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(54) Title: NON-LINEAR CONTROL SYSTEMS AND METHODS FOR HEATING AND ABLATING BODY TISSUE
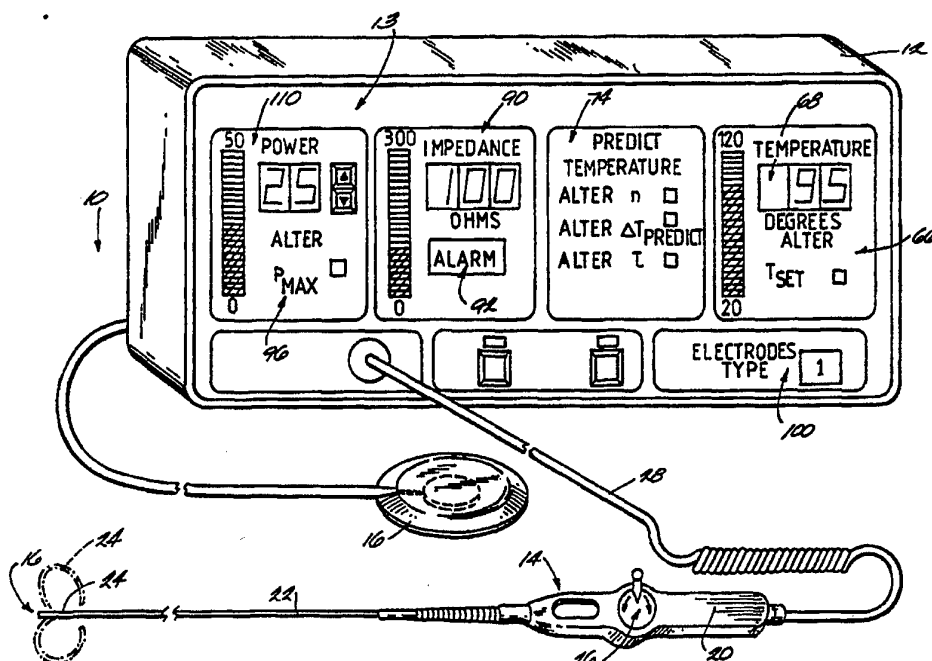
(57) Abstract

Systems and methods employ an energy emitting electrode (16) to heat tissue. The systems and methods control the application of energy to the electrode (16) using adjustments that take into account, in a non-linear fashion, changes in monitored operating conditions.

NON-LINEAR CONTROL SYSTEMS AND METHODS
FOR HEATING AND ABLATING BODY TISSUE

Field of the Invention

5   In a general sense, the invention is directed to systems and methods for creating lesions in the interior regions of the human body. In a more particular sense, the invention is directed to systems and methods for ablating heart tissue for

10   treating cardiac conditions.

Background of the Invention

Physicians frequently make use of catheters today in medical procedures to gain access into interior regions of the body. In some procedures,

15   the catheter carries an energy emitting element on its distal tip to ablate body tissues.

In such procedures, the physician must establish stable and uniform contact between the energy emitting element and the tissue to be

20   ablated. Upon establishing contact, the physician must then carefully apply ablating energy to the element for transmission to the tissue.

The need for precise control over the emission of ablating energy is especially critical

25   during catheter-based procedures for ablating heart tissue. These procedures, called electrophysiology therapy, are becoming increasingly more widespread for treating cardiac rhythm disturbances, called arrhythmias. Cardiac ablation procedures typically

30   use radio frequency (RF) energy to form a lesion in

heart tissue.

The principal objective of the invention is to provide systems and methods for monitoring and reliably controlling the application of energy to ablate body tissue, thereby providing therapeutic results in a consistent and predictable fashion.

Summary of the Invention

The invention provides systems and methods that provide reliable control over tissue heating and ablation procedures using temperature sensing. According to the invention, the systems and methods control the application of energy to an energy emitting electrode using power adjustments that take into account, in a non-linear fashion, changes in monitored operating conditions.

One aspect of the invention provides an apparatus and associated method for supplying energy to an electrode for ablating tissue. The apparatus and method monitor a selected operating condition of the electrode and derive from it an operating value (V_D). The apparatus and method include a processing element that compares the derived operating value V_D to a preselected set value (V_S) for the operating condition to establish an error signal (Δ), where:

$$\Delta = V_S - V_D$$

According to the invention, V_S can either be a fixed, prescribed value or expressed in terms of a value that varies with time as a set temperature curve.

The apparatus and method further issue a command signal $S_{COMMAND}$, where:

$$S_{COMMAND} = f(\Delta_1, \Delta_2, \Delta_3, \ldots, \Delta_N)$$

where, in the general sense, f is a N-

variable nonlinear function that describes the processing element and Δ_1, Δ_2, Δ_3, ... , Δ_N are the values of the error signal Δ at N different moments of time. This means that the processing element can adjust the output signal $S_{COMMAND}$ using a nonlinear function of the present and past values of the error signal Δ.

In a preferred embodiment, $S_{COMMAND}$ can be expressed as:

$$S_{COMMAND} = f(S_{SCALE} \times \Delta)$$

where:

f is a function associated with the processing element (i.e., the algorithm used to analyze data), and

S_{SCALE} is a nonlinear scaling factor that equals a first value (X) when Δ > a value Z and equals a second value (Y), different than X, when Δ < Z, and Z is a desired Δ.

In a preferred embodiment, Z and, therefore the desired Δ is zero.

In a preferred embodiment, the command signal $S_{COMMAND}$ adjust the level of power applied to the electrode. In this preferred embodiment, Y > X. Due to the asymmetric, non-linear scaling factor S_{SCALE}, the apparatus and method serve to decrease power to the electrode at a faster rate than increasing power to the electrode.

Another aspect of the invention provides an apparatus and associated method for supplying energy to an electrode for ablating tissue. The apparatus and method monitor operating conditions of the electrode. The apparatus and method derive a power control signal $S_{DERIVED}$ based upon a monitored first operation condition. The apparatus and method also

compare a monitored second operating condition with preselected criteria for the second operating condition and generate an error signal (E) when the second operating condition fails to meet the preselected criteria.

According to this aspect of the invention, the apparatus and method issue a command signal $S_{COMMAND}$ to set power supplied to the electrode. Absent the error signal E, $S_{COMMAND}$ sets the power according to $S_{DERIVED}$. When the error signal E is generated, $S_{COMMAND}$ sets the power at a prescribed low power condition (P_{LOW}), regardless of $S_{COMMAND}$. According to a preferred aspect of the invention, P_{LOW} is a selected value above zero but at a level that does not sustain tissue ablation over time.

In a preferred embodiment, P_{LOW} is about 1 watt.

In a preferred embodiment, the second monitored operating condition includes a measurement of the power delivered by the generator. In this embodiment, the preselected criteria includes an established maximum power value.

In a preferred embodiment, the second monitored operating condition also includes a measurement of temperature at the electrode. In this embodiment, the preselected criteria includes an established maximum temperature value. In this embodiment, the preselected criteria can also include an established set temperature value adjusted by an established incremental value.

The apparatus and methods that embody the features of the invention are well suited for use in the field of cardiac ablation. They also are applicable for use in other tissue heating and ablation applications, as well. For example, the

various aspects of the invention have application in procedures for ablating tissue in the prostrate, brain, gall bladder, uterus, and other regions of the body, using systems that are not necessarily

5   catheter-based.

In a preferred embodiment, the apparatus and method also measure impedance. Because P_{LOW} is above zero, impedance measurements can continue, even after tissue ablation has been halted.

10   Other features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended claims.

Brief Description of the Drawings

15   Fig. 1 is a perspective view of a system for ablating tissue that comprises an energy emitting electrode and associated energy generator;

Figs. 2, 3 and 4 are, respectively, an elevated side view, an end view, and a side section

20   view (taken along line 4-4 in Fig. 3) of the electrode associated with the system shown in Fig. 1, the electrode having a temperature sensing element;

Fig. 5 is a schematic view of the generator

25   for supplying energy to the electrode in the system shown in Fig. 1, the generator using a specialized modified PID control technique to maintain a desired set temperature by altering power in response to sensed temperature;

30   Figs. 6A and 6B are graphs showing curves of set temperature conditions for the generator to maintain over time;

Fig. 7 is a schematic view of an alternative system for use in association with the

35   generator shown in Fig. 5 to alter applied power in

response to sensed temperature, using adaptive
control techniques;

Fig. 8 is a schematic view of a system for
use in association with the generator shown in Fig.
5 for scaling down power in response to prescribed
power or temperature conditions;

Fig. 9 is a schematic view of systems for
use in association with the generator shown in Fig.
5 for establishing the maximum power condition for
use by the scale back power system shown in Fig. 8;

Fig. 10 is a more detailed schematic view
of one of the systems shown in Fig, 9 for
automatically establishing the maximum power
condition based upon the physical characteristics of
the ablation electrode;

Figs. 11A and B are schematic views of the
implementation of a neural network predictor to
maintain a desired set temperature by altering power
in response to a prediction of maximum tissue
temperature; and

Fig. 12 is a schematic view of the
implementation of fuzzy logic to maintain a desired
set temperature condition.

The invention may be embodied in several
forms without departing from its spirit or essential
characteristics. The scope of the invention is
defined in the appended claims, rather than in the
specific description preceding them. All embodi-
ments that fall within the meaning and range of
equivalency of the claims are therefore intended to
be embraced by the claims.

Description of the Preferred Embodiments

Fig. 1 shows a system 10 for ablating human
tissue that embodies the features of the invention.

In the illustrated and preferred

embodiment, the system 10 includes a generator 12 that delivers radio frequency energy to ablate tissue. Of course, other types of energy can be generated for tissue ablating purposes.

5   The system 10 also includes a steerable catheter 14 carrying a radio frequency emitting ablation electrode 16. In the illustrated embodiment, the ablation electrode 16 is made of platinum.

10   In the illustrated embodiment, the system 10 operates in a unipolar mode. In this arrangement, the system 10 includes a skin patch electrode that serves as an indifferent second electrode 18. In use, the indifferent electrode 18 attaches to the patient's back or other exterior skin area.

15   Alternatively, the system 10 can be operated in a bipolar mode. In this mode, the catheter 14 carries both electrodes.

20   The system 10 can be used in many different environments. This specification describes the system 10 when used to provide cardiac ablation therapy.

          When used for this purpose, a physician steers the catheter 14 through a main vein or artery (typically the femoral vein or artery) into the interior region of the heart that is to be treated. The physician then further manipulates the catheter 14 to place the electrode 16 into contact with the tissue within the heart that is targeted for ablation. The user directs radio frequency energy from the generator 12 into the electrode 16 to ablate and form a lesion on the contacted tissue.

I.   **THE ABLATION CATHETER**

35   In the embodiment shown in Fig. 1, the

catheter 14 includes a handle 20, a guide tube 22, and a distal tip 24, which carries the electrode 16.

The handle 20 encloses a steering mechanism 26 for the catheter tip 24. A cable 28 extending from the rear of the handle 20 has plugs (not shown). The plugs connect the catheter 14 to the generator 12 for conveying radio frequency energy to the ablation electrode 16.

Left and right steering wires (not shown) extend through the guide tube 22 to interconnect the steering mechanism 26 to the left and right sides of the tip 24. Rotating the steering mechanism 26 to the left pulls on the left steering wire, causing the tip 24 to bend to the left. Also, rotating the steering mechanism 26 to the right pulls on the right steering wire, causing the tip 24 to bend to the right. In this way, the physician steers the ablation electrode 16 into contact with the tissue to be ablated.

Further details of this and other types of steering mechanisms for the ablating element 10 are shown in Lunquist and Thompson U.S. Patent 5,254,088, which is incorporated into this Specification by reference.

A.   **Temperature Sensing**

As Figs. 2 to 4 show, the ablation electrode 16 carries at least one temperature sensing element 30. As will be described in greater detail later, the power that the generator 12 applies to the electrode 16 is set, at least in part, by the temperature conditions sensed by the element 30.

In the embodiment illustrated in Figs. 3 to 4, the ablation electrode 16 includes an interior well 32 at its tip end. The temperature sensing

element 30 occupies this well 32.

In Figs. 3 to 4, the temperature sensing element 30 includes a small bead thermistor 34 with two associated lead wires 36 and 38. The temperature sensing tip of the thermistor 34 is exposed at the tip end of the ablation electrode 16 for tissue contact. The thermistor 34 of the type shown is commercially available from the Fenwal Co. (Massachusetts) under the trade designation 111-202CAK-BD1. The lead wires 36 and 38 comprise #36 AWG signal wire Cu+ clad steel (heavy insulation).

Potting compound 40 encapsulates the thermistor 34 and lead wires 36 and 38 within the electrode well 32. Insulating sheaths 42 also shield the encapsulated lead wires 36 and 38. Together, the compound 40 and sheaths 42 electrically insulate the thermistor 34 from the surrounding ablation electrode 16.

The potting compound 40 and insulation sheathes 42 can be made with various materials. In the illustrated embodiment, loctite adhesive serves as the potting compound 40, although another cyanoacrylate adhesive, an RTV adhesive, polyurethane, epoxy, or the like could be used. The sheathes 42 are made from polyimide material, although other conventional electrical insulating materials also can be used.

In the illustrated and preferred embodiment, a thermal insulating tube 44 envelopes the encapsulated thermistor 34 and lead wires 36 and 38. The thermal insulation tube 44 can itself be adhesively bonded to the interior wall of the well 32.

The thermal insulating material of the tube 44 can vary. In the illustrated embodiment, it is

a polyimide material having a wall thickness of about .003 inch. Other thermal insulating materials like mylar or kapton could be used.

The lead wires 36 and 38 for the thermistor 34 extend through the guide tube 22 and into the catheter handle 20. There, the lead wires 36 and 38 electrically couple to the cable 28 extending from the handle 20. The cable 28 connects to the generator 12 and transmits the temperature signals from the thermistor 34 to the generator 12.

In the illustrated and preferred embodiment (as Fig. 10 shows), the handle 20 carries a calibration element R_{CAL} for the thermistor 34. The element R_{CAL} accounts for deviations in nominal resistance among different thermistors. During manufacture of the catheter 10, the resistance of thermistor 34 is measured at a known temperature; for example, 75 degrees C. The calibration element R_{CAL} has a resistance value equal to the measured value. Further details of this will be discussed later.

II. **THE RF GENERATOR**

As Fig. 5 shows, the generator 12 includes a radio frequency power source 48 connected through a main isolation transformer 50 to outlet and return lines 52 and 54. Outlet line 52 leads to the ablation electrode 16. Return line 54 leads from the indifferent electrode 18.

In the illustrated embodiment, when used for cardiac ablation, the power source 48 is typically conditioned to deliver up to 50 watts of power at a radio frequency of 500 kHz.

The generator 12 further includes a first processing stage 56. The first processing stage 56 receives as inputs an instantaneous power signal

$P_{(t)}$, a set temperature value T_{SET}, and a temperature control signal $T_{CONTROL}$. Analyzing these inputs using prescribed criteria, the first processing stage 56 derives a demand power signal P_{DEMAND}.

The generator 12 also includes a second processing stage 58. The second processing stage 58 receives as input the demand power signal P_{DEMAND} from the first processing stage 56. The second processing stage 58 also receives as inputs the instantaneous power signal $P_{(t)}$ and a maximum power value P_{MAX}. Analyzing these inputs according to prescribed criteria, the second processing stage 58 adjusts the amplitude of the radio frequency voltage of the source, thereby adjusting the magnitude of the generated power, which $P_{(t)}$ represents.

The generator 12 preferably includes an interactive user interface 13, which is only generally shown in schematic form in Fig. 1. It should be appreciated that the interface 13 can, in conventional ways, make full use of conventional input devices (for example, a key board or mouse); output display devices (for example, a graphics display monitor or CRT); and audio and visual alarms.

A.   The First Processing Stage

The generated power signal $P_{(t)}$ input for the first processing stage 56 is generated by a multiplier 60. The multiplier 60 receives an instantaneous current signal $I_{(t)}$ from an isolated current sensing transformer 62 and an instantaneous voltage signal $V_{(t)}$ from an isolated voltage sensing transformer 64.

The isolated current sensing transformer 62 is electrically coupled to the return line 54. The transformer 62 measures the instantaneous radio

frequency current $I_{(t)}$ emitted by the ablation electrode 16 through body tissue to the indifferent electrode 18.

The isolated voltage sensing transformer 64 is electrically coupled between the outlet and return lines 52 and 54. The voltage sensing transformer 64 measures the instantaneous radio frequency voltage $V_{(t)}$ across body tissue between the ablation electrode 16 and the indifferent electrode 18.

The multiplier 60 multiples $I_{(t)}$ by $V_{(t)}$ to derive the instantaneous radio frequency power $P_{(t)}$, which passes through the low pass filter 61 to eliminate ripple. The filtered $P_{(t)}$ serves as the power input signal for the first processing stage 56.

In the illustrated and preferred embodiment, the generator 12 includes, as part of its overall interface 13, a display 110 (see Fig. 1 also) to show $P_{(t)}$.

The set temperature value T_{SET} for the first processing stage 56 can be inputted by the physician through an interface 66, which is part of the overall interface 13 of the generator 12 (see Fig. 1 also). The set temperature value T_{SET} represents the temperature the physician wants to maintain at the ablation site. The value T_{SET} can be established in other ways. For example, the value T_{SET} can vary over time to define a set temperature curve. Further details of this will be described later.

The set temperature value T_{SET} selected depends upon the desired therapeutic characteristics of the lesion. Typical therapeutic lesion characteristics are the surface area of the tissue that is ablated and depth of the ablation. Typically, the

set temperature T_{SET} is in the range of 50 to 90
degrees C.

The temperature control signal $T_{CONTROL}$ input
is based upon the actual instantaneous temperature
conditions sensed $T_{M(t)}$ by the sensing element 30.

In the particular illustrated embodiment,
the first processing stage 56 receives as $T_{CONTROL}$ the
output resistance value of the thermistor 84 (in
ohms). It divides this resistance value by the
calibration value R_{CAL} to normalize the resistance
value of the thermistor 34. This normalized
resistance value is the input to a read only memory
(ROM) table in the generator 12, which contains
stored thermistor temperature data. The ROM output
is the actual measured temperature $T_{M(t)}$ (in degrees
C).

The $T_{M(t)}$ output is preferably shown in a
display 68, which is part of the overall interface
13 for the generator 12 (see Fig. 1 also).

The actual instantaneous temperature $T_{M(t)}$
can be used directly by the first processing stage
56. However, in the illustrated and preferred
embodiment, the first processing stage 56 includes
a predicted temperature processor 70 (PTP). The PTP
70 derives from $T_{M(t)}$ a predicted temperature value
(designated $T_{PRED(t)}$).

(i) The Predicted Temperature
Processor

The PTP 70 continuously samples $T_{M(t)}$ over
prescribed sample periods ΔT_{SAMPLE}. Applying
prescribed criteria to these samples, the PTP 70
predicts at the end of each sample period a
temperature condition $T_{PRED(t)}$ that would exist at the
end of a future time period (greater than
ΔT_{SAMPLE}), assuming that power supplied to the ablating

electrode 16 is not changed. This future time
period is called the prediction period $\Delta T_{PREDICT}$.

The length of the prediction period $\Delta T_{PREDICT}$
can vary. Its maximum length depends largely upon
5   the thermal time constant of the tissue, to take
into account the expected physiological response of
the tissue to temperature conditions generated
during ablation. The prediction period $\Delta T_{PREDICT}$ should
not exceed the time period at which the tissue can
10   be expected to experience cellular transformation
when exposed to ablating heat.

In the case of heart tissue, the thermal
time constant is such that the maximum length of the
prediction period $\Delta T_{PREDICT}$ should typically not exceed
15   about two seconds. After about two seconds, cardiac
tissue can be expected to begin experiencing
cellular transformation when exposed to the range of
temperatures generated during ablation.

ΔT_{SAMPLE} is selected to be smaller than
20     $\Delta T_{PREDICT}$. The PTP 70 measures the instantaneous
temperature $T_{M(t)}$ at the end of the present sample
period and compares it to the measured temperature
at the end of one or more preceding sample periods
$T_{M(t-n)}$, where n is the number of preceding sample
25   periods selected for comparison. Based upon the
change in the measured temperature over time during
the selected sample periods, and taking into account
the relationship between the magnitude of ΔT_{SAMPLE} and
$\Delta T_{PREDICT}$, the PTP 70 predicts $T_{PRED(t)}$ as follows:

$$T_{PRED(t)} = T_{M(t)} \left(\frac{i+K}{i} \right) - T_{M(t-i)} \left(\frac{K}{i} \right)$$

30   where:

$$K= \frac{\Delta T_{PREDICT}}{\Delta T_{SAMPLE}}$$

and i = 1 to n.

In a representative implementation of the PTP 70 for cardiac ablation, $\Delta T_{PREDICT}$ is selected to be 0.48 second, and ΔT_{SAMPLE} is selected to be 0.02 second (a sampling rate of 50Hz). Therefore, in this implementation, K = 24.

Furthermore, in this implementation, n is selected to be 1. That is, the PTP 70 takes into account $T_{M(t)}$ for the instant sample period (t) and $T_{M(t-1)}$ for the preceding sample period (t-1).

In this implementation, the PTP 70 derives $T_{PRED(t)}$ as follows:

$$T_{PRED(t)}=25T_{M(t)}-24T_{M(t-1)}$$

In the illustrated and preferred embodiment, the PTP 70 includes a low pass filter 72 with a selected time constant (τ). The PTP 70 averages $T_{PRED(t)}$ through the filter 72 before supplying it to a demand power processor DPP 76, which will be described later.

The time constant (τ) of the filter 72 selected can vary, according to the degree of accuracy desired. Generally speaking, a mid-range time constant (τ) of about 0.2 second to about 0.7 second will provide the required accuracy. In the above described representative implementation, a time constant (τ) of 0.25 second is used.

The degree of accuracy of the PTP 70 can also be altered by varying K. More particularly, by lowering the value of K, one can expect the PTP 70 to achieve a greater degree of accuracy in predicting the future temperature $T_{PRED(t)}$. The value

of K can be varied by selecting values for ΔT_{SAMPLE} or $\Delta T_{PREDICT}$, or both. Preferably, the value of K is varied by selecting $\Delta T_{PREDICT}$.

The degree of accuracy PTP 70 can also be improved, if desired, by selecting greater values for n; that is, by taking into account more past values of $T_{M(t)}$ in calculating $T_{PRED(t)}$.

In the illustrated and preferred embodiment, the PTP 70 includes a user interface 74, which is part of the overall interface 13 of the generator 12 (see Fig. 1 also). Using the interface 74, the physician can select and modify the sampling history (n); the prediction period $\Delta T_{PREDICT}$; and the time constant (τ) in real time, on line.

As will be described in greater detail later, the ability to vary the accuracy of the PTP 70 in calculating $T_{PRED(t)}$ with on line changes provides flexibility in adapting the first processing stage 56 to differing ablating conditions.

(ii) The Demand Power Processor (DPP)

The first processing stage 56 further includes a demand power processor (DPP) 76. The DPP 76 periodically compares $T_{PRED(t)}$ to the set temperature value T_{SET}. Based upon this comparison, and taking into account the magnitude of the instantaneous power $P_{(t)}$ supplied to the ablating electrode 16, the DPP 76 derives the demand power output P_{DEMAND}. The DPP76 also takes into account other system operating goals and criteria, like response time, steady state temperature error, and maximum temperature overshoot.

The demand power output P_{DEMAND} of the first processing stage 56 represents the magnitude of the radio frequency power that should be supplied to the

ablating electrode 16 to establish or maintain the
desired local temperature condition T_{SET} at the
ablating electrode 16.

The manner in which the DPP 76 derives P_{DEMAND}

5   can vary. For example, it can employ proportional
control principles, proportional integral derivative
(PID) control principles, adaptive control, neural
network, and fuzzy logic control principles.

(a) Modified PID Control Using

10   Fixed T_{SET}

In the illustrated and preferred
embodiment, the DPP 76 employs a modified velocity
PID control technique specially adapted for cardiac
ablation. Using this technique, the DPP 76 controls

15   the magnitude of P_{DEMAND} based upon a fixed value of
T_{SET} established by the physician.

In the preferred and illustrated
implementation, the DPP 76 compares a derived
operating value V_D to a preselected set value $(\overset{\vee}{y})$

20   for the operating condition. The DPP 76 establishes
an error signal (Δ) based upon the comparison,
where:

$$\Delta = V_S - V_D$$

The DPP 76 issues the power demand signal
for the next time period $P_{DEMAND(t+1)}$ based upon a non-

25   linear function of the present and past values of
the error signal Δ, i.e.,:

$$P_{DEMAND(t+1)} = f(\Delta_1, \Delta_2, \Delta_3, \ldots, \Delta_N)$$

In the general sense, f is a N-variable
nonlinear function that the DPP 76 follows in
performing its processing function. $\Delta_1, \Delta_2, \Delta_3, \ldots$

30     $, \Delta_N$ are the values of the error signal Δ at N
different moments of time. The DPP 76 thereby

adjusts the power by an increment based upon a nonlinear function of the present and past values of the error signal Δ.

More particularly, in the illustrated and preferred implementation, at the end of each sample period (t), the DPP 76 derives the demand power output required for the next sample period (t+1), as follows:

$$P_{DEMAND(t+1)} = P_{(t)} + S[\alpha E_{(t)} - \beta E_{(t-1)} + \delta E_{(t-2)}]$$

where

the nonlinear function f(Δ) is expressed as:

$$f(\Delta) = S[\alpha E_{(t)} - \beta E_{(t-1)} + \delta E_{(t-2)}]$$

the error signal Δ is expressed as $E_{(t)}$, where V_D is T_{PRED} and V_S is T_{SET}, so that $E_{(t)} = T_{SET} - T_{PRED(t)}$. In this implementation, a threshold value of T_{SET} is selected, which remains essentially constant as $T_{PRED(t)}$ is determined by the PTP 70, and

α, β, and δ are conventional velocity PID expressions based upon a proportional constant K_p (relating to the magnitude of the difference); an integral constant K_i (relating to the change in the difference over time); and a derivative constant K_d (relating to rate at which the difference is changing over time); and ΔT_{SAMPLE}, as follows:

$$\alpha = K_p + \frac{K_i \Delta T_{SAMPLE}}{2} + \frac{K_d}{\Delta T_{SAMPLE}}$$

$$\beta = \frac{K_i \Delta T_{SAMPLE}}{2} - K_p - \frac{2K_d}{\Delta T_{SAMPLE}}$$

$$\delta = \frac{K_d}{\Delta T_{SAMPLE}}$$

and

and S is a selected scaling factor, whose value depends upon whether $T_{PRED(t)}$ is greater than or less than T_{SET} , as follows:

5   S = X when $E_{(t)}$ > 0 (i.e., T_{SET} > $T_{PRED(t)}$),

           S = Y when $E_{(t)}$ < 0 (i.e., T_{SET} < $T_{PRED(t)}$), and

           The value of S is asymmetric;
10 that is, X is different than Y and, most preferably, Y > X.

           The above relationships assume that the desired error $E_{(t)}$ to be maintained is zero. Other desired error values could be used. Using the
15 asymmetric scaling factor S provides the desired nonlinear response f(Δ) over time to maintain the desired error $E_{(t)}$. In maintaining the desired error at zero, the f(Δ) of the DPP 76 decreases power faster (when $T_{PRED(t)}$ > T_{SET}) than increasing power
20 (when $T_{PRED(t)}$ < T_{SET}).

           In the illustrated and preferred embodiment, the DPP 76 uses fixed values for the coefficients K_p, K_i, and K_d, regardless of the particular ablating conditions.
25   The calculation for P_{DEMAND} can be adapted on line by the physician to changing ablating conditions encountered, by adjusting the front end calculation of $T_{PRED(t)}$ by the PTP 70. Because of the flexibility to make on line adjustments that the PTP
30 70 provides, multiple value tables of K_p, K_i, and K_d are not necessary in the system to accommodate changes in ablating conditions.

Applicants have determined that the following values of for K_p, K_i, and K_d can be used in the DPP 76:

$$K_p = 0.025375$$
$$K_i = 97.0695$$
$$K_d = 7.82 \times 10^{-5}$$

In a representative implementation of the DPP 76,

$$\Delta T_{SAMPLE} = 0.02, \text{ and therefore}$$
$$\alpha = 0.99998$$
$$\beta = 0.93750$$
$$\delta = 3.91 \times 10^{-3}.$$

In this representative implementation of the DPP 76,

$$S = 2.0 \text{ when } E_{(t)} > 0 \text{ (i.e., } T_{SET} > T_{PRED(t)}), \text{ and}$$

$$S = 8.0 \text{ when } E_{(t)} < 0 \text{ (i.e., } T_{SET} < T_{PRED}).$$

This representative implementation adjusts $P_{DEMAND(t)}$ to reach $T_{SET} \pm 3°$ C within 5.0 seconds, if not limited by available power. It also aims to keep a peak steady state temperature error (defined as $T_{SET} - T_{PRED(t)}$) of less than $3°$ C. The implementation also adjusts $P_{DEMAND(t)}$ over time to avoid overshooting T_{SET} by more than $3°$ C.

(b) Modified PID Control Using Variable T_{SET}

In an alternative embodiment, the DPP 76 uses modified velocity PID control described above to control the magnitude of P_{DEMAND} based upon varying values of T_{SET} over time. In this embodiment, T_{SET} is expressed as a function with respect to time (see Figs. 6A and 6B), which can be linear or nonlinear or both. In this embodiment, T_{SET} comprises a temperature versus time curve (see Figs. 6A and 6B)

for heating tissue. The curve has a first temperature value set at a first time period and at least one additional temperature value, different than the first temperature value, set at a second time period after the first time period.

As Fig. 6A shows, T_{SET} can be expressed in terms of a linear function at the outset of the ablation procedure (for example, during the first 5 seconds). From t=0 to t=5 seconds, the value of T_{SET} progressively increases as a straight line with a selected slope. At t=6 seconds, T_{SET} begins to be expressed in term of a nonlinear function, so that the slope flattens out as T_{SET} approaches a preselected final control value for ablation.

In an alternative implementation (shown in Fig. 6B), the T_{SET} defines a complex curve to accommodate thermal mapping before thermal ablation. As Fig. 6B shows, from t=0 to t=2 seconds, the value of T_{SET} progressively increases as a straight line with a selected slope. At t=3 seconds, T_{SET} begins to be expressed in term of a nonlinear function, and the slope flattens out as T_{SET} approaches a first preselected value for thermal mapping. The slope remains flat until t=10, when the value of T_{SET} again progressively increases as a straight line with a selected slope. At t=13 seconds, T_{SET} again begins to be expressed in term of a nonlinear function, and the slope flattens out as T_{SET} approaches a second preselected value for tissue ablation. In the example shown in Fig. 6B, the first value of T_{SET} for thermal mapping is within 45° C to 50° C, whereas the second value for T_{SET} for tissue ablation is within 50° C to °90 C, and preferable about 70 C. Moreover, T_{SET} can be defined as a true function of time.

In either implementation Fig. 6A or 6B, the
DPP 76 receives as input changing values of T_{SET} over
time, which define the prescribed set temperature
curve. The system calculates $E_{(t)}$ based upon these
5   changing values to derive P_{DEMAND}, in the same manner
that the system derives P_{DEMAND} based upon a constant
value of T_{SET}.

(c) Adaptive Control System

Fig. 7 shows an alternative implantation of
10   the DPP 76, which derives P_{DEMAND} using adaptive
control principles. In this implementation, the DPP
76 receives as input T_{SET} and T_{PRED} in the manner
previously described. The values of T_{SET} can be fixed
or can vary with time, as also previously described.

15   In the implementation shown in Fig. 7, the
DPP 76 further includes a pair of adaptive filters
78 and 80. Each filter 78 and 80 generates an
output based upon an input, expressed in terms of an
assumed relationship between them. In the
20   illustrated implementation, the output comprises an
estimate, based upon the assumed relationship, of an
external condition that can be independently
measured by the DPP 76. The DPP 76 compares the
estimated output to the actually measured external
25   condition and adjusts the coefficients of the
assumed relationship to minimize the error between
the two.

In the implementation of the DPP 76 shown
in Fig. 7, the filter 78 receives as input the
30   instantaneous power $P_{(t)}$ applied by the RF source 48
to the ablating electrode 16. The filter 78
generates as output an estimate of the temperature
condition $T_{EST(t)}$ that the sensing element 30 should
sense, given $P_{(t)}$ and the assumed relationship
35   between $P_{(t)}$ and the temperature $T_{(t)}$ at the ablation

site. The filter 78 therefore approximates the heat transfer function of the tissue contacting the ablating electrode 16.

The DPP 76 includes a summing junction 82, which derives a temperature error signal T_E by subtracting the estimated temperature $T_{EST(t)}$ from the temperature $T_{(t)}$ actually sensed by the sensing element 30. The DPP 76 feeds back the error signal T_E to the filter 78. The filter 78 adjusts the coefficients of the assumed relationship between $P_{(t)}$ and $T_{(i)}$ to minimize the magnitude of the error T_E.

In a preferred implementation, the filter 78 uses a finite linear sequence to express the assumed relationship between $P_{(i)}$ and $T_{(i)}$. The sequence estimates a future temperature $T_{EST(t+1)}$ based upon present instantaneous power $P_{(t)}$ and the past power $P_{(t-n)}$, where n represents the number of past power conditions taken into account. The quantity n can vary according to the accuracy desired.

In an illustrative implementation, the filter 78 takes into account the present power $P_{(t)}$ and the preceding power $P_{(t-1)}$ (i.e., n = 1). In this implementation, the finite linear sequence is expressed as follows:

$$T_{EST(t+1)} = aP_{(t)} + bP_{(t-1)}$$

where a and b represent the assumed transfer coefficients.

The assumed transfer coefficients comprise initially selected values which are then adjusted to minimize the error signal T_E. This adaptive adjustment can be accomplished using various known techniques. For example, the coefficients can be adjusted based upon the Least Mean Square (LMS) method, which tends to minimize the square of the

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error T_E.

     The LMS method updates the coefficients a and b, as follows:

$$T_{E(t)} = T_{(t)} - T_{EST(t)}$$

5

$$a_{(t+1)} = a_{(t)} + \mu P_{(t)} T_{E(t)}$$

$$b_{(t+1)} = b_{(t)} + \mu P_{(t-1)} T_{E(t)}$$

where μ is the step-size of the algorithm.

     A larger μ provides a faster convergence rate but a larger ripple about the optimal

10   coefficients. A smaller μ reduces both the convergence rate and the ripple about the optimal solution. The optimal value of μ depends on the characteristics of the system to be modeled. In the case of the illustrated electrode-blood-tissue

15   system, μ lies in the interval between 0.01 and 0.5.

     The filter 80 is the inverse of the filter 78. The filter 80 receives as input a temperature error signal ΔT generated by the summing junction 84. The summing junction 84 subtracts $T_{PREDICT(t)}$ from

20   T_{SET} to generate the error signal ΔT.

     The filter 80 generates as output ΔP, which represents an approximation of how much the power $P_{(t)}$ should be altered in view of ΔT, based upon the inverse of the assumed relationship between power

25    $P_{(t)}$ and temperature $T_{(t)}$ that the filter 78 uses. In the context of the assumed relationship given for the filter 78, the relationship used by the filter 80 can be approximated using a second order Taylor series, as follows:

$$\Delta P_{(t)} = \frac{1}{a} \Delta T_{(t)} - \frac{b}{a^2} \Delta T_{(t-1)} + \frac{2b^2}{a^3} \Delta T_{(t-2)}$$

30

     The filter 80 adjusts its coefficients in relation to the adjustments made by the filter 78 to

the coefficients a and b, based upon the error signal T_E of the summing junction 82, to minimize the magnitude of this error signal T_E.

The output ΔP of the filter 80 is fed through another summing junction 86, which is initialized at the outset of the ablation procedure at the beginning power level P_0. The summing junction 86 continuously adjusts the beginning power value with the ΔP output of the inverse filter 80. The output of the summing junction 86 therefore comprises P_{DEMAND}.

The DPP 76 shown in Fig. 7 sends the output P_{DEMAND} to the second processing stage 58 to modify $P_{(t)}$.

(d) Neural Network Prediction Control

Because of the particular heat exchange conditions between the tissue and the metallic ablation electrode 16 contacting it, the temperatures measured by the sensing element 30 may not correspond exactly with the actual maximum tissue temperature. This is because the region of hottest temperature occurs beneath the surface of the tissue at a depth of about 0.5 to 1.0 mm from where the energy emitting electrode 16 (and the sensing element 30) contacts the tissue. If the power is applied to heat the tissue too quickly, the actual maximum tissue temperature in this region may exceed 100° C and lead to tissue desiccation.

Fig. 11A shows an alternative embodiment of the DPP 76 which derives P_{DEMAND} using neural network control principles. In this implementation, the PTP 70 receives as input a predicted temperature of the hottest tissue region $T_{MAXPRED(t)}$ from a neural network predictor 200. The DPP 76 derives $P_{DEMAND(t+1)}$ based upon

the difference between this $T_{MAXPREDICT(t)}$ and T_{SET}. The values of T_{SET} can be fixed, or they can vary with time, as previously described.

In this implementation, the predictor 200 comprises a two-layer neural network, although more hidden layers could be used. The predictor 200 receives as inputs a set of k past samples of temperatures sensed by the element 30 $(T_{M(t-k+1)})$. For example, to cover the past two seconds at a sampling period of 0.02 second, k = 100.

The predictor 200 includes a first and second hidden layers and four neurons, designated $N_{(L,X)}$, where L identifies the layer 1 or 2 and X identifies a neuron on that layer. The first layer (L=1) has three neurons (X = 1 to 3), as follows $N_{(1,1)}$; $N_{(1,2)}$; and $N_{(1,3)}$. The second layer (L=2) comprising one output neuron (X=1), designated $N_{(2,1)}$.

The weighted past samples of the sensing element 30 $T_{M(t-i+1)}$ (i = 1 to k) are fed as inputs to each neuron $N_{(1,1)}$; $N_{(1,2)}$; and $N_{(1,3)}$ of the first layer. Fig. 11 represents the weighted input samples as $W^{L}_{(k,N)}$, where L=1; k is the sample order; and N is the input neuron number 1, 2, or 3 of the first layer.

The output neuron $N_{(2,1)}$ of the second layer receives as inputs the weighted outputs of the neurons $N_{(1,1)}$; $N_{(1,2)}$; and $N_{(1,3)}$. Fig. 11 represents the weighted outputs as $W^{L}_{(0,X)}$, where L=2; O is the output neuron 1, 2, or 3 of the first layer; and X is the input neuron number 1 of the second layer. Based upon these weighted inputs, the output neuron $N_{(2,1)}$ predicts $T_{MAXPRED(t)}$.

The predictor 200 must be trained on a known set of data that have been previously acquired experimentally. For example, using a back-propagation model, the predictor 200 can be trained

to predict the known hottest temperature of the data
set with the least error. Once the training phase
is completed, the predictor 200 can be used to
predict $T_{MAXPRED(t)}$.

5   As Fig. 11B shows, the first processing
stage 56 can use a single neural network 201 to
derive $P_{DEMAND(t)}$. In this implementation, the network
201 receive as input, in addition to k past samples
of temperatures from the sensor 30, the value of

10   T_{SET}, and the current power $P_{(t)}$. The network 201
derives $P_{DEMAND(t)}$ as output, which reflects the power
level required to keep the hottest predicted
temperature at or about T_{SET}. As before stated, a
set of data containing a solution based upon all the

15   desired inputs is necessary to train the neural
network of the predictor 201 to manipulate the input
and obtain the desired output with the least amount
of error.

                    (e) Fuzzy Logic Control

20   Fig. 12 shows an alternative embodiment of
the first processing stage 56 which derives P_{DEMAND}
using fuzzy logic control principles.   In this
implementation, the first processing stage 56
includes a fuzzifier 202, which receives as inputs

25   the temperature signals $T_{M(t)}$ from the sensor 30. The
fuzzifier 202 also receives T_{SET} as input, either as
a constant value or a value that changes over time.
The fuzzifier 202 converts the $T_{M(t)}$ input data to
fuzzy inputs based upon reference to T_{SET} on a

30   relative basis. For example, the fuzzy inputs can
determine the degree (or membership function) to
which a given $T_{M(t)}$ is, compared to T_{SET} , "cool" or
"warm" or "warmer" or "hot".

          These fuzzy inputs are passed through an

35   I/O mapper 204 which converts them to fuzzy outputs

by translating the inputs into descriptive labels of
power. This is accomplished, for example, by using
linguistic "if... then" rules, like "if the fuzzy
input is ... then the fuzzy output is ...."
5   Alternatively, more complex mapping matricial
operators can be used.

For example, if $T_{M(t)}$ is "cool," the I/O
mapper 204 outputs the descriptive label "Largest
Positive," to indicate that a large relative
10   increase in power is required. By the same token, if
$T_{M(t)}$ is "hot," the I/O mapper 204 outputs the
descriptive label "Largest Negative," to indicate
that large relative decrease in power is required.
The intermediate fuzzy inputs "warm" and "warmer"
15   produce intermediate descriptive labels as fuzzy
outputs, such as "Smallest Positive" and "Smallest
Negative."

These fuzzy outputs are passed through a
defuzzifier 206. The defuzzifier 206 also receives
20   actual power $P_{(t)}$ as an input, since the fuzzy
outputs refer to variations in $P_{(t)}$. Based upon $P_{(t)}$
and the variations required based upon the fuzzy
outputs, the defuzzifier 206 derives $P_{DEMAND(t)}$.

To finely trim the reference sets and the
25   rules of the I/O mapper 204, it may be required that
the fuzzy logic controller be trained on a known set
of data before use.

B.   The Second Processing Stage

In the illustrated and preferred
30   embodiment, the second processing stage 58 (see Fig.
5) includes a converter 112. The converter 112
derives a command voltage signal $V_{DEMAND(t)}$ based upon
a power input signal to adjust the amplitude of the
voltage $V_{(t)}$ supplied to the source 48 to thereby
35   adjust $P_{(t)}$. Alternatively, the converter 112 could

derive a command current signal $I_{DEMAND(t)}$ based upon a power input signal to adjust the amplitude of the current supplied to the source 48, achieving the same results.

(i) The Power Down Stage

In one implementation, the power input to the converter 112 could comprise $P_{DEMAND(t)}$ as derived by the DPP 76. In the illustrated and preferred embodiment, the second processing stage 58 includes a demand power down stage 94 between the DPP 76 and the converter 112. The power down stage 94 receives $P_{DEMAND(t)}$ as input and generates a modified demand power signal $MP_{DEMAND(t)}$, taking into account one or more other operating conditions then existing. The converter 112 receives $MP_{DEMAND(t)}$ as its input.

More particularly, the power down stage 94 monitors certain operating conditions of the electrode. The power down stage 94 compare the monitored conditions with preselected criteria for the second operating condition and generate an error signal when the second operating condition fails to meet the preselected criteria. In response to the error signal, the power down stage 94 modifies $P_{DEMAND(t)}$ in a non-linear fashion to set $MP_{DEMAND(t)}$ at a prescribed low demand power output value P_{LOW}. In the absence of the error signal, the power down stage 94 retains the value of $P_{DEMAND(t)}$ as the value of $MP_{DEMAND(t)}$.

The value of P_{LOW} is selected to be above zero, but preferably below the power level at which tissue ablation occurs.   In the illustrated and preferred embodiment, P_{LOW} is about 1 watt.

The power down stage 94 sets the value of $MP_{DEMAND(t)}$ in a nonlinear fashion back to the value of $P_{DEMAND(t)}$ as soon as the operating conditions giving

rise to the power down mode cease.

In the illustrated and preferred embodiment, the power down stage 94 responds to prescribed power or temperature conditions. Fig. 8 schematically shows a preferred implementation of the power down stage 94.

The power down stage 94 includes microswitches 108 and 110. Microswitch 108 receives as input $P_{DEMAND(t)}$ from the DPP 76 (see Fig. 5, also). The microswitch 110 receives as input the value of P_{LOW}. An output line 114 connects the converter 112 in parallel to the outputs of the switches 108 and 110.

The power down stage also includes three comparators 114, 116, and 118. Each comparator 114, 116, and 118 independently controls the microswitches 108 and 110, taking into account different operating conditions.

In the illustrated and preferred embodiment (see Fig. 8), the outputs of the comparators 114, 116, and 118 are connected to OR gate 122. An output switch line S leads to the microswitch 108, while a negate switch line S_{NEG} leads to microswitch 110. In the absence of any error signal from any comparator 114, 116, and 118 (when all operating conditions meet prescribed criteria), S = 1 (closing switch 108) and S_{NEG} = 0 (opening switch 110). In the presence of an error signal from any comparator 114, 116, and 118 (when at least one operating condition fails to meet prescribed criteria), S = 0 (opening switch 108) and S_{NEG} = 1 (closing switch 110).

(a)   Based Upon Maximum
Power Conditions

The output of the comparator 114 takes into

account prescribed maximum power conditions. The comparator 114 receives current instantaneously power $P_{(t)}$ as its (+) input and a prescribed maximum power value P_{MAX} as its inverse or (-) input.

In this implementation, the comparator 114 compares $P_{(t)}$ to the prescribed maximum power value P_{MAX}. An error free condition exists when $P_{(t)} < P_{MAX}$. In this condition, the comparator 114 sets microswitch 108 closed and microswitch 110 open. In this condition, the microswitch 108 passes through the value of $P_{DEMAND(t)}$ as the output $MP_{DEMAND(t)}$.

An error condition exists when $P_{(t)} \geq P_{MAX}$. In this condition, the comparator 114 sets the microswitch 108 open and microswitch 110 closed. In this condition, the microswitch 108 blocks passage of the value of $P_{DEMAND(t)}$, and P_{LOW} becomes the output $MP_{DEMAND(t)}$. In effect, when $P_{(t)} \geq P_{MAX}$, the stage 94 reduces $P_{DEMAND(t)}$ to P_{LOW} in an instantaneous, nonlinear fashion.

The value of P_{MAX} can vary according to the particular requirements of the ablation procedure. The generator 12 can include, as part of its overall interface 13, an interface 96 for the physician to select and adjust P_{MAX} (see Fig. 1 also). For cardiac ablation, it is believed that P_{MAX} should lie in the range of about 50 watts to about 200 watts, with P_{MAX} increasing as the surface area of the ablating electrode increases.

As Fig. 9 shows, the value of P_{MAX} can also be set, not upon direct power input settings by the physician, but rather upon the physical and/or functional characteristics of the ablating electrode being used, or both.

The physical and/or functional characteristics of the ablating electrode can

include surface area, electrode configuration, electrode orientation, and electrode field dispersion properties. For example, an electrode with a smaller surface area can usually be expected
5   to be operated at lower power settings.

The relationships among electrode type and P_{MAX} can be determined by empirical testing. The test results can be transcribed in a look-up power criteria table 102 resident in ROM of the generator
10   12 (as Fig. 9 shows).

In the preferred embodiment, the power down stage 94A includes a register 98 for automatically setting P_{MAX} based upon the power criteria transcribed in the look-up table 102.

15   The register 98 includes an input 100 (which is part of the overall interface 13 of the generator, as Fig. 1 also shows) for the physician to enter the electrode type being used. The register 98 then automatically sets P_{MAX} in the second
20   processing stage 58 based upon the power criteria table 102.

Alternatively (as Fig. 9 also shows), the catheter 14 can itself carry means for automatically producing an identification signal representing the
25   electrode type when the catheter 14 is connected to the generator 12. The signal uniquely identifies the particular physical and/or performance characteristics of the connected electrode 16.

In this arrangement, a data acquisition
30   element 106 queries and reads the identification signal of the catheter 14 to identify the electrode type. The element 106 then refers to the look-up table 102 to automatically set P_{MAX} via the register 98.

35   The means for automatically generating the

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electrode-type identification signal can vary. Fig. 10 shows a preferred arrangement.

In the illustrated embodiment, the catheter handle 20 carries a resistor R having a prescribed ohm value. The ohm value of R represents the sum of calibration resistance value R_{CAL} (as previously described) and a selected add-on resistance value R_I. The calibration resistance R_{CAL} is a fixed value, depending upon the thermistor 34 the catheter 14 carries. The magnitude of the add-on value R_I varies in predetermined increments depending upon the electrode type.

For example, a Type 1 Electrode is assigned an add-on value R_I of 5000 ohms; a Type 2 Electrode is assigned an add-on value R_I of 10,000 ohms; a Type 3 Electrode is assigned an add-on value R_I of 15,000 ohms, and so on.

Assuming a fixed calibration resistance R_C for the thermistor 34 used of 4000 ohms, the handle 20 for a Type 1 Electrode will carry a resistor R of 9000 ohms (4000 ohms calibration resistance R_C plus 5000 ohms add-on resistance R_I); the handle 20 for a Type 2 Electrode will carry a resistor R of 14,000 ohms (4000 ohms calibration resistance R_C plus 10,000 ohms add-on resistance R_I); and the handle 20 for a Type 3 Electrode will carry a resistor R of 19,000 ohms (4000 ohms calibration resistance R_C plus 15,000 ohms add-on resistance R_I).

A look-up table 104 in the data acquisition element 106 (shown in Fig. 9) stores the fixed value R_{CAL} of the calibration resistance, the range of add-on resistances R_I corresponding to the identified electrode types, and their sum (which is the value of the resistor R that the system actually senses).

When connected to the generator 12 the

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element 106 senses the total ohm value of the re-
sistor R in the handle 20. The element 106 refers
to the look-up table 104. In the look-up table 104,
a sensed total resistance R of less than 10,000 ohms
5   identifies a Type 1 Electrode; a sensed total
resistance R of 10,000 ohms to 15,000 ohms iden-
tifies a Type 2 Electrode; and a sensed total
resistance R of over 15,000 ohms up to 20,000 ohms
identifies a Type 3 Electrode.

10   The element 106 then refers to the power
criteria look-up table 102 to obtain the cor-
responding power condition. The register 98
automatically sets P_{MAX} in the power down stage 94A.

Referring still to the look-up table 104,
15   the data acquisition element 106 subtracts the known
add-on value for the identified Electrode Type. In
this way, the generator 12 also derives the value of
the calibration resistance R_{CAL} for the thermistor
34. As already described (and as Fig. 5 shows), the
20   first processing stage 56 processes the calibration
resistance and the resistance sensed by the thermis-
tor to derive the temperature $T_{M(t)}$, as previously
described.

In an alternative embodiment (not shown),
25   instead of the resistor R, the handle can carry a
solid state micro-chip, ROM, EEROM, EPROM, or non-
volatile RAM.

The micro-chip can be pre-programmed with
digital values representing the calibration resis-
30   tance for the thermistor 34 (or the calibration
resistances for the multiple thermistors) and the
appropriate value representing the Electrode Type.
In this arrangement, the micro-chip outputs these
values to the register 98, when queried by the data
35   acquisition element 106.

(b) **Based Upon Maximum**
Absolute Temperature
Conditions

The output of the comparator 116 responds

5   to prescribed maximum absolute temperature
conditions. The comparator 116 receives at its (+)
input the temperature value $T_{PRED(t)}$ from the PTP 70.
The comparator 116 receives as its inverse or (-)
input a prescribed maximum temperature value T_{MAX}.

10 In this implementation, the comparator 116
compares $T_{PRED(t)}$ to the prescribed maximum temperature
value T_{MAX}. An error-free condition exists when
$T_{PRED(t)} < T_{MAX}$. In this condition, the comparator 116
sets microswitch 108 closed and microswitch 110

15 open. In this condition, the microswitch 108 passes
through the value of $P_{DEMAND(t)}$ as the output $MP_{DEMAND(t)}$.

An error condition exists when $T_{PRED(t)} \geq T_{MAX}$.
In this condition, the comparator 116 sets the
microswitch 108 open and microswitch 110 closed. In

20 this condition, the microswitch 108 blocks passage
of the value of $P_{DEMAND(t)}$, and P_{LOW} becomes the output
$MP_{DEMAND(t)}$. In effect, when $T_{PRED(t)} \geq T_{MAX}$, the stage 94
reduces $P_{DEMAND(t)}$ to P_{LOW} in an instantaneous, nonlinear
fashion.

25 The value of T_{MAX} can be prescribed in
various ways. It can, for example, be a selected
absolute value that the physician inputs. For
cardiac ablation, the value of T_{MAX} is believed to
lie in the range of 80° C and 95° C, with a preferred

30 representative value of about 90° C.

(c) **Based Upon Incremental**
Temperature Conditions

The output of the comparator 118 responds
to prescribed incremental temperature condition T_{INCR}

35 based upon T_{SET}, as follows:

$$T_{INCR} = T_{SET} + INCR$$

where INCR is a preselected increment.

The value of INCR can vary, just as T_{SET} can vary, according to the judgment of the physician and empirical data. A representative value of INCR for cardiac ablation is believed to lie in the range of $2°$ C to $8°$ C, with a preferred representative value of about $5°$ C.

The comparator 116, like the comparator 114, receives at its (+) input the temperature value $T_{PRED(t)}$ from the PTP 70. The comparator 116 receives as its inverse or (-) input the prescribed incremental temperature value T_{INCR}.

In this implementation, the comparator 116 compares $T_{PRED(t)}$ to the prescribed incremental temperature value T_{INCR}. An error-free condition exists when $T_{PRED(t)} < T_{INCR}$. In this condition, the comparator 116 sets microswitch 108 closed and microswitch 110 open. In this condition, the microswitch 108 passes through the value of $P_{DEMAND(t)}$ as the output $MP_{DEMAND(t)}$.

An error condition exists when $T_{PRED(t)} \geq T_{INCR}$. In this condition, the comparator 116 sets the microswitch 108 open and microswitch 110 closed. In this condition, the microswitch 108 blocks passage of the value of $P_{DEMAND(t)}$, and P_{LOW} becomes the output $MP_{DEMAND(t)}$. In effect, when $T_{PRED(t)} \geq T_{INCR}$, the stage 94 reduces $P_{DEMAND(t)}$ to P_{LOW} in an instantaneous, nonlinear fashion.

(d) Generating Demand Voltage

If any comparator 114, 116, or 118 opens switch 108 and closes switch 110 (i.e., when at least one error condition exists), P_{LOW} is instantaneously set as $MP_{DEMAND(t)}$. Under this condition, the converter 112 receives P_{LOW} as

$MP_{DEMAND(t)}$. If none of the comparators 114, 116, or 118 opens switch 108 and closes switch 110, the converter 112 receives $P_{DEMAND(t)}$ as $MP_{DEMAND(t)}$.

5   The manner in which the converter 112 of the second processing stage 58 generates $V_{DEMAND(t)}$ to adjust $P_{(t)}$ can vary. For example, the converter 112 can employ proportional control principles, proportional integral derivative (PID) control principles, neural network, fuzzy logic, and

10   adaptive control principles.

In one implementation, the converter 112 employs known PID principles to derive V_{DEMAND}. In this implementation, the converter 112 compares $MP_{DEMAND(t)}$ to the generated power signal $P_{(t)}$, which it

15   receives from the multiplier 60. In this implementation, the converter 112 also takes into account the changes of the generated power signal $P_{(t)}$ over time. Based upon these considerations, the converter 112 of the second processing stage 58

20   derives the demand voltage signal V_{DEMAND}.

Alternatively, the converter 112 can use proportional control principles to directly convert $MP_{DEMAND(t)}$ to the demand voltage $V_{DEMAND(t)}$, as follows:

25

$$V_{DEMAND(t)} = \sqrt{MP_{DEMAND(t)} Z_{(t)}}$$

where $Z_{(t)}$ is the sensed impedance of the system and $V_{DEMAND(t)}$ is the RMS value of the output voltage.

(e) Monitoring Impedance

30   For this and other purposes, the generator 12 preferably includes an impedance microprocessor 88. The impedance microprocessor 88 receives the

instantaneous current signal $I_{(t)}$ and the instantaneous voltage signal $V_{(t)}$ from the sensing transformers 62 and 64, already described. The microprocessor 88 derives impedance $Z_{(t)}$ (in ohms) as
5   follows:

$$Z_{(t)} = \frac{V_{(t)}}{I_{(t)}}$$

Preferably, the generator 12 includes a display 90 as part of its overall interface 13 to show the measured impedance $Z_{(t)}$ (see Fig. 1 also).

The microprocessor 88 also preferably
10   maintains a record of sampled impedances $Z_{(t)}$ over time. From this, the microprocessor calculates the changes in impedance during a selected interval and generates appropriate control signals based upon predetermined criteria. Even when the power down
15   stage 94 sets $P_{DEMAND(t')}$ as P_{LOW} to stop tissue ablation, the microprocessor still serves to continuously compute $Z_{(t)}$ for the purposes set forth below.

For example, if measured impedance falls
20   outside a predetermined set range, the microprocessor 88 generates a command signal to shut off power to the ablation electrode 16. The set range for impedance for a cardiac ablation procedure is believed to be about 50 to 300 ohms.

25   When impedance begins in the set range and, over time, increases beyond it, the most likely cause is coagulum formation on the ablation electrode 16. A sudden rise in impedance over the set range suggests the sudden onset of coagulum
30   formation or a sudden shift in the position of the ablation electrode 16. Rapid fluctuations of the impedance also could suggest poor contact between

the ablation electrode 16 and the targeted tissue.
All require prompt response; for example, withdrawal
and cleaning of the ablation electrode 16, or
repositioning of the ablation electrode 16.

5   The generator 12 preferably includes visual
and auditory alarms 92 as part of its overall
interface 13 (see Fig. 1 also), to transmit a
warning to the user when these impedance-related
conditions occur.

10   A very high impedance value could suggest
poor skin contact with the indifferent electrode 18,
or an electrical problem in the generator 12.
Again, this calls for prompt corrective action.

(f)   Error Shutdown Mode

15   The power down stage 94 rapidly reduces but
does not shut down power, based upon prescribed
instantaneous high power or high temperature
conditions.   In the illustrated and preferred
embodiment, the second processing stage 58 also
20   includes an error shutdown stage 128.   The error
shutdown stage 128 responds to the persistence, over
a set time period, of a prescribed over-temperature
condition or conditions indicative of an actual or
developing system failure.   The error shutdown phase
25   126 turns off all power to the electrode 16.   The
error shutdown phase 128 can work separately from or
in tandem with the power down mode.

          For example, as long as $T_{PRED(t)}$ exceeds T_{SET}
by an amount less than INCR, the power down stage
30   94C will not be triggered to set P_{LOW}.   Still, if
this over-temperature situation persists for more
than a prescribed period of time (for example, 2 to
5 seconds), the second processing stage 58 can be
conditioned to assume an actual or developing system
35   failure, and institute a power shutdown.

By way of another example, if $T_{PRED(t)} \geq T_{MAX}$ or T_{INCR}, the power down stage 94B or C will be triggered to set P_{LOW}. If this over-temperature situation persists during the power down conditions for a prescribed period of time (for example, 2 to 5 seconds), the second processing stage 58 can be conditioned to assume an actual or developing system failure, and institute a power shutdown.

The generator 12 as described provides control over the ablation procedure. The monitoring and control of power assure the effective distribution of radio frequency energy to the ablation electrode 16, while setting safe physiological limits.

The generator 12 can also include an alternative control mode based upon power. In this mode, the generator 12 seeks to maintain a set power condition, independent of measured temperature conditions. The generator 12 would switch to the power control mode, for example, when the electrode 16 in use does not carry a temperature sensing element 30, or upon selection by the physician, even when the electrode 16 has a temperature sensing element 30.

The illustrated and preferred embodiments envision the use of micro-processor controlled components using digital processing to analyze information and generate feedback signals. It should be appreciated that other logic control circuits using micro-switches, AND/OR gates, invertors, and the like are equivalent to the micro-processor controlled components and techniques shown in the preferred embodiments.

Various features of the invention are set forth in the claims that follow.

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WE CLAIM:

1. An apparatus for supplying energy to an electrode for ablating tissue comprising

a sampling element to monitor a selected operating condition of the electrode and derive from
5   it an operating value (V_D),

a processing element to compare the derived operating value V_D to a preselected set value ($\not{V}$) for the operating condition to establish an error signal (Δ), where:

$$\Delta = V_S - V_D$$

10   an output element to issue a command signal $S_{COMMAND}$ to adjust power to the electrode above a zero value, thereby maintaining power without interruption, where:

$$S_{COMMAND} = f(\Delta)$$

and where f is a nonlinear function.

2. An apparatus for supplying energy to an electrode for ablating tissue comprising

a sampling element to monitor a selected operating condition of the electrode and derive from
5   it an operating value (V_D),

a processing element to compare the derived operating value V_D to a preselected set value (V_S) for the operating condition to establish an error signal (Δ), where:

$$\Delta = V_S - V_D$$

10   an output element to issue a command signal $S_{COMMAND}$ to adjust power to the electrode above a zero value, thereby maintaining power without interruption, where:

$$S_{COMMAND} = f(\Delta_1, \Delta_2, \Delta_3, \ldots, \Delta_N)$$

15

where f is a N-variable nonlinear function that describes the processing element and Δ_1, Δ_2, Δ_3, ... , Δ_N are the values of the error signal Δ at N different moments of time.

3.   An apparatus according to claim 1 or 2

wherein V_S remains essentially constant over time.

4.   An apparatus according to claim 1 or 2

wherein V_S changes at least once as a function of time.

5.   An apparatus for supplying energy to an electrode for ablating tissue comprising

a generator adapted to be electrically coupled to an electrode to supply energy to the
5   electrode for ablating tissue, and

  .   a controller coupled to the generator to supply power to the generator, the controller comprising

a sampling element to monitor a
10   selected operating condition and derive from it an operating value (V_D),

a processing element to compare the derived operating value V_D to a preselected set value (V_S) for the operating condition to establish an
15   error signal (Δ), where:

$$\Delta = V_S - V_D$$

an output element to incrementally adjust the power supplied to the electrode according to the following expression:

$$\Delta P = f\,(S_{SCALE} \times \Delta)$$

20   where:

ΔP is the incremental power adjustment;

f is a mathematical function; and

S_{SCALE} is a nonlinear scaling
25   factor that equals a first value (X) when Δ > Z and
equals a second value (Y), different than X, when Δ
< Z, where Z is a desired Δ.

      6.   An apparatus according to claim 5
wherein Y > X.

      7.   An apparatus according to claim 5 or
6

wherein Z = 0.

      8.   An apparatus according to claim 5
wherein the sampling element includes a
sensing element for measuring temperature at the
electrode.

      9.   An apparatus according to claim 8
wherein the sampling element monitors
changes in temperature measured by the sensing
element over time to derive V_D.

      10. An apparatus according to claim 9
wherein V_D comprises a temperature
prediction for a future time derived from one or
more temperatures measured by the sensing element.

      11. An apparatus according to claim 5
wherein V_S remains essentially constant over
time.

      12. An apparatus according to claim 5
wherein V_S changes at least once as a
function of time.

      13. An apparatus for supplying energy to
an electrode for ablating tissue comprising

a generator adapted to be electrically coupled to an electrode to supply energy to the electrode for ablating tissue, and

a controller coupled to the generator to supply power to the generator, the controller comprising

sampling means for monitor operating conditions,

a first processing element to derive a power control signal $S_{DERIVED}$ based upon a first operation condition monitored by the sampling means,

a second processing element to compare a second operating condition monitored by the sampling means with preselected criteria for the second operating condition and to generate an error signal (E) when the second operating condition fails to meet the preselected criteria, and

an output element to issue a command signal $S_{COMMAND}$ to set power supplied to the generator,

wherein, absent the error signal E, $S_{COMMAND}$ sets the power according to $S_{DERIVED}$, and

wherein, when the error signal E is generated, $S_{COMMAND}$ sets the power at a prescribed low power condition (P_{LOW}), regardless of $S_{COMMAND}$, P_{LOW} being a value above zero.

14. An apparatus for supplying energy to an electrode for ablating tissue comprising

a generator adapted to be electrically coupled to an electrode to supply energy to the electrode for ablating tissue, and

a controller coupled to the generator to supply power to the generator, the controller comprising

first sampling means for monitor operating conditions,

second sampling means for deriving impedance,

a first processing element to derive a power control signal $S_{DERIVED}$ based upon a first operation condition monitored by the first sampling means,

a second processing element to compare a second operating condition monitored by the first sampling means with preselected criteria for the second operating condition and to generate an error signal (E) when the second operating condition fails to meet the preselected criteria, and

an output element to issue a command signal $S_{COMMAND}$ to set power supplied to the generator, wherein, absent the error signal E, $S_{COMMAND}$ sets the power according to $S_{DERIVED}$, and wherein, when the error signal E is generated, $S_{COMMAND}$ sets the power at a prescribed low power condition (P_{LOW}), regardless of $S_{COMMAND}$, P_{LOW} being a value above zero to permit derivation of impedance by the second sensing means.

15. An apparatus according to claim 13 or 14

wherein the second monitored operating condition includes a measurement of the power delivered to the generator, and

wherein the preselected criteria includes an established maximum power value.

16. An apparatus according to claim 13 or 14

wherein the second monitored operating condition includes a measurement of temperature at the electrode, and

wherein the preselected criteria includes an established maximum temperature value.

17. An apparatus according to claim 13 or

14

wherein the second monitored operating
condition includes a measurement of temperature at

5   the electrode, and

wherein the preselected criteria includes
an established set temperature value adjusted by an
established incremental value.

18. A method for ablating body tissue
comprising the steps of

applying ablating energy to an electrode,

monitoring a selected operating condition

5   of the electrode and derive from it an operating
value (V_D),

comparing the derived operating value V_D to
a preselected set value (V_S) for the operating
condition to establish an error signal (Δ), where:

$$\Delta = V_S - V_D$$

10   issuing a command signal $S_{COMMAND}$ to adjust
power to the electrode above a zero value, thereby
maintaining   power   to   the   electrode   without
interruption,, where:

$$S_{COMMAND} = f(\Delta)$$

where f is a nonlinear function.

19. A method according to claim 18

wherein, in the step of issuing the command
signal $S_{COMMAND}$:

$$S_{COMMAND} = f(S_{SCALE} X \Delta)$$

where S_{SCALE} is a nonlinear scaling
5   factor that equals a first value (X) when $\Delta > Z$ and
equals a second value (Y), different than X, when Δ
$< Z$, and Z is a desired Δ.

20. A method according to claim 19
wherein Y > X.

21. A method according to claim 19
wherein Z = 0.

22. A method for ablating body tissue
comprising the steps of

applying ablating energy to an electrode,

monitor operating conditions for the
5   electrode,

deriving a power control signal $S_{DERIVED}$ based
upon a first monitored operation condition,

comparing a second monitored operating
condition with preselected criteria for the second
10   operating condition to generate an error signal (E)
when the second operating condition fails to meet
the preselected criteria,

issuing a command signal $S_{COMMAND}$ to set power
supplied to the electrode,

15   wherein, absent the error signal E,
$S_{COMMAND}$ sets the power according to $S_{DERIVED}$, and

wherein, when the error signal E is
generated, $S_{COMMAND}$ sets the power at a prescribed low
power condition (P_{LOW}), regardless of $S_{COMMAND}$, P_{LOW}
20   being a value above zero.

23. A method for ablating body tissue
comprising the steps of

applying ablating energy to an electrode,

monitor operating conditions for the
5   electrode, including measuring impedance,

deriving a power control signal $S_{DERIVED}$ based
upon a first monitored operation condition,

comparing a second monitored operating
condition with preselected criteria for the second
10   operating condition to generate an error signal (E)
when the second operating condition fails to meet

- 48 -

the preselected criteria,

issuing a command signal $S_{COMMAND}$ to set power supplied to the electrode,

15   wherein, absent the error signal E, $S_{COMMAND}$ sets the power according to $S_{DERIVED}$, and

wherein, when the error signal E is generated, $S_{COMMAND}$ sets the power at a prescribed low power condition (P_{LOW}), regardless of $S_{COMMAND}$, P_{LOW}

20   being a value above zero so that measurement of impedance can continue.

24.   A method according to claim 22 or 23 wherein the second monitored operating condition includes a measurement of the power delivered to the generator, and

5   wherein the preselected criteria includes an established maximum power value.

25.   A method according to claim 22 or 23 wherein the second monitored operating condition includes a measurement of temperature at the electrode, and

5   wherein the preselected criteria includes an established maximum temperature value.

26.   A method according to claim 22 or 23 wherein the second monitored operating condition includes a measurement of temperature at the electrode, and
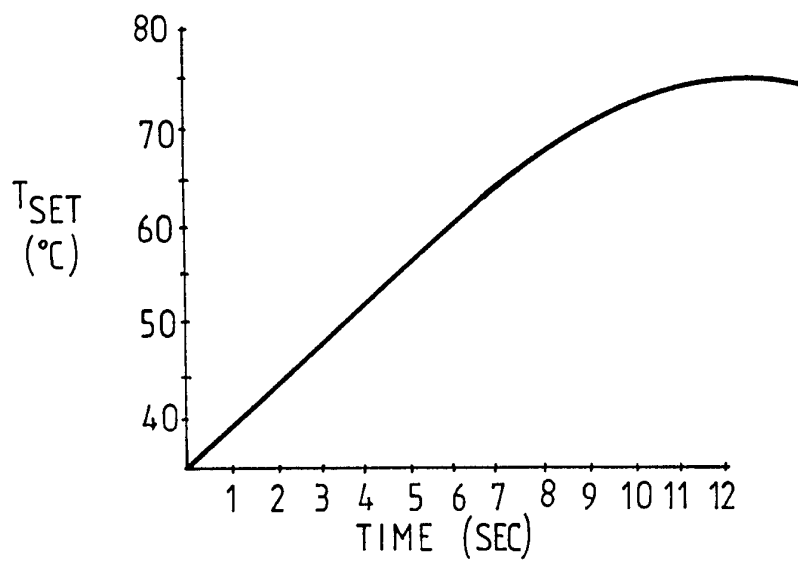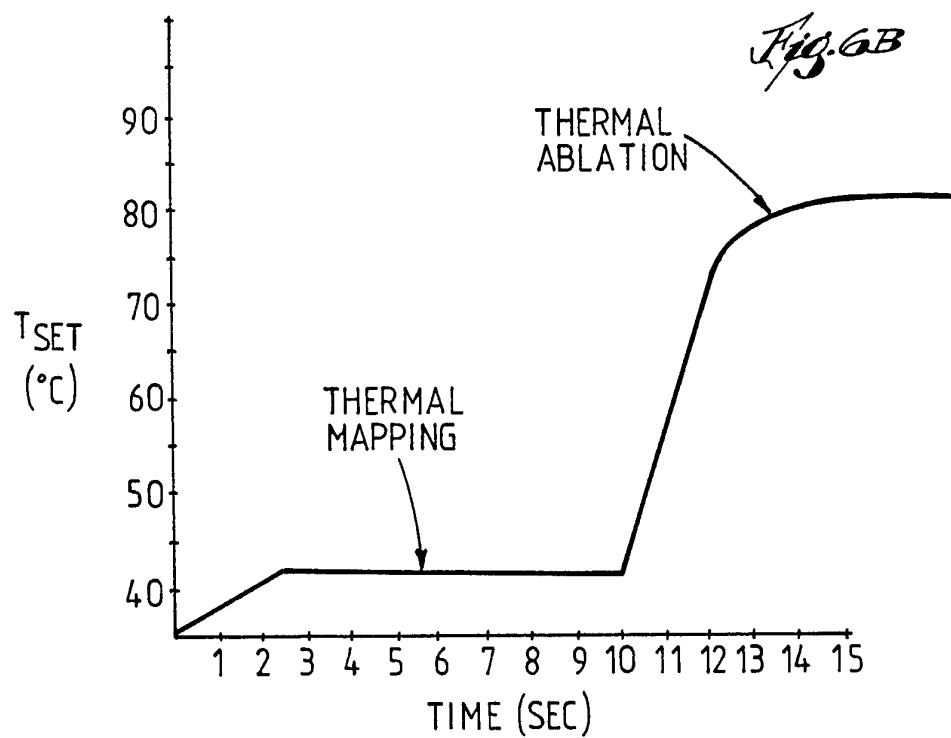
5   wherein the preselected criteria includes an established set temperature value adjusted by an established incremental value.
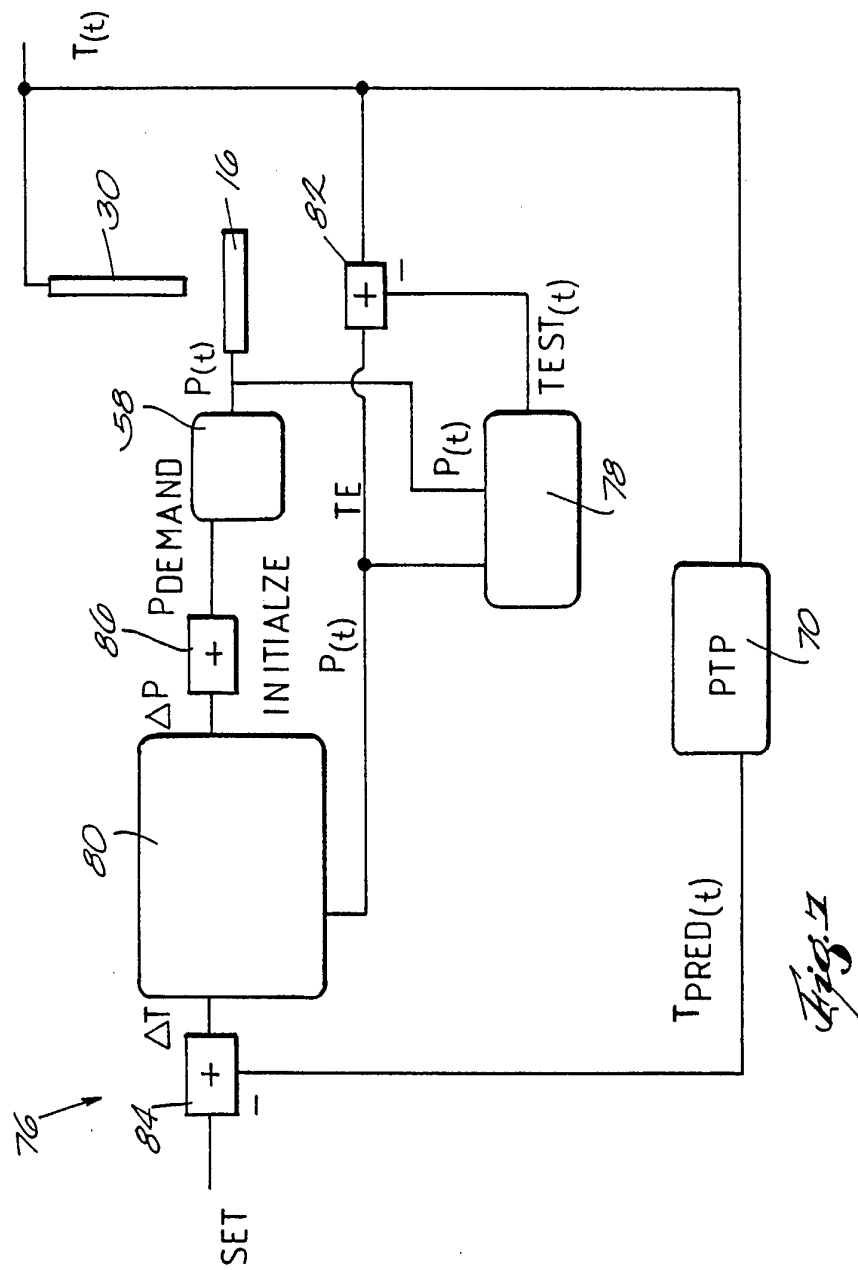
Fig. 1

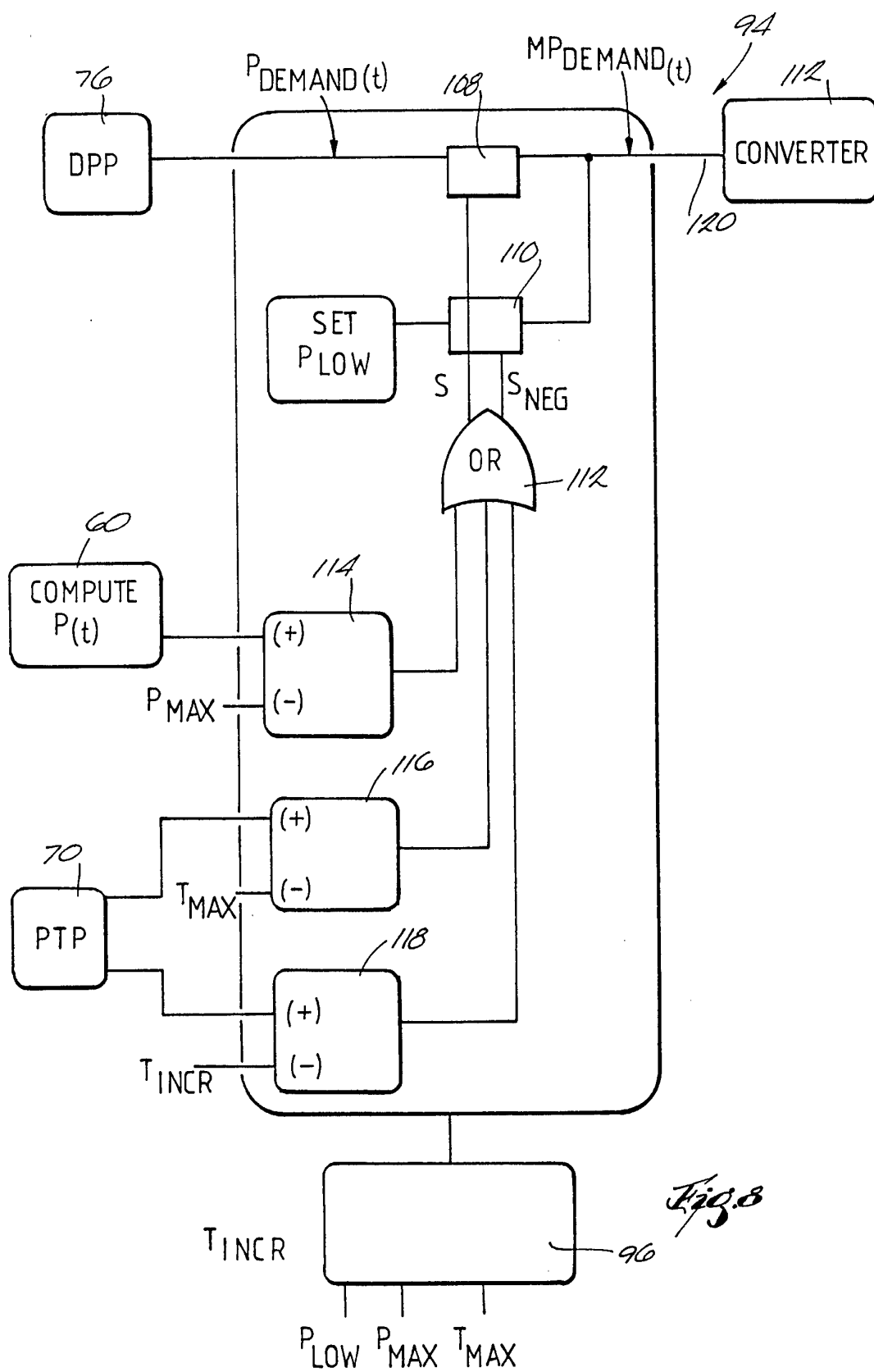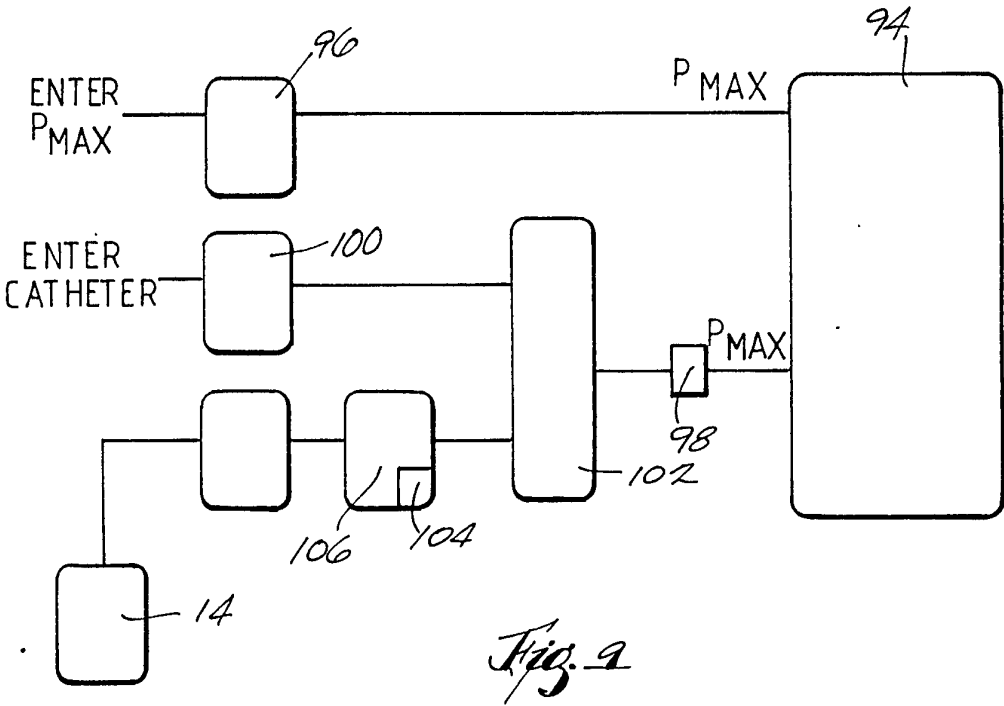Fig. 2

Fig. 3
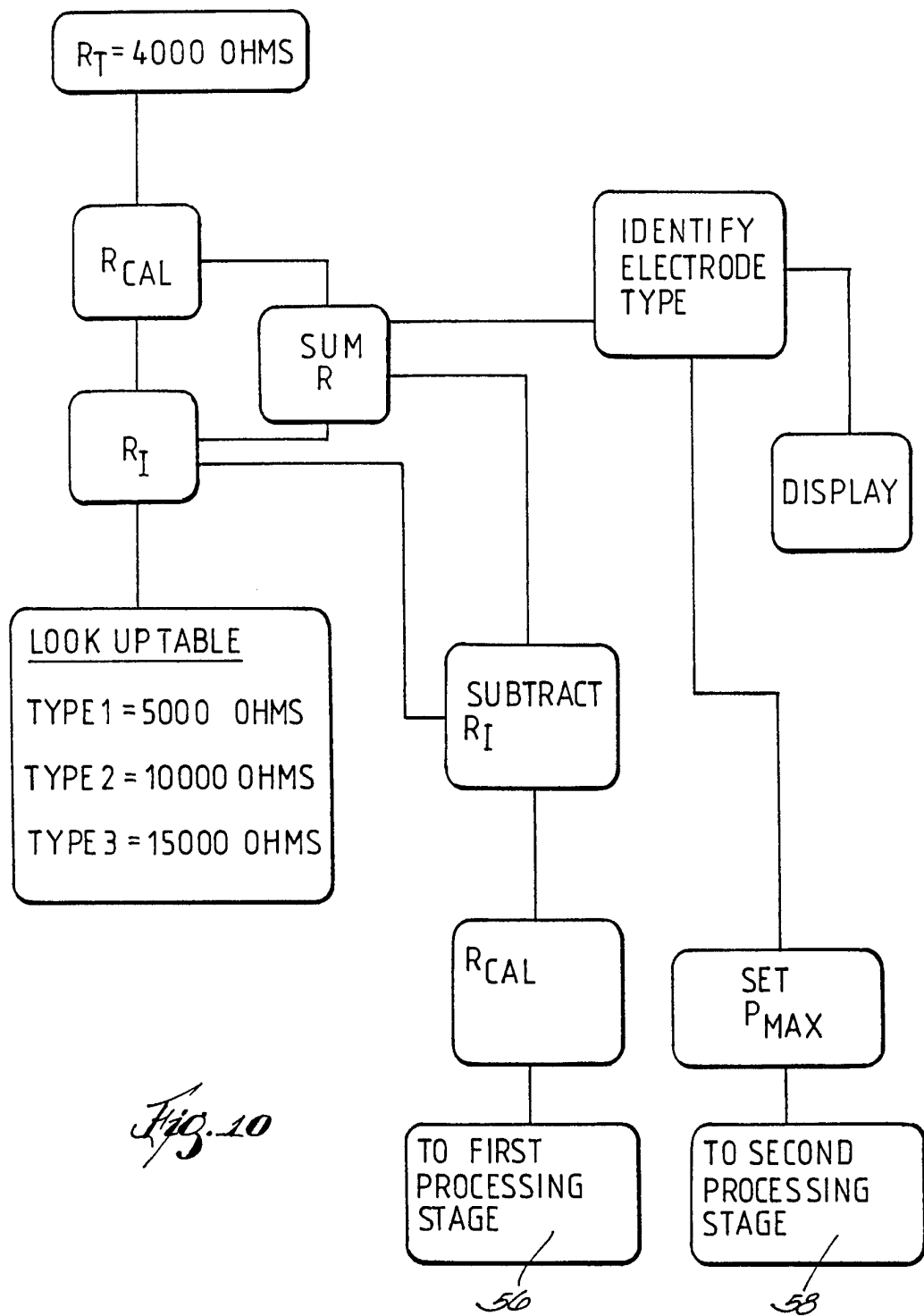
Fig. 4

Fig. 5

Fig.6A

Fig.6B

Fig. 7

Fig.8

Fig. 9

Fig. 10

Fig.-11A

Fig. 11B

Fig.11.

30

56

T_{SET} ———   202

204

$P_{(t)}$ ———   206

$P_{DEMAND}(t+1)$
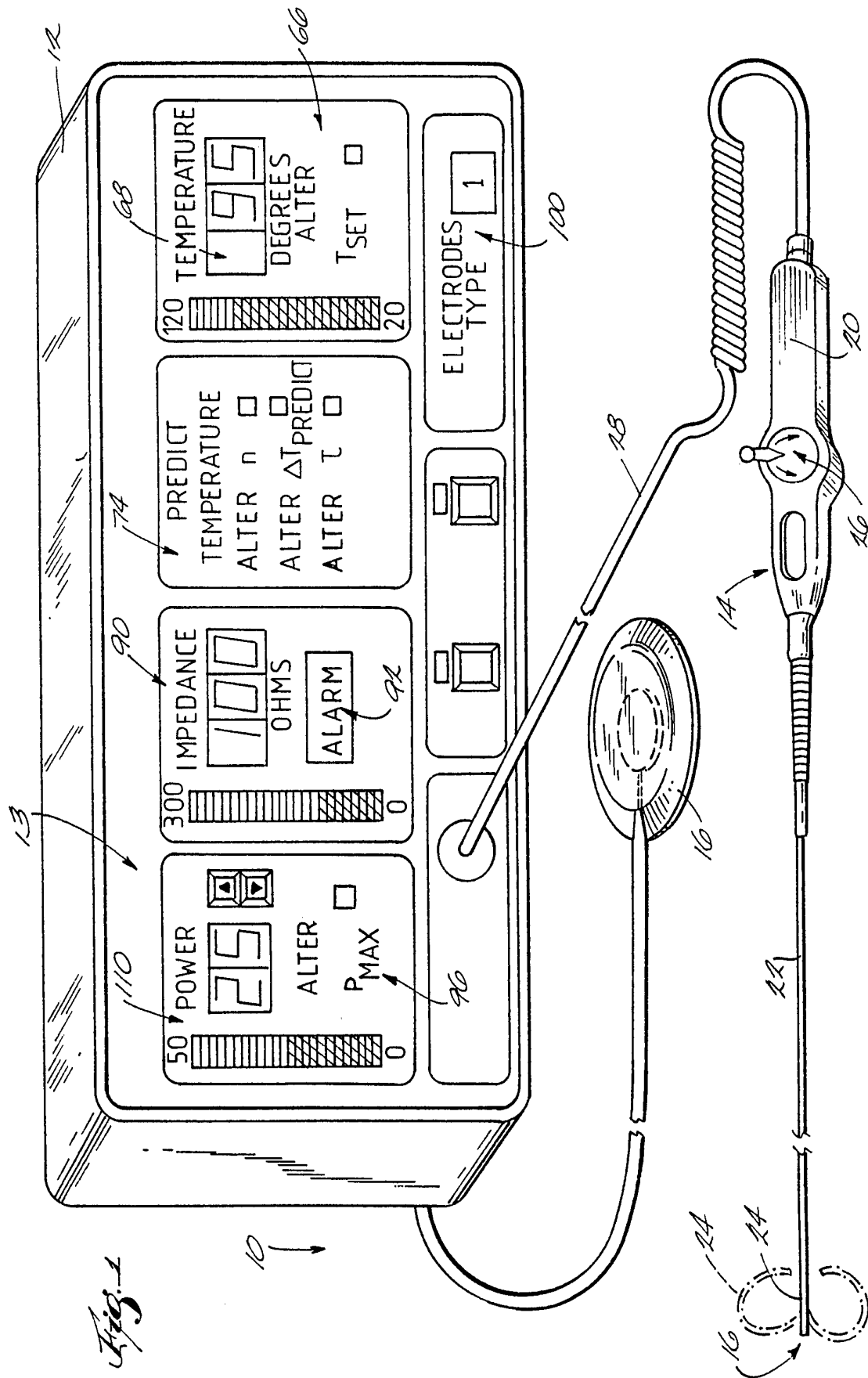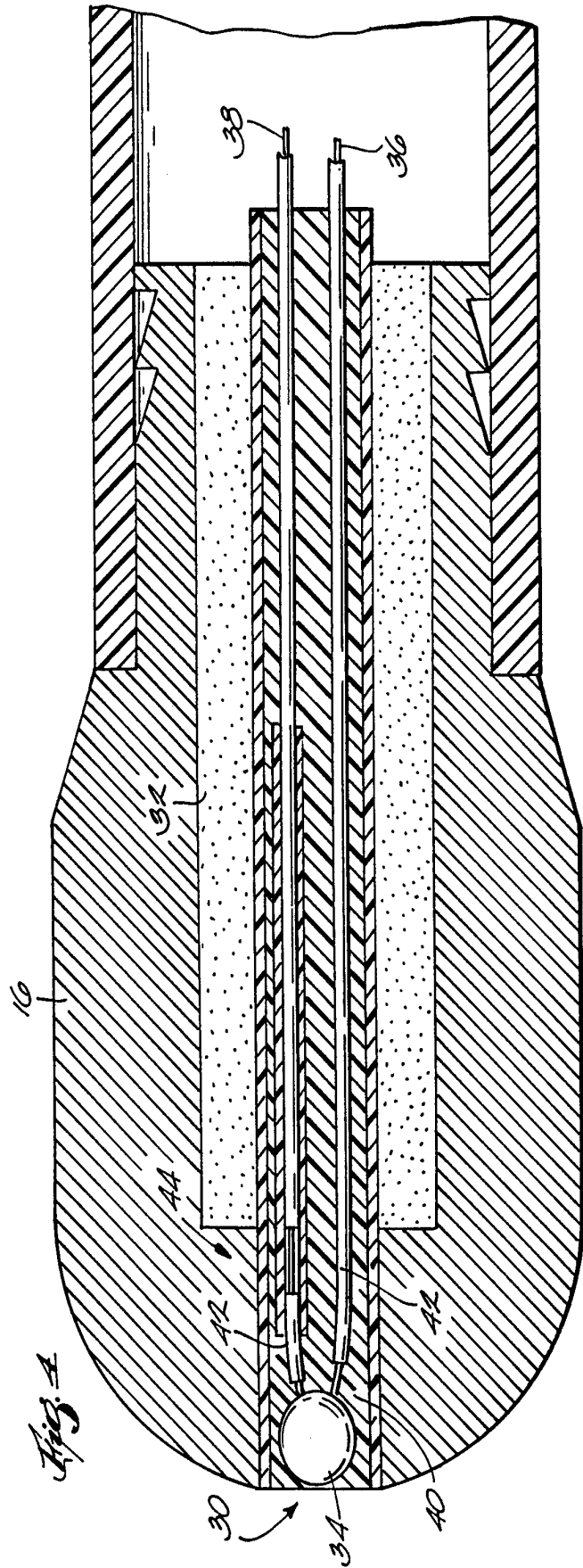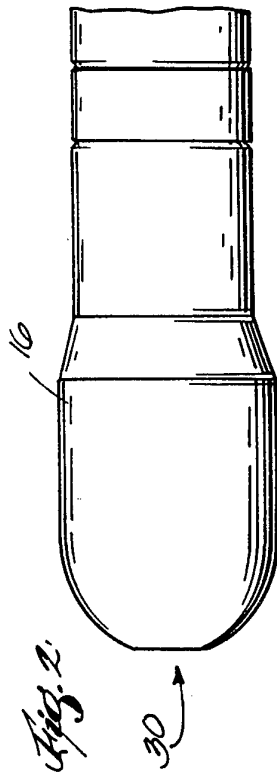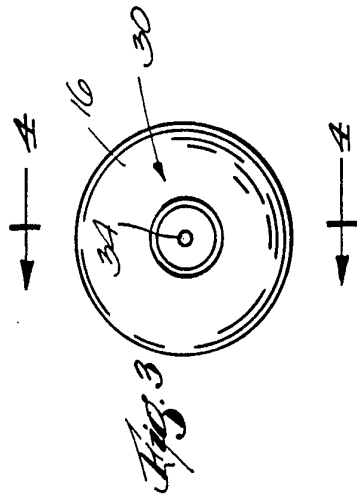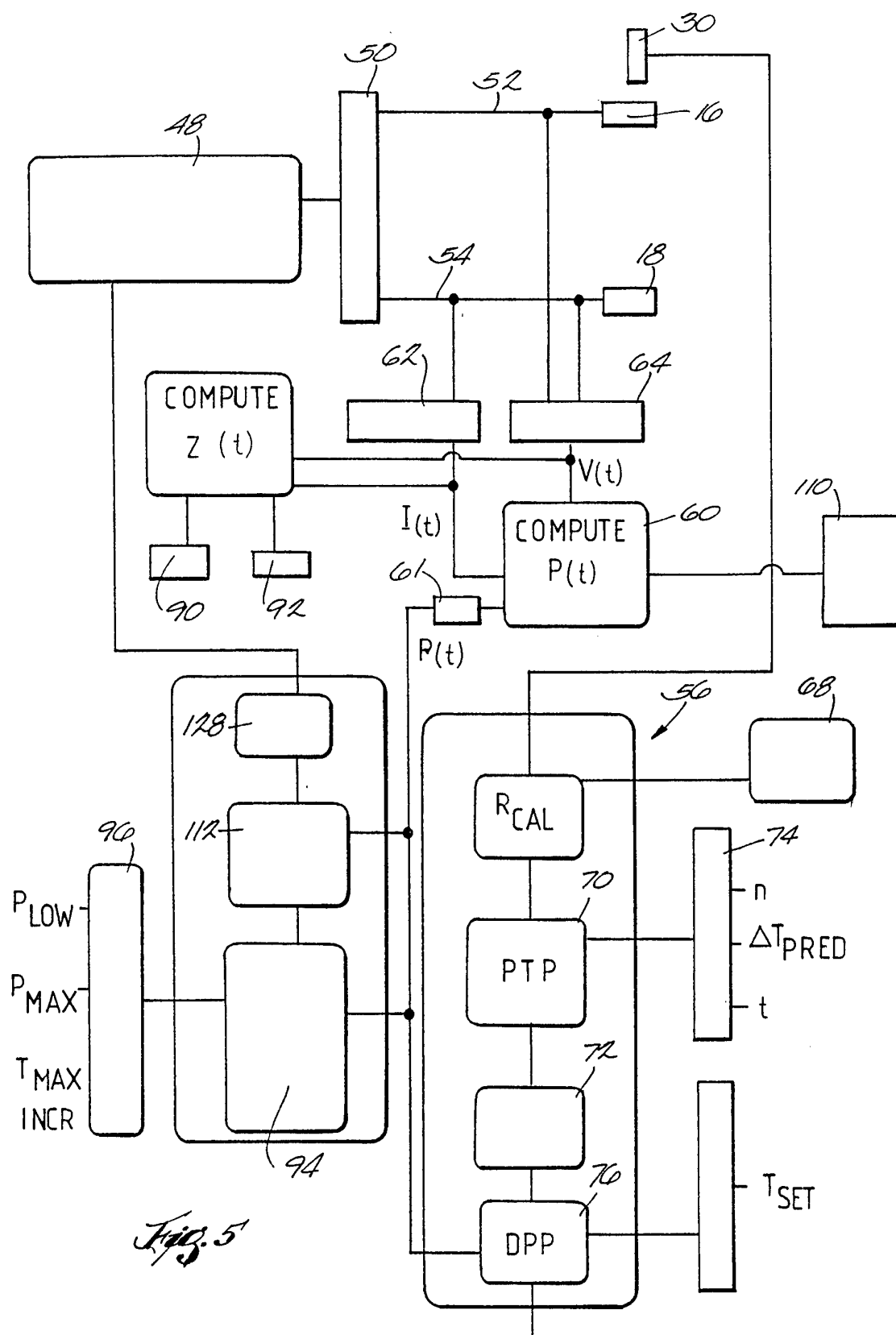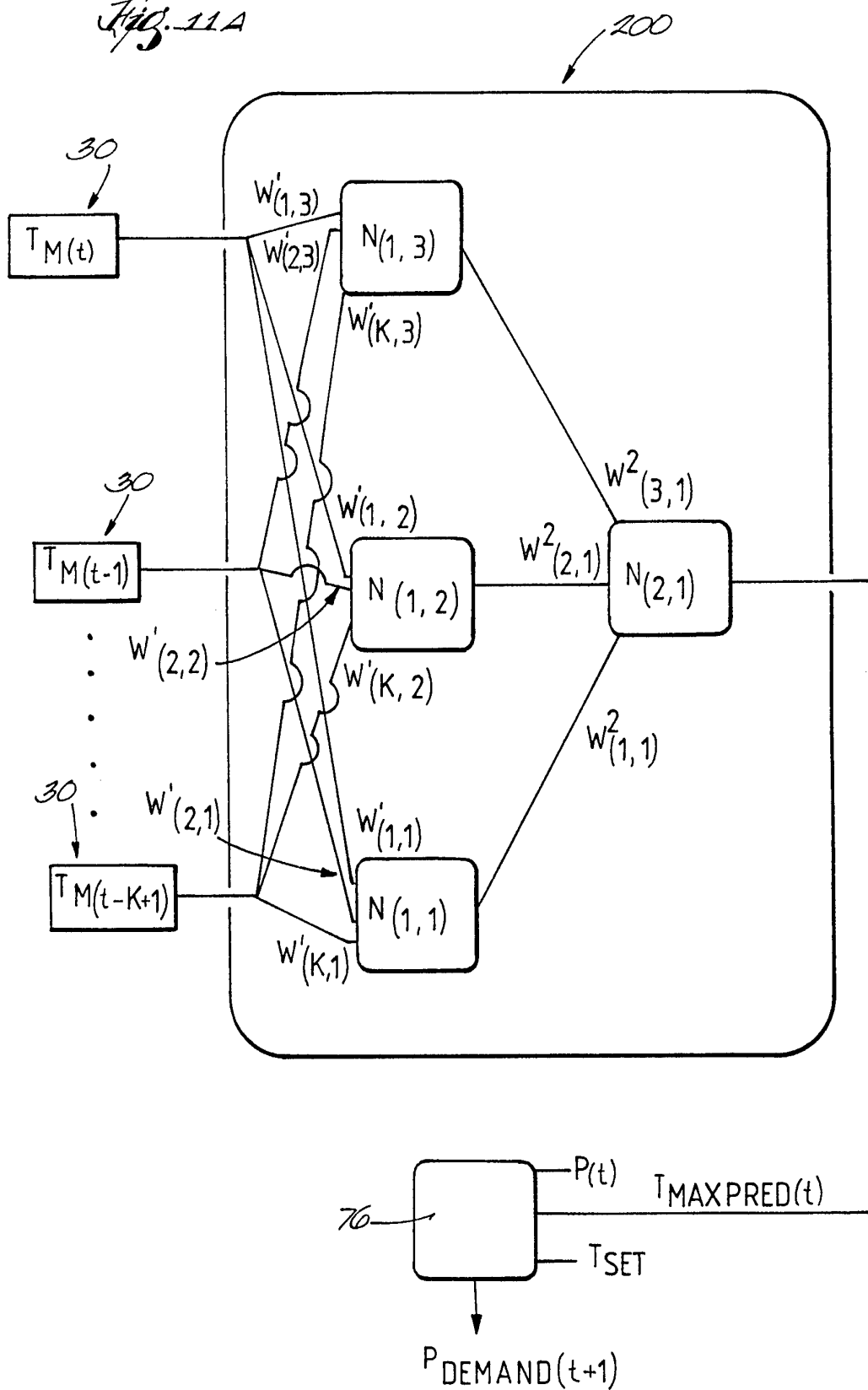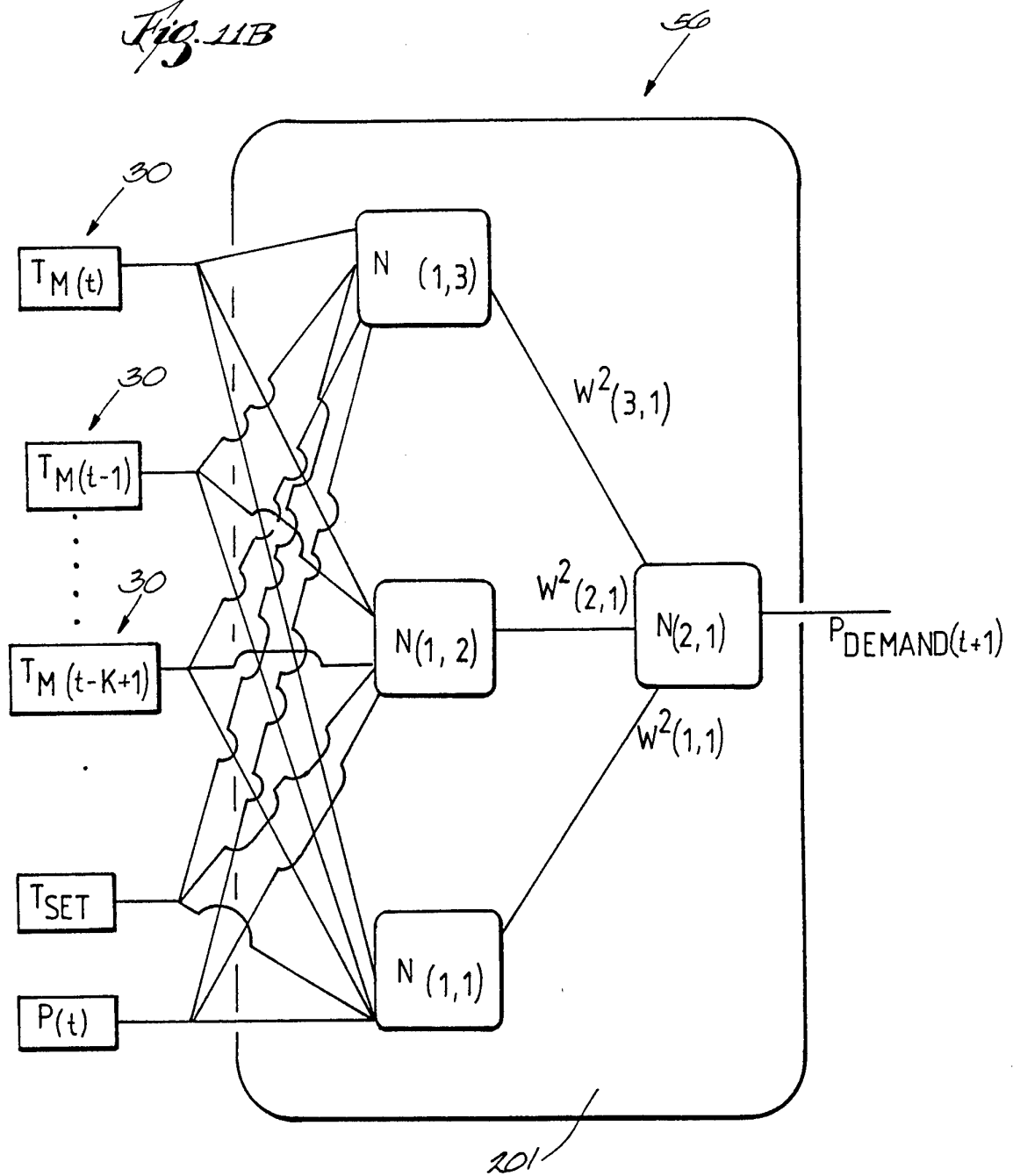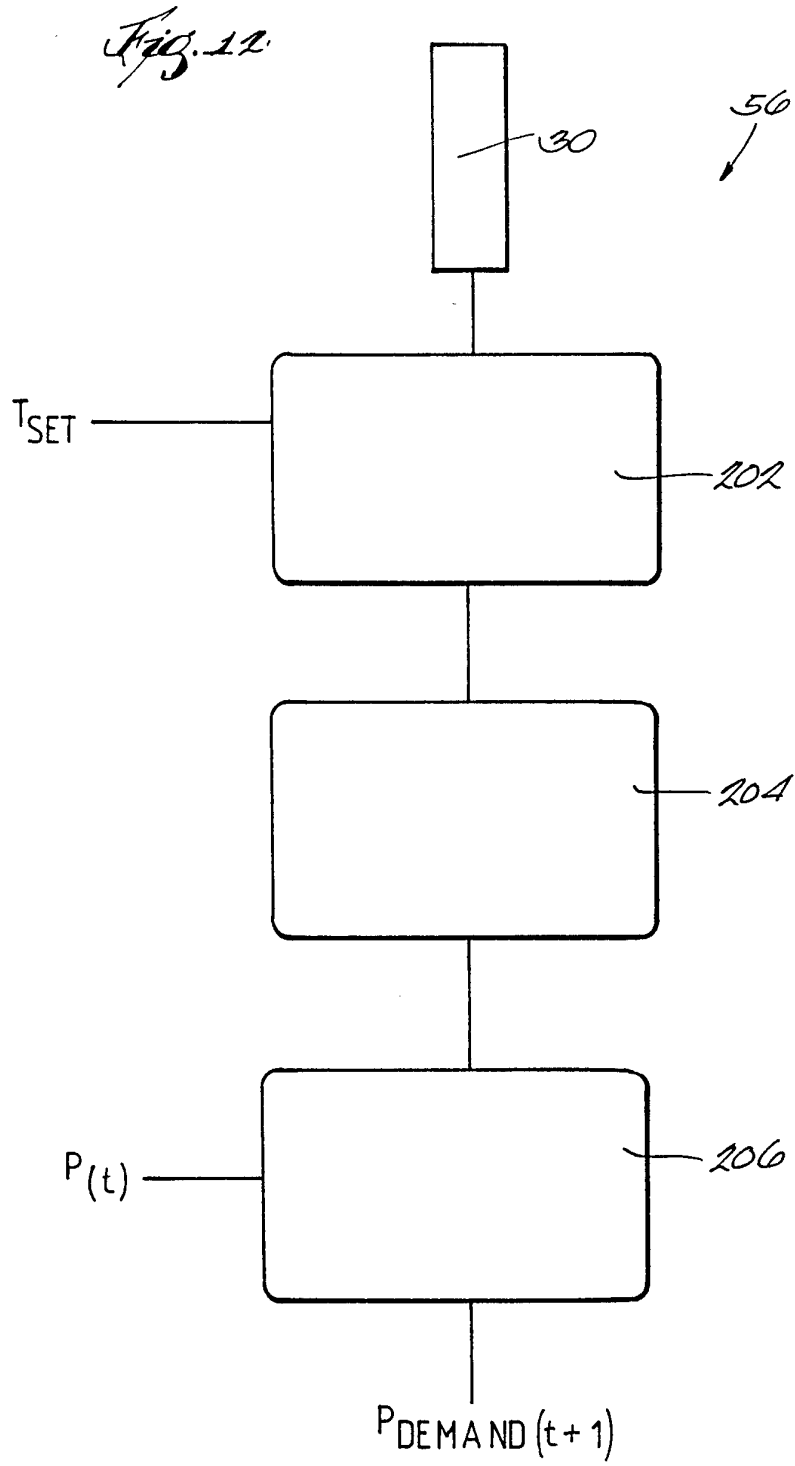
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6)   :A61B 17/39
US CL   :606/001
According to International Patent Classification (IPC) or to both national classification and IPC

B.   FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. :   606/1, 27-34, 37-42, 45, 48; 607/100-102, 115, 116, 122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US, A, 4,860,744 (JOHNSON ET AL.) 29 August 1989. See the whole document.	1-4, 18 ---------------- 5-12, 19-21
A	US, A, 5,122,137 (LENNOX) 16 June 1992. See the whole document.	1-26

☐ Further documents are listed in the continuation of Box C.   ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance		
"E"	earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family

Date of the actual completion of the international search 31 JULY 1995	Date of mailing of the international search report 1 6 AUG 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer _Stacia Sinwik_ MICHAEL PEFFLEY Telephone No. (703) 308-4305

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