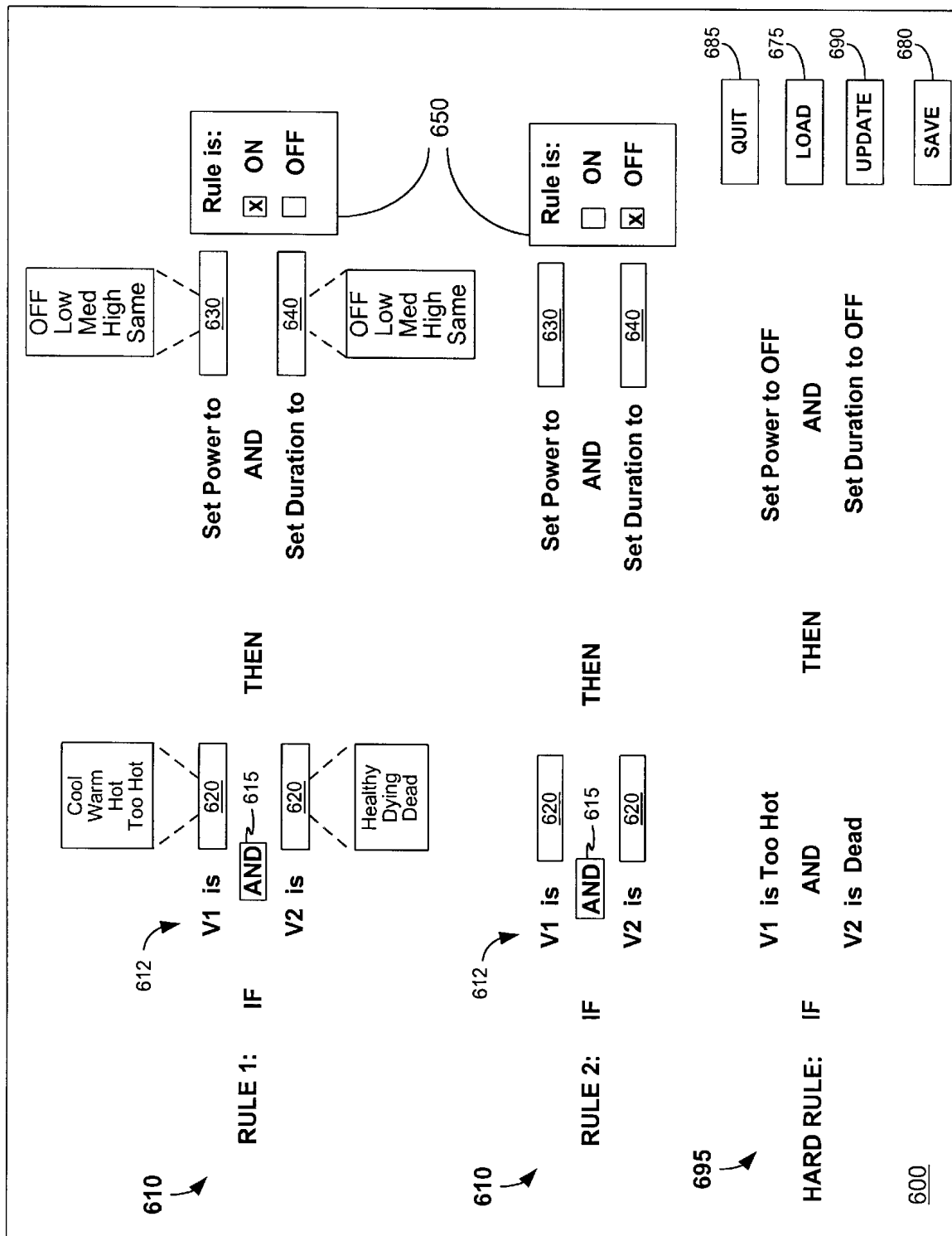


FIG. 6

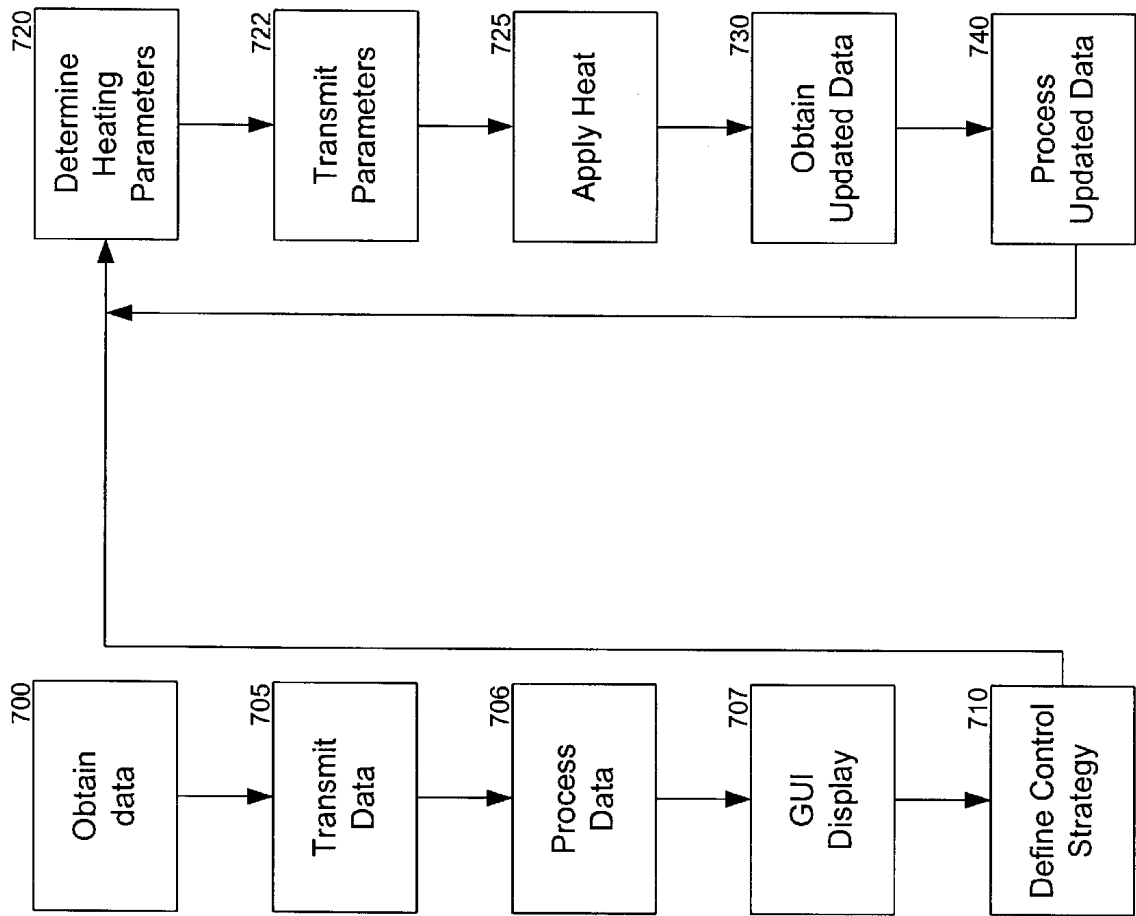


FIG. 7

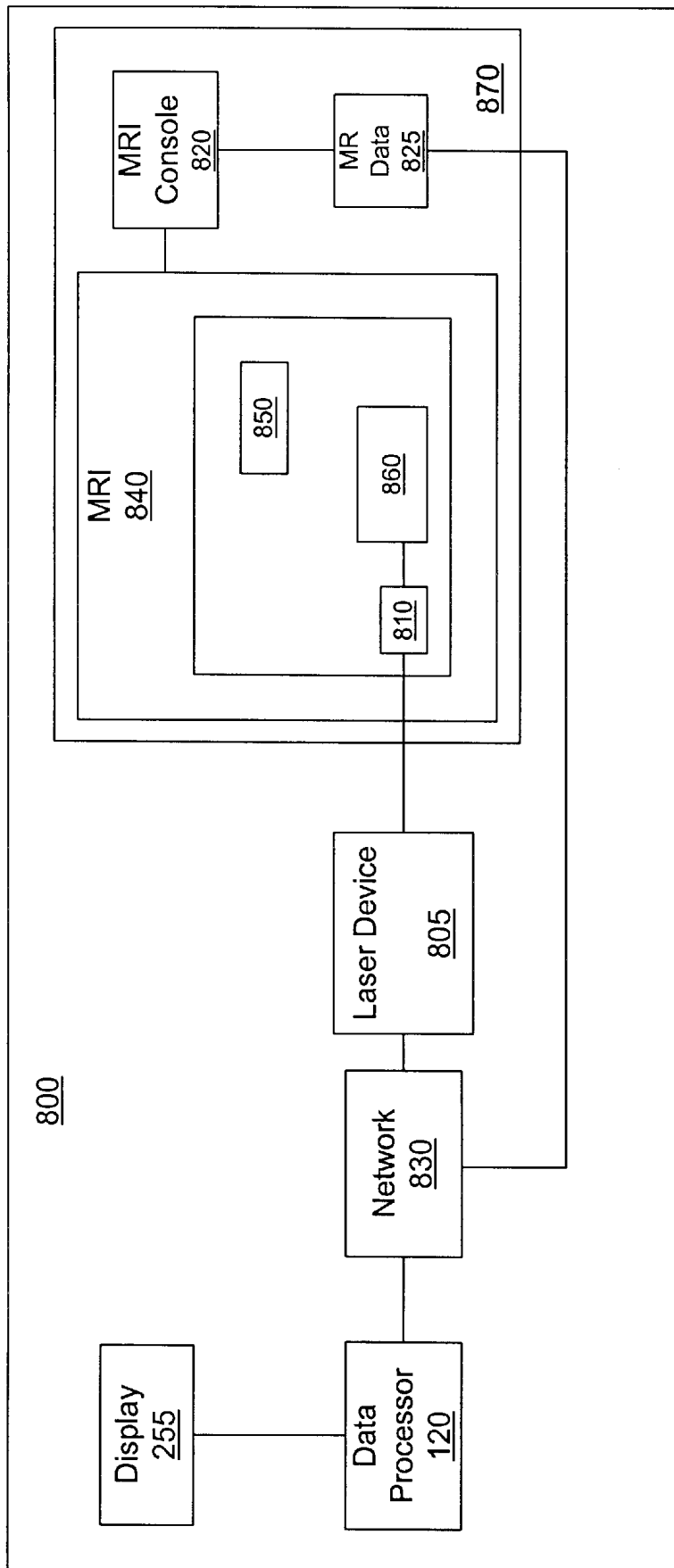


FIG. 8

METHOD AND SYSTEM FOR CONTROLLING HEAT DELIVERY TO A TARGET

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit of U.S. Provisional Patent Application Serial No. 60/164,416 filed Nov. 9, 1999 entitled "Method And System For Controlling Heat Delivery To A Target," of common assignee herewith.

FIELD OF THE INVENTION

The present invention relates generally to controlling heat delivered to a target, and more particularly to controlling heat delivered to a target based upon temperature sensitive information from a device that interrogates a target with radiation as part of acquiring input data used for controlling heat delivery.

BACKGROUND OF THE INVENTION

It is recognized in the medical industry that undesirable lesions can be treated through their removal. It is known to have a practitioner, such as a doctor, physically remove such lesions through surgery. It is also known to have a practitioner destroy lesions by controlling an application of heat local to the lesion. Known processes whereby a practitioner destroys the lesion by using heat require the practitioner to control the process based on visual data and temperature data. Based upon this information, the practitioner will modify the heat source to change an attribute of the heat, such as its location, direction, and intensity. The proper application of the heat delivery process is dependent upon the ability of the practitioner to interpret available visual and temperature data, and to implement an appropriate treatment in response. As a result, the ability to control processes in a predictable manner varies between practitioners, and even varies day-to-day for a given practitioner.

Therefore, a method and or system that allows for improved control in treating a target, such as a lesion, would be useful.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a diagram illustrating a real time feedback-controlled energy delivery system according to at least one embodiment of the present invention;

FIG. 2 is a diagram illustrating a data processor according to at least one embodiment of the present invention;

FIG. 3 is a diagram illustrating a heat generating system according to at least one embodiment of the present invention;

FIG. 4 is diagram illustrating a graphical user interface according to at least one embodiment of the present invention;

FIG. 5 is a diagram illustrating a fuzzy logic membership tuning interface according to at least one embodiment of the present invention;

FIG. 6 is a diagram illustrating a fuzzy logic rule set tuning interface according to at least one embodiment of the present invention;

FIG. 7 is a flow diagram illustrating a method for real-time feedback control of an energy delivery system according to at least one embodiment of the present invention; and

FIG. 8 is a diagram illustrating an implementation of an energy delivery system according to at least one embodiment of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

In accordance with at least one embodiment of the present invention, data is received at a data processor from a temperature detection system, wherein the data corresponds to a material, such as a tissue portion, and includes temperature sensitive information. The data processor determines a first characteristic for a heat generating device based on the temperature information. Additionally, the data processor provides the heat generating device control data based on the first characteristic to control the heat generating device. One advantage of the present invention is that it is possible to provide a method for non-invasively determining the temperature distribution inside of an object, and in real time or near real time using the temperature distribution and/or damage distribution of the material to control an excessive heat output and/or to avoid an insufficient heat output, or to otherwise effect a desired result.

FIGS. 1-8 illustrate an energy delivery system in accordance with a specific embodiment of the present invention having one or more temperature detection systems, one or more data processors, and one or more heat generating systems, as well as a method for its use. As described in greater detail below, the energy delivery system uses a temperature detection system to either periodically or continuously measure the temperature and/or cell damage of a target receiving heat energy. In at least one embodiment, a user inputs desired parameters to define a control strategy for the heat generating system. The data processor uses the control strategy to govern the behavior of the heat generating system in real time, or near real time, using feedback from the temperature detection system. The data processor is also capable of displaying temperature, damage, and structure images to the user, as well as inputting user-defined parameters, with a graphical user interface (GUI).

Referring now to FIG. 1, a feedback-controlled energy delivery system **100** is illustrated according to one embodiment of the present invention. Energy delivery system **100** includes temperature detection system **110**, data processor **120**, and heat generating system **130**. Temperature detection system **110** includes a device that uses radiation to interrogate a target or other suitable system capable of acquiring temperature information of target **140**. In one embodiment, target **140** includes a biological tissue to be destroyed by heating, or any other object having specific localized areas to be heated without damaging surrounding areas. Temperature detection system **110** may include a magnetic resonance device, an ultrasound device, an infrared device, a radio frequency device, x-ray device, infrared detection device, computerized tomography (CT) device, and the like:

Data processor **120** can include any data processing system capable of receiving and processing data from temperature detection system **110** to control, on a real-time or near realtime basis, heat generating system **130**. Data processor **120** may include a workstation, personal computer, supercomputer, dedicated hardware, and the like. Heat generating system **130** can include any device capable of generating heat, or energy that may be transformed to heat, and further capable of conveying this heat or energy to target **140** via one or more applicators. Heat generating system **130** may include a laser device, a microwave device, a resistive heater, and the like. It will be appreciated that data processor **120** may be either locally or remotely connected to temperature detection system **110** and heat generating system **130**. It will also be appreciated that energy delivery system **100** may include more than one of each of temperature measuring system **110**, data processor **120**, and heat gener-

ating system **130** without departing from the spirit or the scope of the present invention.

In one embodiment of the present invention, temperature detection system **110** is capable of obtaining temperature sensitive data on a periodic or continuing basis. The temperature sensitive data can represent the absolute or relative temperature distribution of a point, area plane, contour, or volume of a portion of target **140**. For example, a magnetic resonance device can be used to capture data to be processed for determining the structure of selected portions of target **140**, as well as the selected portions' relative temperature distribution at a given point in time. After temperature detection system **110** captures data **105** from target **140** for one cycle, data **105** may be either stored in a database in temperature detection system **110** and transmitted at a later time to data processor **120**, or the captured data (data **105**) may be immediately sent to data processor **120**. It will be appreciated that temperature detection system **110** may pre-process data **105** before it is transmitted to data processor **120**.

In a specific embodiment of the present invention, data processor **120** is capable of receiving data **105** as input data from temperature detection system **110** and processing data **105** to control the operation of heat generating system **130** and/or to display information to the user via a graphical user interface (GUI) **250**. Some of the information displayed to the user using GUI **250** may include images displaying the temperature of a portion of target **140**, the structure of a portion of target **140**, the dead and dying cells in a portion of target **140** (where target **140** is biological tissue), and the like. Other information displayed may include the status of heat generating system **130**, the temperature history of one or more points, areas, contours, planes, or volumes of a portion of target **140**, etc. In one embodiment, data processor **120** also is capable of accepting user-defined parameters input through GUI **250**.

For example, a user may be capable of using a contrast adjuster on GUI **250** to change the contrast of an image, or to select points, areas, planes, or volumes of a portion of target **140** for monitoring of temperatures or tissue damage.

Data processor **120** processes data **105** using control strategy **127** to produce control parameters that direct the behavior of heat generating system **130**. In one embodiment, heat generating system **130** receives and implements the control parameters from data processor **120** to perform the desired action. For example, data processor **120** may determine, using control strategy **127** and data **105**, that the temperature of a portion of target **140** is exceeding a desired maximum temperature. In this example, data processor **120** may develop and send heating system parameter set **135** to heat generating system **130** that direct heat generating system **130** to lessen the intensity and/or duration of heat output. Heat generating system **130**, upon receiving the heating system parameter set **135**, modifies its heat energy output as directed. It will be appreciated that the term "intensity", as used herein, may refer to the relative instantaneous output, or the term may refer to the measure of the fraction of a cycle that heat generating system **130** is outputting energy, such as a duty cycle.

In at least one embodiment, energy delivery system **100** continuously or periodically measures a temperature distribution and/or a tissue damage distribution of a select portion of target **140** and processes the measurements (data **105**) for feedback used in controlling the behavior of heat generating system **130** on a real-time, or near real-time basis. It will be appreciated that the periodic measurement of the select

portion of target **140** may include measurements taken on a fixed frequency, intermittently, randomly, as directed by a user, and the like. It will also be appreciated that the term "real-time", as used herein, refers to the ability of energy delivery system **100** to measure and process data obtained from a select portion of target **140** and control the output of heat generating system **130** in a manner fast enough so that undesired results occurring to target **140** are minimized before being detected. For example, if temperature detection system **110** and data processor **120** capture and process data every ten seconds for real time operation, the heat output of heat generating system **130** should be limited such that undesired results, such as healthy tissue damage, tissue charring, and the like, are unlikely to occur between the ten second data capturing and processing cycle. Similarly, in at least one embodiment, the term "near real time" refers to the ability of energy delivery system **100** to affect control before significant undesired results occur in target **140**.

The degree to which energy delivery system **100** approximates real-time feedback may be dependent on one or more of the following: the speed in which temperature detection system **110** is capable of measuring with a desired accuracy a portion of target **140**; the size, shape, and/or resolution of the measured portion of target **140**; the data transfer rate between temperature detection system **110** and data processor **120**; the speed at which data processor **120** is capable of processing data **105** received from temperature detection system **110**, producing control parameters for heat generating system **130**, and producing images and information on GUI **250** for the user; the speed at which heat generating system **130** is capable of responding and producing the desired outcome of the heating system parameter set **135** transmitted from data processor **120**; and the data transfer rate between data processor **120** and heat generating device **130**. The desired resolution of the images representative of characteristics of the measured portion of target **140** may also affect the real-time capacity of energy delivery system **100**. For example, an image with a higher signal-to-noise ratio (SNR) may take longer to measure and/or process than an image with a lower SNR. The desired SNR may be defined by the user, the limitations of the hardware and/or software of energy delivery system **100**, etc.

Referring next to FIG. 2, data processor **120** is illustrated in greater detail, according to at least one embodiment of the present invention. Reference numerals in FIG. 2 that are common to reference numerals in FIG.1 indicate like, similar or identical features or elements. Data processor **120** includes thermal detection system interface **200**, data route **202**, image processor **210**, heating device control processor **220**, heating device system interface **230**, control route **232**, and connections to graphical user interface (GUI) **250** implemented using display **255**. In one embodiment, data processor **120** further includes data server **205** and/or log file **260**. It will be appreciated that one or more elements of data processor **120** may be physically or logically located on one or more processing devices. It will also be appreciated that one or more elements of data processor **120** may be physically or logically located on temperature detection system **110** or heat generating system **130** without departing from the spirit or scope of the present invention. In addition, one or more of the elements illustrated in FIG. 2 can be implemented in software or firmware.

It should be understood that the specific steps indicated in the methods herein, and/or the functions of specific systems herein, may generally be implemented in hardware and/or software. For example, a specific step or function may be performed using software and/or firmware executed on one or more processing systems.

Typically, a system for processing of data associated with temperature measurements will include generic or specific processors. The processors can be based on a single processing device or a plurality of processing devices. Such a processing device may be a microprocessor, a microcontroller, a digital processor, a microcomputer, a portion of a central processing unit, a state machine, logic circuitry, and/or any device that manipulates the data.

The manipulation of the data is generally based upon operational instructions represented in a memory. The memory may be a single memory device or a plurality of memory devices. Such a memory device (machine readable media) may be a read only memory, a random access memory, a floppy disk memory, magnetic tape memory, erasable memory, a portion of a system memory, any other device that stores operational instructions in a digital format. Note that when the processor implements one or more of its functions, it may do so where the memory storing in the corresponding operational instructions is embedded within the circuitry comprising a state machine and/or other logic circuitry.

In at least one embodiment of the present invention, data processor 120 continuously or periodically receives data 105 collected by temperature detection system 110 as it becomes available and processes data 105 to provide real-time feedback control of heat generating system 130. In one embodiment, data 105 is transmitted from temperature detection system 110 to data server 205 via temperature detection system interface 200 and data route 202. When temperature detection system 110 is local to data processor 120, data route 202 may include a serial connection, a parallel connection, an infrared connection, a wireless connection (such as a radio frequency or microwave connection), a point-to-point connection, and the like. In implementations where temperature detection system 110 is remote to data processor 120, data route 202 may include an Ethernet connection, a modem connection, a digital subscriber line connection, a satellite connection, etc. Accordingly, temperature detection system interface 200 includes an input/output interface compatible with data route 202. For example, if data route 202 is an Ethernet network, temperature detection system interface 200 could include an Ethernet card. In at least one embodiment, temperature detection system interface 200 includes a point-to-point interface, such as a RS-232 interface, an IEEE-488 interface, a digital I/O interface, and the like.

In one embodiment, data 105 is stored on temperature detection system 110 until retrieved by data processor 120. Data processor 120 may either poll temperature detection system 110 for updated data 105, or temperature detection system 110 may signal data processor 120 that updated data 105 is ready for retrieval. One method of polling is to use the creation of a file as a signal. For example, temperature detection system 110 can use a UNIX file system to store data 105 in a file data_file.dat. When temperature detection system 110 has completed the measurement of target 140 and stored all measured data 105 for a given cycle in data file.dat, temperature detection system 110 creates a file data.new. Data processor 120 periodically checks for the existence of the file data.new. After temperature detection system 110 creates the file data.new and it is detected by data processor 120, data processor 120 may then download the file data_file.dat. After data processor 120 has downloaded data_file.dat, data processor 120 erases the file data.new, and temperature detection system 110 may then start storing data for the next control cycle in data_file.dat. An alternate method of polling is to use a file system and semaphores for

mutual exclusion. For example, temperature detection system 110 and data processor 120 may make use of a UNIX file system to store data 105 in a file temp_data.001, and use a semaphore associated with this file. When temperature detection system 110 is updating data 105, it places a mutual exclusion lock using the semaphore on the temp_data.001 file and begins to store updated data 105 in the temp_data.001 file. Once temperature detection system 110 is finished storing data 105 in the temp_data.001 file, it releases, or unlocks, its mutual exclusion lock on temp_data.001. Data processor 120 continuously attempts to place a mutual exclusion lock using the semaphore associated with the temp_data.001 file. When temperature detection system 110 releases its mutual exclusion lock, data processor 120 is then capable of placing its own lock on temp_data.001 and begins to download the data in the temp_data.001. When data processor 120 is finished downloading data 105, it releases its lock on the temp_data.001 file, and temperature detection system 110 may begin to store newly updated data 105 in temp_data.001 for the next cycle, and so on. It will be appreciated that other methods of retrieving data 105 from temperature detection system 110 may be used, such as interprocess communication (IPC). IPC generally refers to the data exchange between one process and another, either within the same processor or over a network. IPC is often accomplished using a transmission protocol that guarantees a response to a request. Examples of IPC include UNIX sockets, OS/2 named pipes, etc. IPC often utilizes many types of system calls. For example, one or more Unix sockets could be opened up between temperature detection system 110 and data processor 120, and data 105 could be transmitted over data route 202 according to methods known to those skilled in the art. It will be appreciated that data 105 may be transferred all at once when temperature detection system 110 is finished capturing all of data 105 for one cycle, or data 105 may be continuously transmitted as it is captured.

In one embodiment, data 105 is transferred from temperature detection system 110 to central data server 270 accessible by at least one temperature detection system 110 and at least one data processor 120. Data processor 120 may then retrieve data 105 when data processor 120 is ready for it. Use of central data server 270 has the benefit of allowing more than one data processor 120 to access data 105 from temperature detection system 110, and more than one temperature detection system 110 may provide data 105 to data processor 120. For example, many hospitals use a digital imaging and communications in medicine (DICOM) protocol server (central data server 270) to centrally store images captured by medical imaging devices (temperature detecting system 110) and make those images accessible to a wide variety of users. The medical imaging devices may be locally or remotely connected to the DICOM protocol server using a network interface, such as an Ethernet interface or a point-to-point interface. In one embodiment, one or more elements of data processor 120 may also function as central data server 270.

In one embodiment, image processor 210 retrieves data 105 from data server 205 and processes data 105 to develop a plurality of images for display on GUI 250 implemented using display 255 and for further processing to construct heat generating system control parameters or characteristics that can be used to determine actual control parameters. In one embodiment, image processor 210 constructs one or more of magnitude image 235, temperature image 240, and damage image 245 for each cycle of feedback in energy delivery system 100. Magnitude image 235, in at least one

embodiment, includes an image representative of the physical structure of the measured portion of target **140**. Temperature image **240** includes an image representative of the temperature mapping of the measured portion of target **140**. Damage image **245** includes an image representative of an estimate of the location of biological tissue (target **140**) that is dead or dying. Magnitude image **235**, temperature image **240**, and damage image **245** are formatted and displayed on display **255** using GUI **250**. GUI **250** is discussed in further detail with reference to FIG. **4**. In one embodiment, images **235**, **240**, and/or **245** are representative of a three-dimensional distribution of the structure, temperature, and/or damage. It will be appreciated that images **235**, **240**, and/or **245** may be black and white, grayscale, or color images. For example, different colors could represent different temperature ranges. In one embodiment, a plurality of images **235**, **240**, and/or **245** of different selection portions of target **140** may be displayed. The plurality of images **235**, **240**, and/or **245** may be displayed on a periodically alternating basis, or on demand as directed by a user.

As previously discussed, image processor **210** processes data **105** and/or images **235**, **240**, and **245** to produce target data **215** for heating device control processor **220**. Target data **215** may include a temperature distribution, a damage distribution, structure information, and the like. Heating device control processor **220** uses target data **215** and control strategy **127** to produce heating system parameter set **135** for use in controlling heat generating system **130**. Control strategy **127** uses one or more rule sets **262** and strategy parameter sets **264** to determine the desired operation of heat generating system **130**. Rule set **262** includes an algorithm to determine the desired action of heat generating system **130** using target data **215** and at least one strategy parameter set **264**. Strategy parameter set **264** may include parameters such as temperature membership values for lexical temperature values, damage membership values for lexical damage values, heat generating system **130** intensity levels, and the like. For example, one rule of rule set **262** may state that the heat source of heat generating system **130** is to be shut off if a maximum temperature (lexically defined by strategy parameter set **264** as “too hot”) of a selected portion of target **140** is reached. In this example, analysis of target data **215** by heating device control processor **220** determines that the temperature of the portion of target **140** has exceeded the maximum temperature (“too hot”), so heating device control processor **220** produces, using control strategy **127**, heating system parameter set **135** that will cause heat generating system **130** to shut off the heat source. In at least one embodiment, control strategy **127** includes fuzzy logic control and is discussed in greater detail with reference to FIGS. **5** and **6**.

In at least one embodiment, after heating system parameter set **135** is produced by heating device control processor **220**, it is transmitted to heat generating system **130** via heat generating system interface **230** and control route **232**. When heat generating system **130** is local to data processor **120**, control route **232** may include a serial connection, a parallel connection, an infrared connection, a wireless connection, a direct connection, such as a data bus or shared memory, and the like. In implementations where heat generating system **130** is remote to data processor **120**, control route **232** may include an Ethernet connection, a modem connection, a digital subscriber line connection, a satellite connection, etc. Accordingly, heat generating system interface **230** includes an input/output interface compatible with control route **232**. For example, if control route **232** is a serial cable, heat generating device interface **230** may

include a serial input/output (I/O) card. In at least one embodiment, heat generating system interface **230** includes a point-to-point interface, such as a RS-232 interface, an IEEE-488 interface, a digital I/O interface, and the like.

Referring next to FIG. **3**, heat generating system **130** is illustrated in greater detail according to at least one embodiment of the present invention. Reference numerals in FIG. **3** that are common to reference numerals in FIGS. **1** and **2** indicate like, similar or identical features or elements. Heat generating system **130** includes input/output (I/O) interface **300**, control unit **310**, heat generator **320**, and applicator **330**. In at least one embodiment, heat generating system **130** receives heating system parameter set **135** (FIG. **2**) from data processor **120** via I/O interface **300** and control route **232**.

Control unit **310** processes heating system parameter set **135** transmitted from data processor **120** to control heat generator **320**. For example, if heat generator **320** is a laser device, and heating system parameter set **135** indicates a specified laser intensity, duration, and/or duty cycle, control unit **310** produces the proper voltage and/or current for the proper duration and/or duty cycle to the laser device (heat generator **320**) to cause the laser to have the specified intensity, duration, and/or duty cycle. In one embodiment, control unit **310** can monitor the operation of one or more elements of heat generating system **130** and transmits their statuses to data processor **120** via I/O interface **300** and control route **232**. Data processor **120** may utilize the status of one or more elements of heat generating system **130** to modify control strategy **127** (FIG. **1**).

Heat generator **320** is capable of producing heat or energy to be transformed into heat. In at least one embodiment, heat generator **320** is further capable of producing a varied intensity, duration, and/or duty cycle of energy based on input from control unit **310**. Heat generator **320** can include, but is not limited to, a laser, a microwave device, a resistive heating element, a focused ultrasound device, an incoherent light device, a radio frequency (RF) probe, or other suitable application device. In an alternate embodiment, heat generator **320** includes a plurality of homogeneous or heterogeneous heat generating devices. For example, a laser device may be used in concert with a microwave device to deliver heat to target **140** (FIG. **1**). The heat or energy produced by heat generator **320** is transmitted to target **140** via at least one applicator **330**. Applicator **330** can include one or more optical fibers, one or more antennae, one or more transducers, and the like. For example, heat generator **320** may be implemented using a laser, and applicator **330** may be implemented as an optical fiber to deliver the energy produced by the laser into target **140**. In at least one embodiment, one or more applicators **330** may be used to create a spatial radiation pattern of heat energy. For example, multiple ultrasound transducers (heat generators **320** and applicators **330**) may be implemented using phase delays to create a specific energy radiation pattern. It will be appreciated that in some implementations of the present invention, applicator **330** and heat generator **320** may be integrated into a single element. For example, a resistive wire placed in target **140** may act as both heat generator **320** and applicator **330** when a voltage potential is placed across the resistive wire.

Referring next to FIG. **4**, GUI **250** is illustrated in greater detail, according to at least one embodiment of the present invention. Reference numerals in FIG. **4** that are common to reference numerals in FIGS. **1–3** indicate like, similar or identical features or elements. In at least one embodiment, GUI **250** includes magnitude image **235**, temperature image

240, damage image 245, image adjustment display 410, temperature history display 435, image selector 445, heating device status display 455, and utility panel display 465. It will be appreciated GUI 250 may further include one or more additional interactive displays without departing from the spirit and the scope of the present invention.

As discussed previously, magnitude image 235, temperature image 240, and damage image 245 can be derived from measurements of target 140 taken by temperature detection system 110 and transmitted to data processor 120 in the form of data 105 (FIG. 1). Magnitude image 235 displays an image representative of structure 401 of a selected portion of target 140 (FIG. 1) and temperature image 240 displays an image representative of temperature distribution 402 of a selected portion of target 140. In cases where target 140 is biological tissue, damage image 245 displays, in one embodiment, an image representative of cell damage region 400, which may be displayed alone or superimposed on either an image representative of temperature distribution 402 or an image representative of structure 401. In one embodiment, cell damage region 400 represents the portions of a selected portion of target 140 where cell death has occurred or is likely to occur as a result of the heat energy applied. Images 235, 240, and 245 may be a two-dimensional view representative of a selected section of target 140, such as a sagittal, coronal, axial section, or other arbitrary plane, or may be a three-dimensional view representative of a selected volume of target 140.

Image adjustment display 410 may be used to modify the display of images 235, 240, and/or 245 by GUI 250. Image adjustment display 410 includes contrast adjustment 415, brightness adjustment 420, color adjustment 425, and zoom adjustment 430. Contrast adjustment 415 adjusts the contrast of images 235, 240, and 245. Brightness adjustment 420 adjusts the brightness of images 235, 240, and 245. Color adjustment 425 adjusts the color properties when images 235, 240, and 245 are in color. Zoom adjustment 430 adjusts the magnification factor of images 235, 240, and 245 displayed. Adjustments 410, 415, 420, 425, and 430 may be modified through GUI 250 using a sliding knob, a turning dial, a value input field, or other methods known to those skilled in the art. It will be appreciated that additional image adjustments may be implemented without departing from the spirit and the scope of the present invention. For example, a user may strike the up and down arrow keys on a keyboard attached to data processor 120 to increase or decrease the zoom value of zoom adjustment 430.

In at least one embodiment, a user of energy delivery system 100 (FIG. 1) uses image selector 445 to select a portion of target 140 for monitoring and control. Image selector 445 includes, in one embodiment, structural image 235, but can also include temperature image 240 or damage image 245. The user may select one or more image interest selections 450 for monitoring by energy delivery system 100 using an input device, such as a mouse, a touchpad, a touchscreen, a trackball, and the like. Image interest selections 450 may include individual points, areas, planes, or contours in implementations where the image (magnitude image 235, temperature image 240, or damage image 245) is displayed in two dimensions, or points, areas, contours, planes, or volumes in implementations where the image is displayed in three dimensions. In one embodiment, image interest selections 450 are associated with one or more membership sets, such as cold, medium, hot, and too hot temperature sets, or healthy, dying, and dead cell sets, and the like. Image interest selections 450 are input by GUI 250 to data processor 120 as elements of a strategy parameter set

for use in controlling the operation of heat generating system 130. Membership sets and strategy parameter sets are discussed in greater detail with respect to FIG. 5.

As described previously, the user may use continuously or periodically updated temperature image 240, damage image 245, and magnitude image 235 to select image interest selections 450 in image selector 445 of GUI 250 (FIG. 4). In one embodiment, the image displayed in image selector 445 may include temperature image 240, damage image 245, magnitude image 235, or a combination thereof. For example, a combination image of temperature image 240 and damage image 245 may be displayed in image selector 445. In this example, the temperature distribution could be represented by pixels with a color spectrum between blue and red, and cells considered dead or dying could be represented by pixels with a white color. If image selector display is a two dimensional image, the user could select, using an input device such as a trackball, one or more points or contours (image interest selections 450) for data processor 120 to monitor and use in control strategy 127 (FIG. 2). These points could be associated with a temperature membership or cell damage membership, as discussed in greater detail with reference to FIGS. 5 and 6. Additionally, in at least one embodiment, multiple images representative of the structure, temperature distribution and/or damage distribution of different areas, planes, or volumes of a plurality of selected portions of target 140 may be displayed. The different areas, planes, or volumes of the selected portions may be parallel or perpendicular to each other, or they may be oriented at any angle to one another. One or more of the plurality of images may be displayed simultaneously, or groups of one or more may be displayed sequentially. The selection of the desired areas, planes, and/or volumes and display of the plurality of images representative of the areas, planes, and/or volumes may occur on a periodic basis or may be initiated and directed by the user. The selection and display of the images may also be determined by data processor 120 or temperature detection system 110 based on characteristics of the selection portion of target 140, such as the locations of the hottest temperature or the area with the greatest damage.

In at least one embodiment, the user-selected image interest selections 450 can be used to provide feedback to temperature detection system 110. For example, a user may select one or more of the hottest points and have temperature detection system 110 monitor the temperature of these points more frequently than the rest. In one embodiment, either temperature detection system 110 or data processor 120 is capable of automatically adjusting the monitoring of a selected portion of target 140 based on image interest selections 450. For example, suppose a user selects an area of target 140 to be monitored and data processor 120 determines that the upper half of the selected area has no appreciable temperature change, or the temperature distribution of the upper half is well within the acceptable temperature limits. In this example, it is determined that the bottom edge of the selected area is approaching a user-defined critical temperature. In this case, data processor 120 may instruct temperature detection system 110 to alter the area being monitored, and place the bottom edge of the previously monitored area in the center of the newly monitored area. This action would allow the user and data processor 120 to monitor the critical areas of the selected portion of target 140 by readjusting the image to focus on areas of interest. Likewise, in addition to shifting the area, plane, or volume of interest, data processor 120 may instruct temperature system 110 to change to an entirely different

area, plane, or volume of interest in order to more accurately monitor critical features.

Temperature history display **435** includes one or more temperature history plots **440** associated with the one or more image interest selections **450**. Temperature history plots **440** can be plots of the temperature of the associated image interest selection **450** as a function of time. It will be appreciated that one or more temperature history plots **440** may be illustrated on a single plot display with a common axis, on a separate plot display for each temperature history plot **440**, or a combination thereof. In cases where image interest selections **450** are not single points, such as a plane or a volume, it will be appreciated that temperature history plot **440** may consist of an average temperature history, a temperature history of a single hottest point, etc.

In at least one embodiment, heating device status display **455** is capable of displaying information regarding the status of heat generating system **130**. In one embodiment, heating device status display **455** includes intensity indicator **460**. Intensity indicator **460** displays the intensity of heat output of heat generating system **130**. The intensity may be displayed as a relative percent, such as 0 to 100% of heating capacity, as an actual measurement, such as 0 to 5 Watts, as a graph representative of the duty cycle, or as another physical quantity as may be appropriate to the heat generation method employed. Heating device status display **455** may also include emergency shut off button **462** capable of turning off the energy output of heat generating system **130**. For example, a user may determine that a portion of target **140** has exceeded a desired maximum temperature. The user may then activate emergency shutoff button **462** to prevent or stop any damage to target **140**. It will be appreciated that heating device status display **455** may also display additional information, such as time in use, total power output, and the like. In one embodiment, utility panel display **465** is capable of executing utility programs and processes using one or more buttons **470**. Utility programs and processes can include startup and shutdown processes, add/remove display processes, data saving processes, GUI setup processes, and the like.

Referring now to FIG. 5, fuzzy logic membership tuning interface **500** is illustrated according to at least one embodiment of the present invention. Reference numerals in FIG. 5 that are common to reference numerals in FIGS. 1-4 indicate like, similar or identical features or elements. Fuzzy logic membership tuning interface **500**, herein referred to as membership tuning interface **500**, includes temperature membership group **510**, heating device power membership group **520**, duration membership group **530**, temperature display **540**, power display **550**, duration display **560**, quit button **595**, load button **585**, save button **590**, and update button **575**. In one embodiment, tuning interface **500** is accessed by when a user selects one of buttons **470** in utility panel display **465** (FIG. 4). In implementations where energy delivery system **100** (FIG. 1) is used to produce lesions in biological tissue (target **140**), membership tuning interface **500** further includes damage membership group **570** and damage display **580**. It will be appreciated that membership tuning interface **500** may include other membership groups with out departing from the spirit and the scope of the present invention.

As discussed previously, heating device control processor **220** (FIG. 2) uses control strategy **127**, one or more rule sets **262**, and one or more strategy parameter sets **264** to control the energy output of heat generating system **130**. In one embodiment, a user employs membership tuning interface **500** to input user-preferred parameters into one or more

strategy parameter sets **262**. In one embodiment, a user may modify four types of memberships: temperature, tissue damage, heating device power, and heating device output duration. Temperature membership group **510** is capable of setting membership values for cool temperature membership **511**, warm membership **512**, hot membership **513**, and too hot membership **514**. Heating device power membership group **520** is capable of setting membership values for low membership **521**, medium membership **522**, and high membership **523**. Duration membership group **530** is capable of setting membership values for short membership **531**, medium membership **532**, and long membership **533**. Damage membership group **570** is capable of setting membership values for dead membership group **571**, dying membership group **572**, and healthy membership group **573**. The user may modify the values of each membership by use of a sliding knob, a turning dial, a numerical input box, and the like.

Temperature display **540**, damage display **580**, power display **550**, and duration display **560** are capable of visually displaying the relationships between their associated membership groups (temperature membership group **510**, damage membership group **570**, heating device power membership group **520**, and duration membership group **530**, respectively). As a user modifies the values for a given membership, the associated membership display dynamically updates to reflect the new membership group composition.

For example, an increase in the value of cool membership **511** updates the graph representing cool membership **511** in temperature graph **540**. It will be appreciated that various types of charts and graphs may be used to display membership groups **510**, **520**, **530**, and **570**, such as line graphs, bar graphs, pie charts, etc. Additionally, in one embodiment, temperature display **540**, and the associated values for memberships **510**, **520**, **530**, and **570** may be adjusted by direct manipulation of temperature display **540** and/or damage display **580** by the user. For example, a user could use a mouse to click on one of the graph lines for cool membership **511** and drag and position the graph line into the desired location, and thereby dynamically altering the values and distribution of cool membership **511**. It will be appreciated that a specific membership value and distribution may be modified separately from the other associated memberships, or memberships may be adjusted in relation to one another.

When a user is satisfied with the results of modification of the values of the memberships, the user may save, load, and/or update these values. Save button **590** is capable of saving the displayed membership values in a file, database, and the like. For example, a user may set up membership values for a specific tissue (target **140**) type and select save button **590** to save the setup in a file. Load button **585** is capable, when selected, of loading and displaying membership values previously saved in a file or database. Update button **575** is capable of dynamically updating membership values that are in strategy parameter set **262** that is currently being used by heating device control processor **220**. By selecting update button **575**, the user dynamically modifies the parameters used by data processor **120** to control heat generating system **130**. When selected by the user, quit button **595** terminates membership tuning interface **500** without saving any changes to membership values made since the save button **590** was last selected. In at least one embodiment, membership tuning interface **500** is capable of evaluating strategy parameter set **264** before updating for safety reasons or to prevent unintended results.

13

Referring now to FIG. 6, a fuzzy logic rule set tuning interface is illustrated according to one embodiment of the present invention. Reference numerals in FIG. 6 that are common to reference numerals in FIGS. 1-5 indicate like, similar or identical features or elements. Fuzzy logic rule set tuning interface 600, herein referred to as rule set tuning interface 600 includes one or more rules 610, one or more rule activation boxes 650, load button 675, save button 680, update button 690, and quit button 685. Rule 610 includes at least one control variable 612 associated with the temperature of a given location of target 140 and/or the cell damage of a given location of a biological tissue (target 140), one or more control membership fields 620, one or more power membership fields 630, and one or more duration membership fields 640. Rule 610 may further include one or more fuzzy logic operators 615. Rule activation box 650 includes an ON box and an OFF box.

In one embodiment of the present invention, rule set tuning interface 600 allows a user to construct and/or modify a fuzzy logic control strategy (an embodiment of control strategy 127), which in turn governs the feedback control process of energy delivery system 100 (FIG. 1). The user is capable of building one or more rules 610 combined into rule set 262 that govern the behavior of heat generating system 130 (FIG. 1) using if-then statements and fuzzy logic operators and variables. Using fuzzy logic control, the truthfulness of each variable of each premise (the "if" statement) is evaluated based on its membership to specific membership groups. The extent to which the conclusion (the "then" statement) is performed is based on the evaluated truthfulness of the premise. To construct each of at least one rule 610, the user selects control variable 612 corresponding to an image interest selection 450 (FIG. 4) selected using image selector 445 displayed on GUI 250. If more than one control variable 612 is selected for rule 610, the user also selects an operator for fuzzy logic operator 615. Fuzzy logic operators represented in fuzzy logic operator 615 may include, but are not limited to, AND, OR, NAND (NOT AND), NOR (NOT OR), or other fuzzy logic operators. Additionally, the user selects a lexical value for each control membership field 620 corresponding to the one or more control variables 612. In one embodiment, the lexical values for control membership field 620 include temperature lexical values of cool, warm, hot, and too hot. Lexical values for control membership field 620 may also include damage lexical values, such as healthy, dying, and dead. The user also selects a lexical value for power membership field 630 and duration membership field 640. In one embodiment, the lexical values for power membership field 630 include off, low, medium, high, and same, and the lexical values for duration membership field 640 include short, medium, long, and same. In one embodiment, the numerical equivalents of the lexical values of membership fields 620, 630, and 640 are determined by user input to tuning interface 600. It will be appreciated that the numerical equivalents may also be hard-coded into GUI 250, loaded from a database or a file, and the like.

In an alternate embodiment, a more traditional control methodology is used. For example, a software-based algorithm may be used for closed-loop control of the heat output of energy delivery system 100 (FIG. 1). Alternately, the control method may be hardwired into the hardware of data processor 120. The user may input user-defined parameters for these types of control methodologies in a manner similar to the one presented with reference to FIGS. 5 and 6. It will be appreciated that other control methods may be used without departing from the spirit and scope of the present invention.

14

In one embodiment, rule 610 implements fuzzy logic to define a response to a situation defined by control variables 612, fuzzy logic operator 615, control membership field 620, power membership field 630, and duration membership field 640. Fuzzy logic, as opposed to Boolean logic with absolute truth and absolute false, uses a range of values to represent the truthfulness or falseness of a variable. As a result, the truthfulness of a given statement using fuzzy logic can be represented as a probability. Using an if-then statement, rule 610 determines whether a statement of one or more temperature variables 612 is true using logical operator 612 to evaluate the degree of truthfulness. The values for corresponding power membership field 630 and duration membership field 640 are set according to the degree of truthfulness of the "if" statement of a fuzzy logic operation (logical operator 612) between two or more fuzzy logic variables (control membership fields 620). The power membership field 630 and duration membership field 640 values are implemented by heating device control processor 220 (FIG. 2) to create heating system parameter set 135 (FIG. 1). After heating system parameter set 135 is created, it is transmitted to heat generating system 130. Heat generating system 130 receives heating system parameter set 135 and modifies its heat output to match the parameters set by power membership field 630 and duration membership field 640.

A user also has the capability of shutting off a particular rule 610 using rule activation box 650. For example, if a user determines that one or more rules 610 are interfering with the correct operation of energy delivery system 100 (FIG. 1), the user may dynamically disable the interfering rules 610 by selecting the associated OFF box. Similarly, if the user wishes to enable a disabled rule 610, the user may select ON box to dynamically enable the associated rule 610.

In at least one embodiment of the present invention, rule set 262 further includes one or more hard rules 695. Hard rules 695 include rules used to limit the operating boundaries of heat generating system 130 for safety and/or device limitation reasons. For example, heat generating system 130 may include a diode laser that may have a maximum power setting that exceeds the maximum safe level. In this example, hard rules 695 would include rules that limit the power output of the laser to safe levels only. Hard rules 695, in one embodiment, supercede all user-defined rules 610, and normal users are not capable of modifying or disabling any hard rules 695. In one embodiment, rule set tuning interface 600 is capable of determining if a given rule 610 interferes with one or more hard rules 695. If a rule 610 does interfere, rule set tuning interface 600 is capable of disabling the interfering rule 610 by selecting the OFF box of associated rule activation box 650. It will be appreciated that hard rules 695 may be loaded from a file or database, input by an authorized administrator, etc. In an alternate embodiment, hard rules 695 are hardcoded into the software of data processor 120 or hardwired into the hardware of data processor 120. In this case, hard rules 695 may have been coded or implemented in hardware by the user or by the manufacturer, or a combination therein. Alternately, hard rules 695 may be implemented using data from image interest selections 450 (FIG. 4). For example, a user could pick a point at the source of the heat in target 140 and a point in an outlying area. In this case, the user could define a hard rule (hard rule 695) that prohibits the temperature of the point at the heat source from exceeding a user defined temperature and similarly may set a maximum temperature for the outlying point.

In addition to creating rule sets 262 (FIG. 2), rule set tuning interface 600 is capable of saving created rule sets

262, or loading preexisting rule sets 262 from a file or database. Rule sets 262 may be saved by selecting save button 680, which is capable of saving rule sets 262 as a file or in a database. Preexisting rule sets 262 may be loaded by a user from a database or file by selecting load button 675. Update button 690 is capable of dynamically updating rule set 262 currently used by control strategy 127 to govern the operation of heat generating system 130 (FIG. 1). In the event that a user desires to terminate rule set tuning interface 600 without saving any changes to a given rule set 262, the user can select quit button 685. Additionally, rules 610 for rule set 262 used by control strategy 127 and heating device control processor 220 (FIG. 2) may dynamically be updated during operation by using update button 690.

Referring next to FIG. 7, a method for utilizing real-time, or near real-time, feedback to control an energy delivery system is discussed according to one embodiment of the present invention. Reference numerals in FIG. 7 that are common to reference numerals in FIGS. 1-6 indicate like, similar or identical features or elements. In step 700, temperature detection system 110 (FIG. 1) obtains data 105 from measurements conducted on target 140 for use as initial reference data for data processor 120. This initial reference data may be utilized to develop an initial image representing magnitude image 235, temperature image 240, and damage image 245 (FIG. 2). The initial reference data may also be used to develop an initial reference temperature distribution in implementations where temperature detection system 110 is only capable of detecting temperature differences, rather than absolute temperature.

In step 705, initial data 105 is transmitted from temperature detection system 110 to data processor 120 (FIG. 2). Data 105 may be stored in a database on temperature detection system 110, transmitted immediately after the data capture cycle is completed, transmitted to central data server 270, or transmitted continuously as data 105 is captured. In step 706, data 105 received from temperature detection system 110 is processed by data processor 120. Data 105 is used by image processor 210 (FIG. 2) to develop magnitude image 235, temperature image 240, and damage image 245 for display by GUI 250. In addition, data processor 120 uses data 105 to initiate control of the heat output of heat generating system 130, as described previously. In step 707, data 105 is used by GUI 250 (FIG. 2) to display the initial images for magnitude image 235, temperature image 240, and damage image 245. As no heat has been applied to target 140 when initial data 105 was measured, damage image 245 and temperature image 240 have no temperature or damage related information to display. Similarly, temperature history 435 (FIG. 4) does not have any information to display yet. A user may use the information presented in the images to determine and input user-defined parameters.

One or more image interest selections 450 (FIG. 4), one or more rule sets 262 (FIG. 2) and strategy parameter sets 264 used to develop control strategy 127 (FIG. 1) are input to data processor 120 via GUI 250 (FIG. 2) by a user in step 710. As discussed previously, the user may select one or more points, contours, areas, planes, or volumes of interest for monitoring using an input device in image selector 445. The user may select the one or more image interest selections 450 using an input device, such as a mouse, touch screen, trackball, etc. Alternatively, image interest selections may be predetermined using data from a file or database.

In at least one embodiment, control strategy 127 is implemented using membership tuning interface 500 (FIG. 5) and rule set tuning interface 600 (FIG. 6) to set the values of strategy parameter set 264 and one or more rule sets 262

(FIG. 2). The user may define strategy parameter set 264, in at least one embodiment, by entering or modifying values for memberships groups 510, 520, 530, and 570 (FIG. 5). The inputted values may be determined using past experience as a guide, a standardized table of values, and/or by loading a previously constructed strategy parameter set 264 from a file or a database as described previously. Similarly, one or more rule sets 262 may be input by the user based on experience, tables, or by loading previously constructed rules sets 262 from a file or database.

In step 720, data processor 120 uses control strategy 127 developed in step 710 and information extracted from data 105 obtained by temperature detection system 110 to construct heating system parameter set 135 (FIG. 1). Heating system parameter set 135 is used to govern the behavior of heat generating system 130. Heating system parameter set 135 is generated by heating device control processor 220 by using temperature data extracted from data 105, and/or cell damage data calculated from data 105 if target 140 (FIG. 1) includes biological tissue. For example, one rule set 610 (FIG. 6) states that heat generating system 130 is to be shut off (power membership field 630 value set to off) if the temperature of a given image interest selection 450 (control variable 612) is too hot (control membership field 620 set to too hot). In this example, heating device control processor 220 would construct heating system parameter set 135 in a way that would shut off heat generating system 130 when it received and enacted heating system parameter set 135.

In step 722, heating system parameter set 135 is transmitted to heat generating system 130. In one embodiment, heat generating system 130 is local to data processor 120. In this case, heating system parameter set 135 may be transmitted from data processor 120 to heat generating system 130 using a direct connection, such as shared memory, a serial connection, a parallel connection, universal serial bus connection, and the like. In another embodiment, heat generating system 130 is remotely connected to data processor 120. In this implementation, data processor 120 and heat generating system 130 may be connected by a microwave connection, a satellite link, by Ethernet, by telephone modem, and the like. In either embodiment, heating system parameter set 135 is received by heat generating system 130 and processed to produce the desired heat output. In one embodiment, heat generating system 130 is capable of transmitting an error signal to data processor 120 if heat generating system 130 is unable to perform as directed by heating system parameter set 135. Data processor 120 may then take the error signal into account when constructing subsequent heating system parameter set 135 for the next cycle.

In step 730, the next cycle of data 105 is collected by temperature detection system 110. Temperature detection system 110 (FIG. 2) obtains data 105 from measurements conducted on target 140 for processing by data processor 120. In step 735, data is transmitted to data processor 120 as discussed with reference to step 705. In step 740, data 105 received from temperature detection system 110 is processed by data processor 120. Data 105 is used by image processor 210 (FIG. 2) to develop updated images of magnitude image 235, temperature image 240, and damage image 245 for display by GUI 250. In one embodiment, the initial reference data collected in step 700 is used in conjunction with data 105 obtained in the current cycle to develop an updated temperature image 240 and damage image 245 in implementations where temperature detection system 110 is only capable of detecting temperature differences, rather than absolute temperature. Additionally, data 105 is processed by

image processor 210 to produce target data 215 (FIG. 2) for the next cycle of the real-time closed loop feedback control. Steps 720 through 740 are continuously repeated until the user terminates the process, or data processor 120 determines that termination is necessary for safety or other reasons. For example, the temperature of a image interest selection 450 (FIG. 4) selected by the user may have exceeded the desired maximum temperature as defined by strategy parameter set 264 and rule set 262 (FIG. 2). In this situation, data processor 120 would terminate the heat output of heat generating system 130, and may notify the user of the impending shut down.

Referring next to FIG. 8, a magnetic resonance guided laser energy thermal therapy system is illustrated according to one embodiment of the present invention. Reference numerals in FIG. 8 that are common to reference numerals in FIGS. 1-7 indicate like, similar or identical features or elements. Magnetic resonance guided laser energy thermal therapy system 800, herein referred to as MR thermal therapy system 800, includes data processor 120, display 255, laser device 805 (an embodiment of heat generating system 130), optic fiber 810 (an embodiment of applicator 330), network 830, MR system 870 (an embodiment of temperature detection system 110), and tissue 860 (an embodiment of target 140). MR system 870 includes magnet 840, radio frequency (RF) coil 850, and MR console 820.

In one embodiment of the present invention, MR thermal therapy system 800 is used to produce lesions in biological tissue (tissue 860), such as muscle, organs, and the like. For example, MR thermal therapy system 800 may be used to cause cell necrosis in cancerous cells in a tumor, while leaving most or all of the healthy cells surrounding the tumor intact.

In one embodiment, data processor 120, discussed in greater detail with reference to FIG. 2, is connected to laser 805 and MR system 870 via network 830. Network 830 may include the Internet, a wireless network, a satellite network, and the like. One reason for a remote connection between data processor 120 and laser 805 and MR system 870 is that a doctor/practitioner may consult on the operation of MR thermal therapy system 200 from a remote location without having to be located near MR system 870 or laser 805. For example, MR thermal therapy system 800 could be transported to a difficult to access remote region by a technician, and an experienced doctor located elsewhere who is unable to reach the remote region could direct the actions of the technician, or control the system himself, based on the images displayed to the doctor by GUI 250 (FIG. 2) on display 255 connected to data processor 120. It will also be appreciated that laser 805 may be remotely located from tissue 860 with the laser energy delivered to tissue 860 via optic fiber 810.

MR system 870 continuously or periodically measures and stores data obtained by measurement conducted on tissue 860. One implementation of MR system 870 may be an imaging system equipped to generate proton resonance images. In this implementation, the system is capable of exhibiting a spatial-temperature resolution of 0.16° C. cm or better. MR system 870 uses a magnetic field, created by magnet 840, and radio emissions, emitted from RF coil 850, to continuously obtain MR data 825 (data 105) from an area, plane, or volume of tissue 860. In one embodiment, MR data 825 includes a complex number for each pixel of an MR image obtained by MR console 820. For example, if MR data 825 includes the data for a 256 by 256 pixel resolution MR image, MR data 825 includes 65536 complex numbers. Because of the time involved in interrogating the selected

portion of tissue 860 using magnetic resonance imaging techniques, MR system 870 is generally the limiting factor in the degree to which MR thermal therapy system 800 behaves in a real-time fashion. For example, in one implementation of MR thermal therapy system 800, MR system 870 takes an average of seventeen seconds to measure and collect MR data 825 on an MR image with a resolution of 256 by 256 pixels. It will be appreciated that as the signal-to-noise ratio of a desired MR image decreases, and/or as the measurement speed of MR system 870 for a given signal-to-noise ratio increases, the delay in real-time feedback control will be reduced.

MR data 825 is continuously updated and transmitted to data processor 120 for realtime, or near real-time, feedback control. Data processor 120 processes updated MR data 825 to generate images for GUI 250 and to control the output of laser 805. In one embodiment, data processor 120 performs Fourier transform decoding on MR data 825 to produce image data. In an alternate embodiment, MR system 870 processes MR data 825 to produce image data and transmits the image data to data processor 120 for further processing. For example, data processor 120 could perform a frequency domain analysis on MR data 825 and produce a complex number representative of each pixel of an image to be displayed on GUI 250. It will also be appreciated that the formatting of MR data 825 into image data could be performed by MR console 820. MR console 820 would then transmit the image data to data processor 120. The magnitudes of the pixels' values may be used to create magnitude image 235 (FIG. 2), which represents the physical structure of an area, cross-section or volume of tissue 860. In one embodiment, the physical structure of the area, cross-section, or volume is determined using the localized calculated spin density of hydrogen molecules measured by MR system 870. In at least one embodiment, a reference image is obtained before laser 805 applies any heat. After heat is applied and MR data 825 representing an updated image of tissue 860 is obtained, the resulting phase difference between the reference image pixel and the updated image pixel represents the temperature change. In order to determine the absolute temperature of a pixel, the change in temperature between the updated image and the reference image must be added to the reference image absolute temperature, which is known by measurement, empirical data, etc. In one embodiment, MR system 870 is capable of determining the absolute temperature of tissue 860. It will be appreciated that other methods of processing MR data 825 to produce images displayed by GUI 250 and/or to process to control the output of heat generating system 130 may be used without departing from the spirit or the scope of the present invention.

Irreversibly damaged tissue is displayed using damage image 245 (FIG. 2) in GUI 250. A portion of tissue 860 is considered irreversibly damaged when the cells of the tissue portion are dead, or damaged enough, through protein denaturation, water vaporization, etc., that it is determined, using empirical data, previous experience, or models, that the cells will likely die within a relatively short time span. In one embodiment, damage image 245 is constructed using the temperature history for a given portion of tissue 860. One method of determining tissue damage using temperature history is to determine a total amount of heat absorbed by tissue in an area. This may be achieved by keeping a summation of all temperatures measured for a given portion of tissue 860. If the sum total of heat for the given portion exceeds a predetermined value, the cells in that portion are considered dead or dying. In one embodiment,

the Arrhenius rate equation may be used to calculate irreversible cell damage as a function of the temperature history. The Arrhenius rate equations is commonly expressed as follows:

$$\Omega = \int A * e^{-Ea/(RT)} dt$$

Wherein:

A is the frequency factor constant for a given tissue type;

Ea is the activation energy value specific to the type of tissue;

R is the Universal Gas Constant; and T is the temperature history of the tissue as a function of time; and a cell is considered dead or dying if the value of Ω is greater than or equal to one when the equation is evaluated.

The Arrhenius rate equation is integrated with respect to time for a given location of tissue **860**, and if the integrated value is greater than a determined value, then the cells in the location are considered irreversibly damaged. It will be appreciated that the determined value, based on tissue type, may be a result of empirical analysis, a user's experience, models, or theory. As it is very rare to have a defined, continuous equation for cell temperature as a function of time, the Arrhenius rate equation is usually evaluated numerically by using linear interpolation between temperature history points. It will be appreciated that as the time difference between temperature history points decreases, the degree to which linear interpolation emulates the real temperature history of a given location of tissue **860** increases.

As discussed previously, damage distribution data, in addition to (or in place of) temperature data, may be used to determine the feedback control of laser **805**. Since the damage to a cell in many cases is dependent on the properties of the cell type, location, and the like, the appropriate values for constants of the Arrhenius equation must be determined. The user may use previous experience, tables, or may load the values from a database or a file. Alternately, the values could be hardcoded into software used by data processor **120**, automatically uploaded from a database, etc. Incorrectly determining the total heat needed may result in charring of the cells if the history of heat received is enough to char the cells or if an absolute maximum temperature is exceeded. Similarly, if not enough heat is absorbed by the cells in tissue **870**, or if a minimum temperature needed to cause cell death or irreversible damage is never reached, the cells will not be dead or dying, although they are displayed as dead or dying cells in damage image **245** (FIG. 2).

In the previous detailed description of the embodiments of the present invention, reference is made to the accompanying drawings that form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that logical, mechanical, chemical and electrical changes may be made without departing from the spirit or scope of the invention. To avoid detail not necessary to enable those skilled in the art to practice the invention, the description may omit certain information known to those skilled in the art. The previous detailed description is, therefore, not to be taken in a limiting sense, and the scope of the present invention is defined only by the appended claims.

We claim:

1. A system comprising:

a data processing module having a plurality of input output nodes; and

a memory having a plurality of input output nodes coupled to the plurality of input output nodes of the data processing module, wherein the memory stores operational instructions that cause the processing module to:

receive input data from a detection device that interrogates a tissue portion with radiation as part of acquiring the input data, wherein the input data corresponds to a tissue portion and includes temperature sensitive information;

determine a first characteristic for a heat generating device based on the temperature sensitive information, wherein operation of the heat generating device is to be based on the first characteristic; and

provide control data to the heat generating device, wherein the control data is based on the first characteristic.

2. The system of claim 1, wherein the operational instruction that causes the processing module to determine includes determining the first characteristic being based upon the temperature sensitive information of a first portion of the input data, wherein the first portion of the input data corresponds to a first region of the tissue portion.

3. The system of claim 2, wherein the operational instruction that causes the processing module to determine includes determining a tissue damage of the first region of the tissue portion, and determining the first characteristic based upon the tissue damage of the first region of the tissue portion.

4. The system of claim 3, wherein the operational instruction that causes the processing module to determine includes evaluating a mathematical function that is dependent upon the temperature sensitive information for a specific location with respect to time to determine a damage indicator.

5. The system of claim 4, wherein the operational instruction that causes the processing module to determine includes determining a tissue damage of the first region of the tissue portion, and determining the first characteristic based upon the tissue damage of the first region of the tissue portion.

6. The system of claim 5, wherein the operational instruction that causes the processing module to determine includes evaluating a mathematical function that is dependent upon the temperature sensitive information for a specific location with respect to time to determine a damage indicator.

7. A memory area accessible to a data processor, wherein the memory unit stores executable data for:

receiving input data at a data processor, wherein the input data is from a detection device that interrogates a tissue portion with radiation as part of acquiring the input data, wherein the input data corresponds to a tissue portion and includes temperature sensitive information;

determining at the data processor a first characteristic for a heat generating device based on the temperature sensitive information, wherein operation of the heat generating device is to be based on the first characteristic; and

providing control data to the heat generating device, wherein the control data is based on the first characteristic.

8. A data processor controlled method for treating a lesion comprising the steps of:

determining a temperature of a portion of the lesion using a magnetic resonance imager;

determining an amount of energy to apply to the lesion based on the temperature of the portion of the lesion; and

21

providing control information to an energy delivery device to generate the amount of heat.

9. A method comprising the steps of:

heating a localized portion of a target with a controllable heat source;

receiving data from an imaging device, wherein the data includes information associated with a temperature proximate to the localized portion of the target; and

controlling the heat source in an automated manner based at least in part on the information associated with the temperature proximate to the localized portion of the target.

10. The method as in claim 9, wherein the imaging device is a magnetic resonance imager equipped to generate proton resonance frequency sensitive images.

11. The method as in claim 9, wherein the step of controlling is based at least in part on a history of the temperature proximate to the localized portion of the target.

12. The method as in claim 9, wherein the step of controlling includes increasing or decreasing a rate at which the heat source heats the localized portion of the target.

13. The method as in claim 9, wherein:

the data includes information associated with a temperature of a plurality of locations proximate to the localized portion of the target; and

the step of controlling is eased at least in part on the information associated with the temperature of the plurality of locations.

14. The method as in claim 13, wherein the plurality of locations includes one or more locations selected by a user.

15. The method as in claim 14, wherein the one or more locations are selected in real time.

16. The method as in claim 14, wherein the one or more locations can be specified using a graphical user interface.

17. A method comprising the steps of:

receiving input data at a data processor, wherein the input data is from a detection device that interrogates a tissue portion with radiation as part of acquiring the input data, wherein the input data corresponds to a tissue portion and includes temperature sensitive information;

determining at the data processor a first characteristic for a heat generating device based on the temperature sensitive information, wherein operation of the heat generating device is to be based on the first characteristic; and

providing control data to the heat generating device, wherein the control data is based on the first characteristic.

18. The method of claim 17, wherein the step of receiving includes the detection device being one of an infrared device, a magnetic resonance device, an ultra-sound device, a radio frequency device, an x-ray device, and a computerized tomography device.

19. The method of claim 18, wherein the radiation device is a magnetic resonance device.

20. The method of claim 19, wherein the magnetic resonance device is an imaging system equipped to generate proton resonance frequency sensitive images.

21. The method of claim 17, wherein the step of determining includes determining the first characteristic based upon the temperature sensitive information of a first portion of the input data, wherein the first portion of the input data corresponds to a first region of the tissue portion.

22. The method of claim 21, wherein the first region of the tissue portion includes one or more points defined by a user.

23. The method of claim 21, wherein the first region of the tissue portion includes an area defined by a user.

22

24. The method of claim 21, wherein the first region includes one of a point, a plane, and a volume of the tissue.

25. The method of claim 21, wherein the first region of the tissue portion is specified by a user using a graphical user interface.

26. The method of claim 21, wherein the step of determining includes determining the first characteristic based upon the temperature sensitive information of the first portion of the input data at a first time, and determining the first characteristic based upon the temperature sensitive information of a second portion of the input data at a second time wherein the second portion of the input data corresponds to a second region of the tissue portion.

27. The method of claim 26, wherein in the second region of the tissue portion is specified by a user in real time.

28. The method of claim 27, wherein the second region of the tissue portion can be one of one or more points, and an area of the tissue portion.

29. The method of claim 27, wherein the second region of the tissue portion can be specified by the user using a graphical user interface.

30. The method of claim 21, wherein the step of determining includes determining a tissue damage of the first region of the tissue portion, and determining the first characteristic based upon the tissue damage of the first region of the tissue portion.

31. The method of claim 30, wherein determining the tissue damage includes evaluating a mathematical function that is dependent upon the temperature sensitive information for a specific location with respect to time to determine a damage indicator.

32. The method of claim 31, wherein the tissue damage is considered true when the damage indicator exceeds a pre-defined value.

33. The method of claim 32, wherein the mathematical function evaluated is based upon an Arrhenius rate process.

34. The method of claim 32, wherein the mathematical function is $fAe^{-E_a/RT}$, where A is the frequency factor constant for a tissue, E_a is the activation energy for the tissue at the specific location, R is the universal gas constant, and T is the time dependent temperature at the specific location.

35. The method of claim 17, wherein the step of determining includes determining a current temperature for a plurality of locations within the tissue portion.

36. The method of claim 35, wherein the current temperature for each one of the plurality of location is based upon a current data and a reference data of the input data.

37. The method of claim 36, further including the step of: receiving a temperature value for at least one location of the reference data.

38. The method of claim 17, wherein the step of receiving includes the temperature sensitive information being current temperature values of a plurality of locations within the tissue portion.

39. The method of claim 17, wherein the step of providing includes the control data indicating an intensity of a heat to be generated by the heat generating device, wherein the control data is based upon a representation of the first characteristic.

40. The method of claim 17, wherein the step of providing includes the control data indicating a duration of a heat to be generated by the heat generating device.

41. The method of claim 40, wherein the duration includes a duty cycle specifying a duration of the heat to be generated by the heat generating device.

42. The method of claim 17, wherein the step of providing control data includes providing control data at a network interface.

23

43. The method of claim 42, wherein the network interface is an Ethernet interface.

44. The method of claim 17, wherein the step of providing control data includes providing the control data at a point-to-point interface.

45. The method of claim 44, wherein the point-to-point interface includes one of an RS-232 interface, an EFEE-488 interface, and a digital I/O (input/output) interface.

46. The method of claim 17, further including the step of providing image data to illustrate a representation of damaged tissue portions of the tissue portion.

47. The method of claim 46, wherein determining the tissue damage includes evaluating a mathematical function that is dependent upon the temperature sensitive information for a specific location with respect to time to determine a damage indicator.

48. The method of claim 46, wherein damaged tissue portions are those portions of the tissue portion that are one of dead and dying tissue.

49. The method of claim 46, wherein the damaged tissue portions are identified based on an evaluation of a mathematical function that is dependent upon the temperature sensitive information for a specific location with respect to time to determine a damage indicator.

50. The method of claim 46, further including the step of providing image data representing a structural representation of the tissue portion.

51. The method of claim 50, wherein the structural representation is based upon a calculated spin density of the input data.

52. The method of claim 46, further including the step of providing image data representing a temperature of the tissue portion.

53. The method of claim 46, wherein temperatures for a plurality of locations are identified based upon a proton resonance frequency sensitive portion of the input data.

54. The method of claim 53, further including the step of providing image data representing a structural representation of the tissue portion.

55. The method of claim 17, wherein the step of receiving input data includes receiving the input data at a network interface.

56. The method of claim 55, wherein the network interface is to provide data conforming to a DICOM protocol.

57. The method of claim 56, wherein the network interface is an Ethernet interface.

58. The method of claim 17, wherein the step of receiving input data includes receiving the input data at a point-to-point interface.

59. The method of claim 58, wherein the point-to-point interface includes one of an RS-232 interface, an IEEE-488 interface, and a digital I/O (input/output) interface.

60. The method of claim 17, wherein the step of receiving includes receiving the input data by polling the detection device to determine when the input data is available.

24

61. The method of claim 17, wherein the step of receiving includes receiving the input data by reading the input data from a storage location.

62. The method of claim 61, wherein the storage location is associated with the detection device.

63. The method of claim 17, wherein the step of determining includes determining the first characteristic using a rule set.

64. The method of claim 63, wherein the rule set is implemented using fuzzy logic.

65. The method of claim 63, wherein in variables used by the rule set include temperature values for at least one point of the tissue portion.

66. The method of claim 65, wherein in variables used by the rule set include damage data for at least one point of a tissue portion.

67. The method of claim 63, wherein in variables used by the rule set include damage data for at least one point of a tissue portion.

68. The method of claim 63, wherein variables used by the rule set can be dynamically changed by a user.

69. The method of claim 63, wherein the rule set can be changed dynamically by a user.

70. The method of claim 69, wherein variables used by the rule set can be dynamically changed by a user.

71. The method of claim 17, further including the steps of determining at the data processor a second characteristic for a heat generating device based upon the temperature sensitive information;

providing control data to, the heat generating device to implement the second characteristic.

72. The method of claim 71, wherein the first characteristic is for controlling one of a heat source intensity, a heat source duration, and a heat source location, and the second characteristic is different than the first characteristic and is for controlling one of the heat source intensity, the heat source duration, and the heat source location.

73. The method of claim 17, wherein the step of providing control data includes the control data specifying how to provide heat to a plurality of applicators.

74. The method of claim 73, wherein the plurality of applicators are associated with a single heat generating device.

75. The method of claim 73, wherein the plurality of applicators are associated with a plurality of heat generating devices.

76. The method of claim 75, wherein the plurality of heat generating devices are similar type devices.

77. The method of claim 75, wherein the plurality of heat generating devices are different type devices.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,542,767 B1
DATED : April 1, 2003
INVENTOR(S) : Roger J. McNichols and Ashok Gowda

Page 1 of 1

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

Column 20,

Line 42, replace "includes.evaluating" with -- includes evaluating --

Column 21,

Line 26, replace "is eased at" with -- is based at --

Column 22,

Line 37, replace "is $\int A3-La/Rf dt$ " with -- is $\int Ae^{-Ea/RT} dt$ --

Column 23,

Line 7, replace "an EFEE-488" with -- an IEEE-488 --

Column 24,

Line 32, replace "data to, the heat" with -- data to the heat --

Signed and Sealed this

Twenty-third Day of September, 2003



JAMES E. ROGAN
Director of the United States Patent and Trademark Office

专利名称(译)	用于控制向目标的热传递的方法和系统		
公开(公告)号	US6542767	公开(公告)日	2003-04-01
申请号	US09/710694	申请日	2000-11-08
[标]申请(专利权)人(译)	BIOTEX		
申请(专利权)人(译)	BIOTEX INC.		
当前申请(专利权)人(译)	VISUALASE INC.		
[标]发明人	MCNICHOLS ROGER J GOWDA ASHOK		
发明人	MCNICHOLS, ROGER J. GOWDA, ASHOK		
IPC分类号	A61B18/20 A61B5/00 A61B18/04 A61B18/00 A61B18/18 A61B18/08 A61B19/00 A61B5/055 A61B17/00 A61N5/02 A61N5/04 A61N5/06 A61B5/01 A61N7/00		
CPC分类号	A61B5/0008 A61B18/20 A61B5/015 A61N7/02 A61B5/055 A61B18/08 A61B18/18 A61B19/5225 A61B2017/0007 A61B2017/00084 A61B2018/00636 A61B2018/00642 A61B2018/00714 A61B2018/00791 A61B2019/5236 A61N1/403 A61N5/04 A61N5/0601 A61B90/37 A61B2090/374		
优先权	60/164416 1999-11-09 US		
外部链接	Espacenet USPTO		

摘要(译)

本文公开了一种使用实时闭环反馈来控制热能输送的方法和系统。能量输送系统可用于将热能传递到目标以实现目标的变化。例如，医疗专业人员使用激光能量不可逆地破坏癌症肿瘤中发现的细胞，而不会损害周围的健康细胞。能量输送系统包括温度检测系统，数据处理器和发热装置。温度检测系统从目标获得温度数据并将数据发送到数据处理器。数据处理器可以处理温度数据以向发热系统提供实时反馈控制，以及在图形用户界面上将数据显示为一个或多个图像。发热系统从数据处理器接收控制命令并相应地调制其热输出。

