US 20040230116A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2004/0230116 A1

Cowan et al. (43) Pub. Date: Nov. 18, 2004

(54) METHOD AND APPARATUS FOR DETECTION OF ULTRASOUND TRANSDUCER FAILURE IN CATHETER SYSTEMS

(75) Inventors: **Mark W. Cowan**, Fremont, CA (US); **Paul D. Corl**, Palo Alto, CA (US); **Byron J. Reynolds**, San Jose, CA (US)

Correspondence Address:
TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834 (US)

(73) Assignee: **PHARMASONICS, INC.**, Sunnyvale, CA (US)

(21) Appl. No.: **10/436,966**

(22) Filed: **May 12, 2003**

Publication Classification

(51) **Int. Cl.**[7] **A61B 8/00**

(52) **U.S. Cl.** **600/437**

(57) **ABSTRACT**

Methods and systems for detecting ultrasound transducer failure in an ultrasound catheter system comprise providing a memory device or other data storage element or catheter body having at least one ultrasound transducer disposed. The memory device stores a test current amplitude value which relates to an actual operating peak current for the at least one ultrasound transducer. An average actual operating peak current amplitude during a first period of time is calculated, and an actual operating peak current for the at least one ultrasound transducer over a second period of time may optionally also be calculated. Transducer failure has occurred if the actual operating peak current amplitude passes outside of a fit preferred range during the firs period of time, or the actual operating peak current amplitude passes outside of a second preferred range during a second period of time.

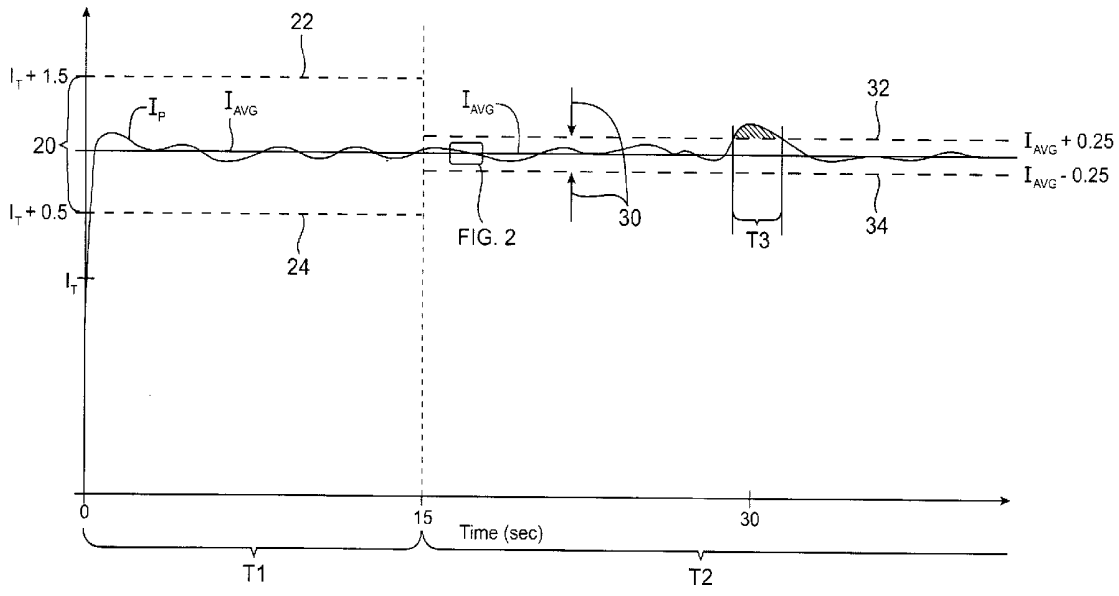

FIG. 2

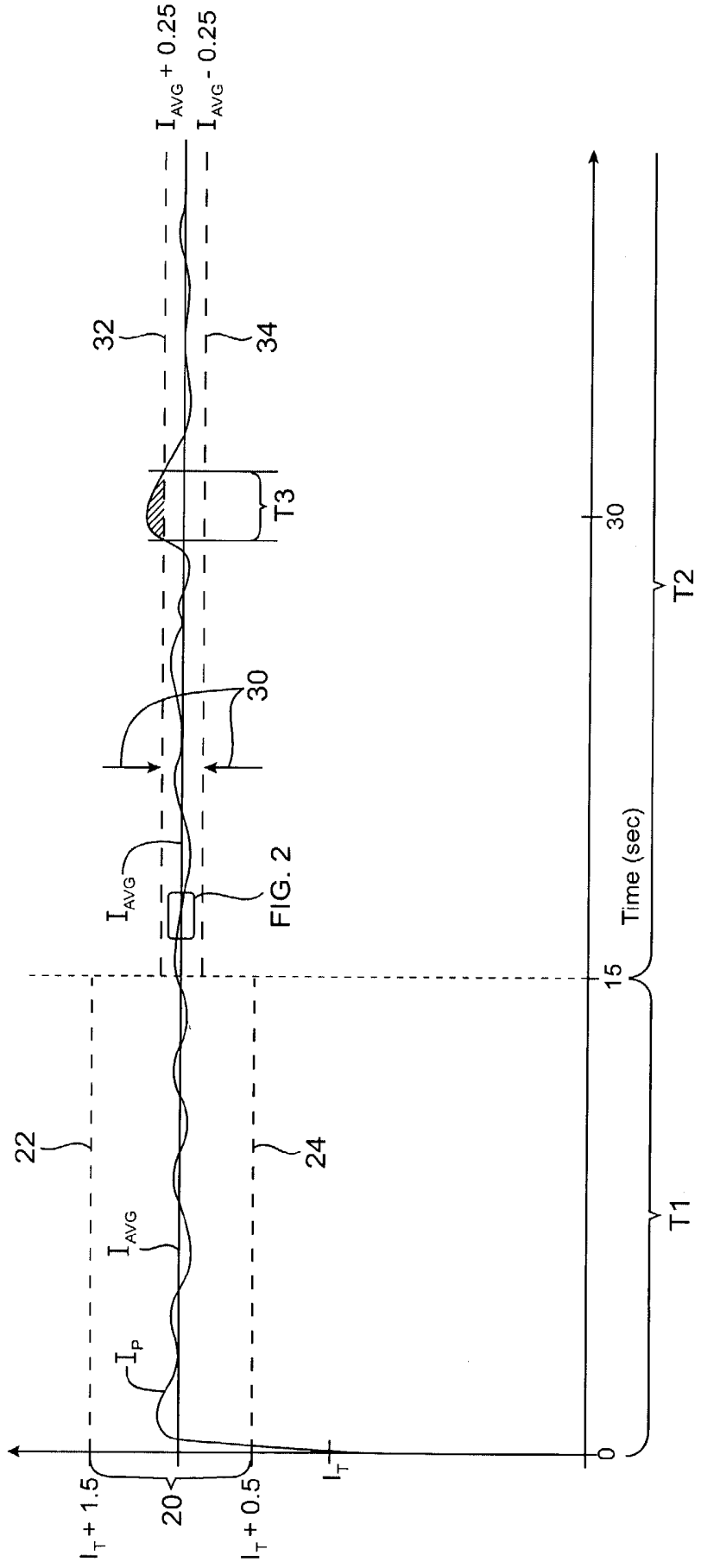
I_{AVG} + 0.25
I_{AVG} - 0.25
32
34
T3
30
I_{AVG}
22
24
I_{AVG}
I_P
I_T + 1.5
20
I_T + 0.5
I_T
0
15
30
Time (sec)
T1
T2

FIG. 2

FIG. 1

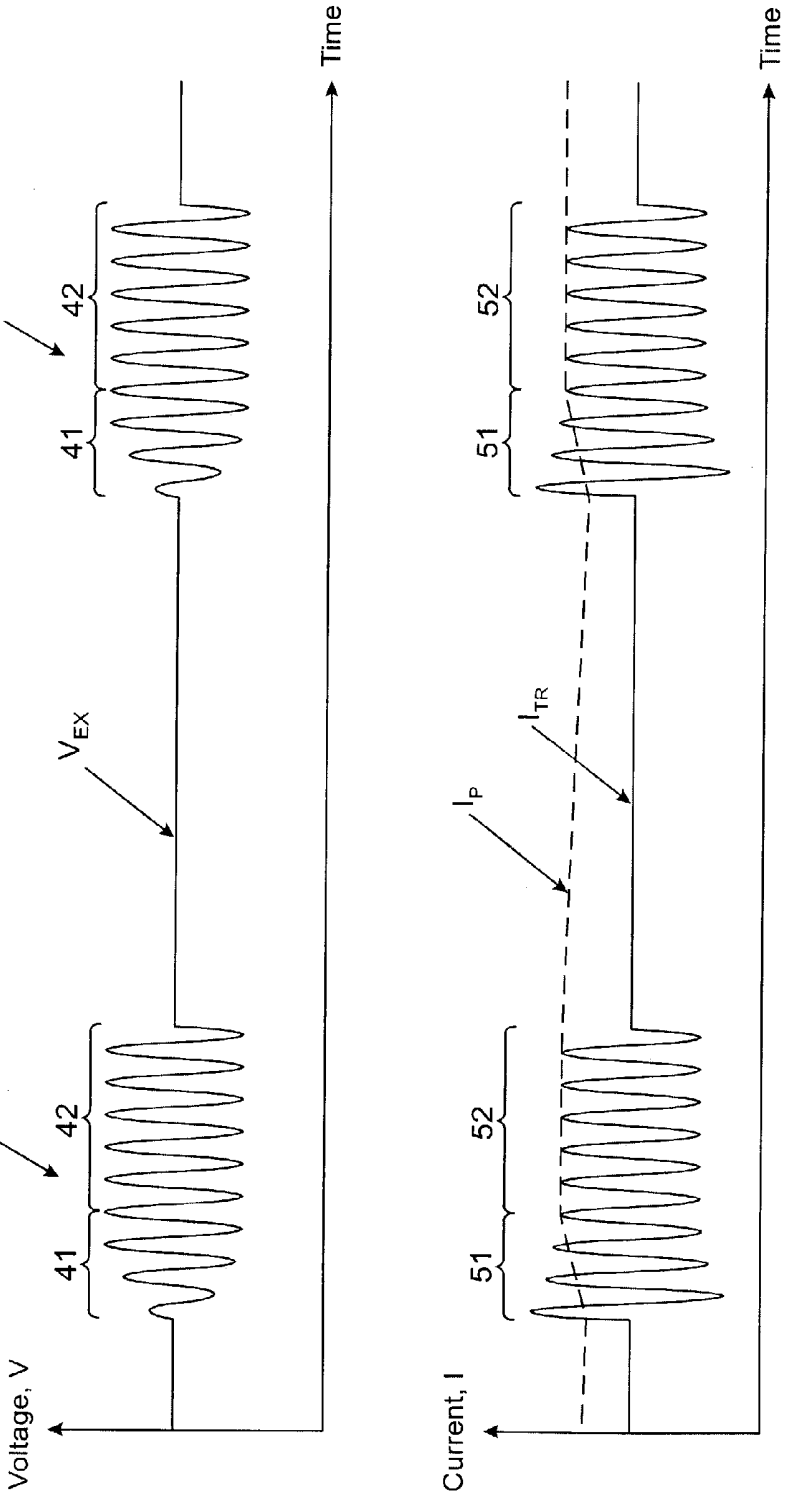
Time
B2
42
41
V_{EX}
B1
42
41
Voltage, V
Time
52
51
I_{TR}
I_P
52
51
Current, I

FIG. 2

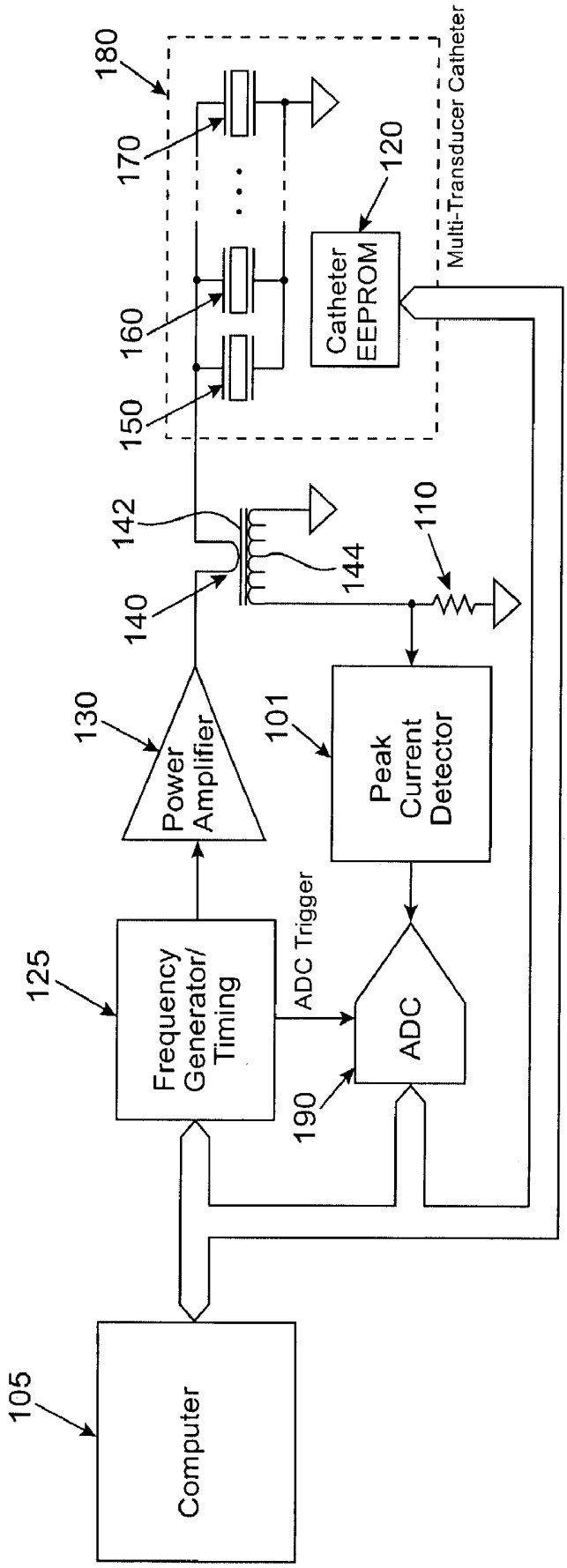
180
170
160
150
Multi-Transducer Catheter
120
Catheter EEPROM
142
144
140
110
130
Power Amplifier
101
Peak Current Detector
125
Frequency Generator/ Timing
ADC Trigger
ADC
190
105
Computer
100

FIG. 3A

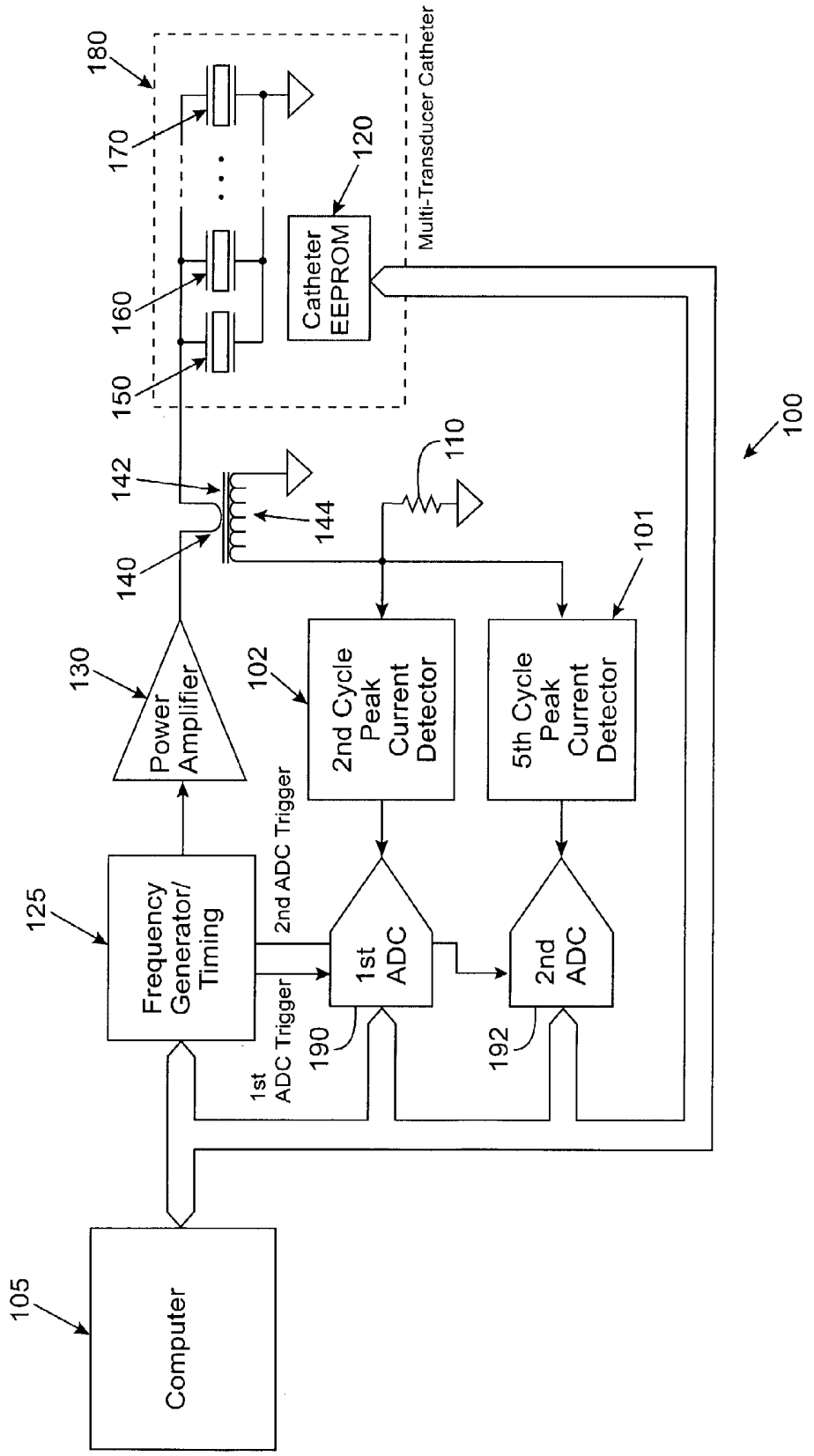
Multi-Transducer Catheter
180
170
160
150
120
Catheter EEPROM
142
144
140
110
100
101
130
Power Amplifier
102
2nd Cycle Peak Current Detector
5th Cycle Peak Current Detector
2nd ADC Trigger
125
Frequency Generator/ Timing
1st ADC
2nd ADC
1st ADC Trigger
190
192
105
Computer

FIG. 3B

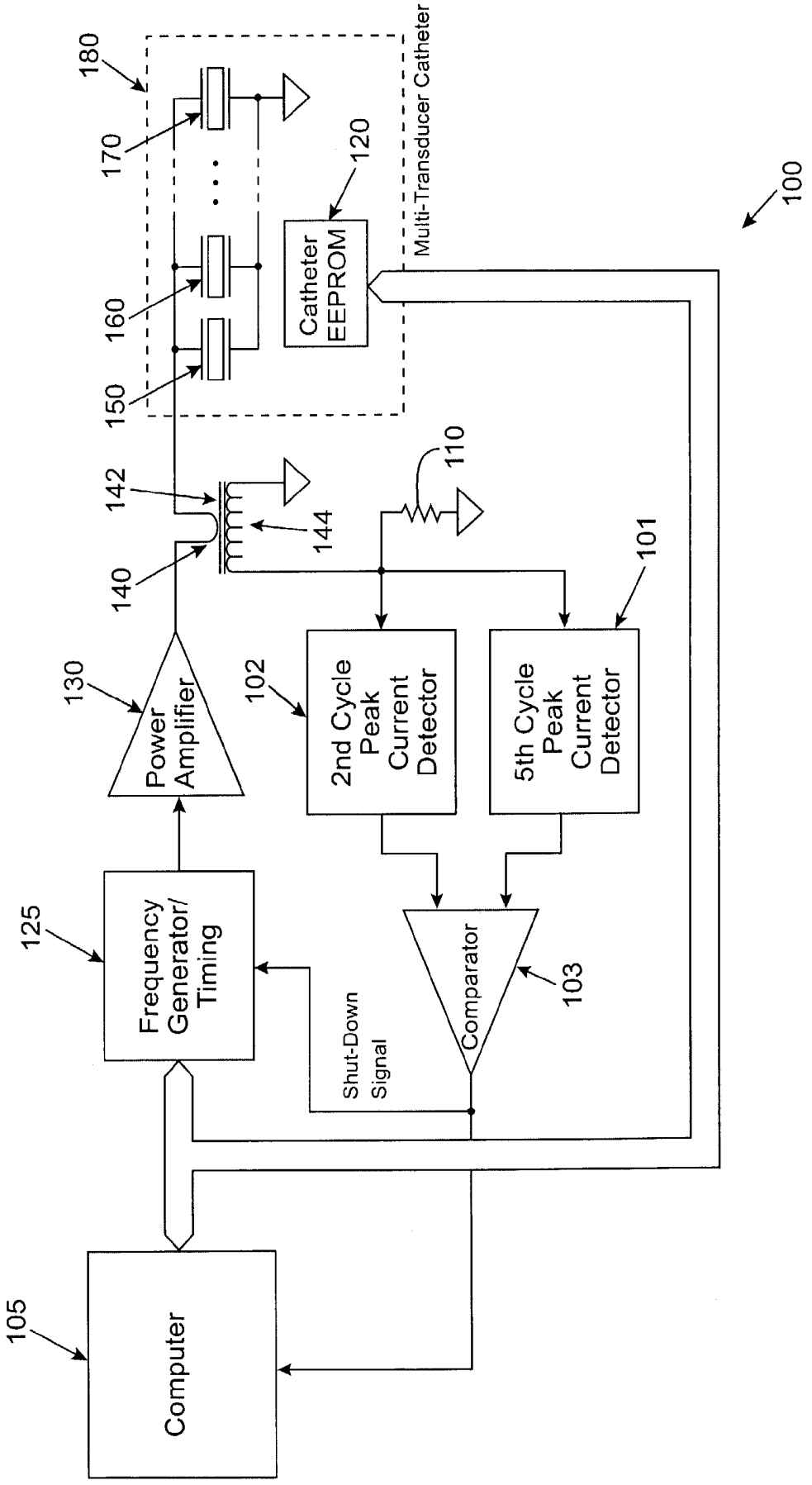
180
170
160
150
120
Catheter EEPROM
Multi-Transducer Catheter
100
142
144
140
110
101
130
Power Amplifier
102
2nd Cycle Peak Current Detector
5th Cycle Peak Current Detector
125
Frequency Generator/ Timing
Comparator
103
Shut-Down Signal
105
Computer

FIG. 3C

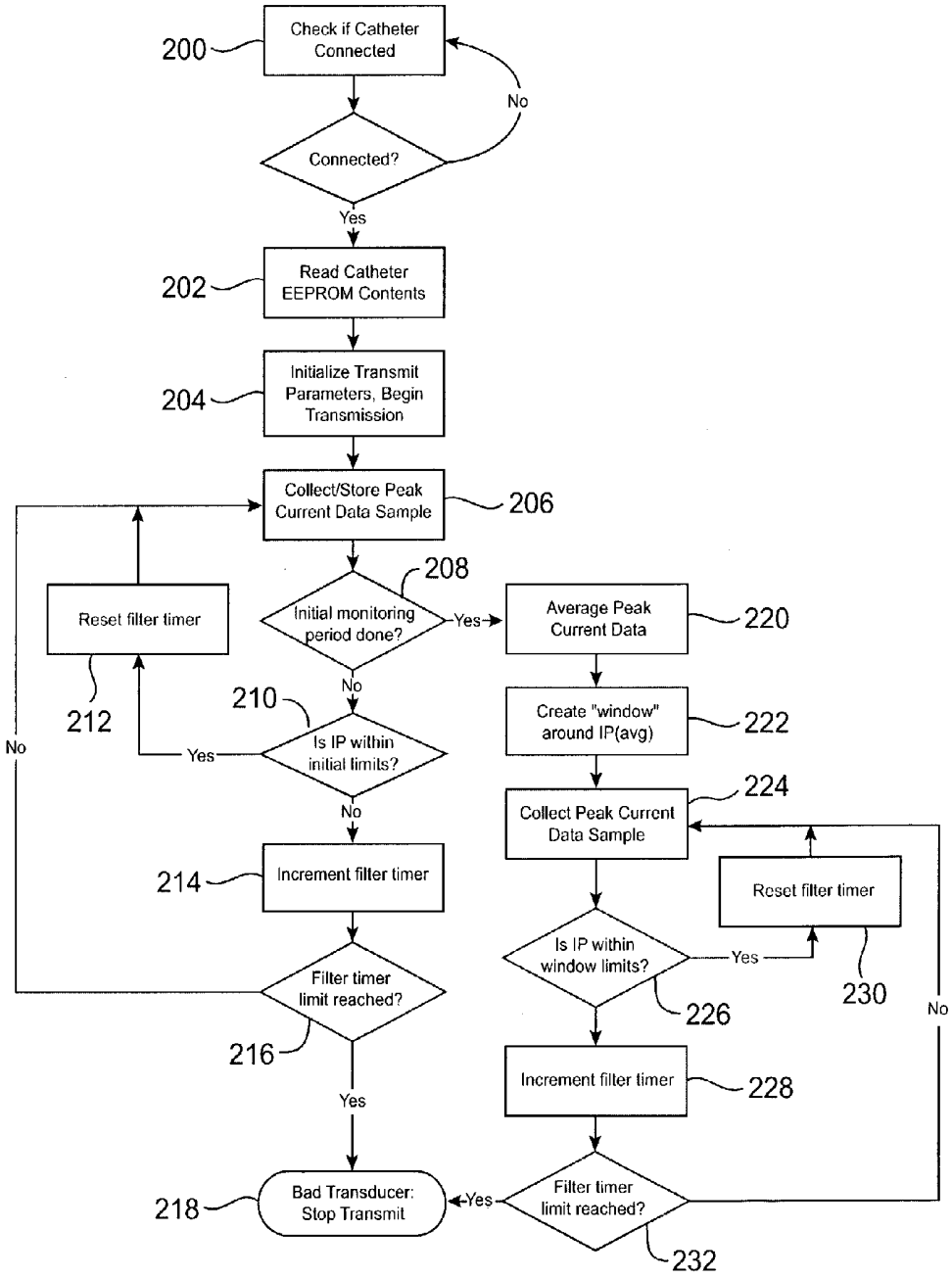
200
Check if Catheter Connected
Connected?
No
Yes
202
Read Catheter EEPROM Contents
204
Initialize Transmit Parameters, Begin Transmission
Collect/Store Peak Current Data Sample
206
208
Initial monitoring period done?
Yes
No
Average Peak Current Data
220
Create "window" around IP(avg)
222
224
Collect Peak Current Data Sample
Reset filter timer
230
Is IP within window limits?
Yes
No
226
Increment filter timer
228
Filter timer limit reached?
Yes
No
232
Bad Transducer: Stop Transmit
218
Reset filter timer
212
210
Is IP within initial limits?
Yes
No
214
Increment filter timer
Filter timer limit reached?
216
Yes
No

FIG. 4

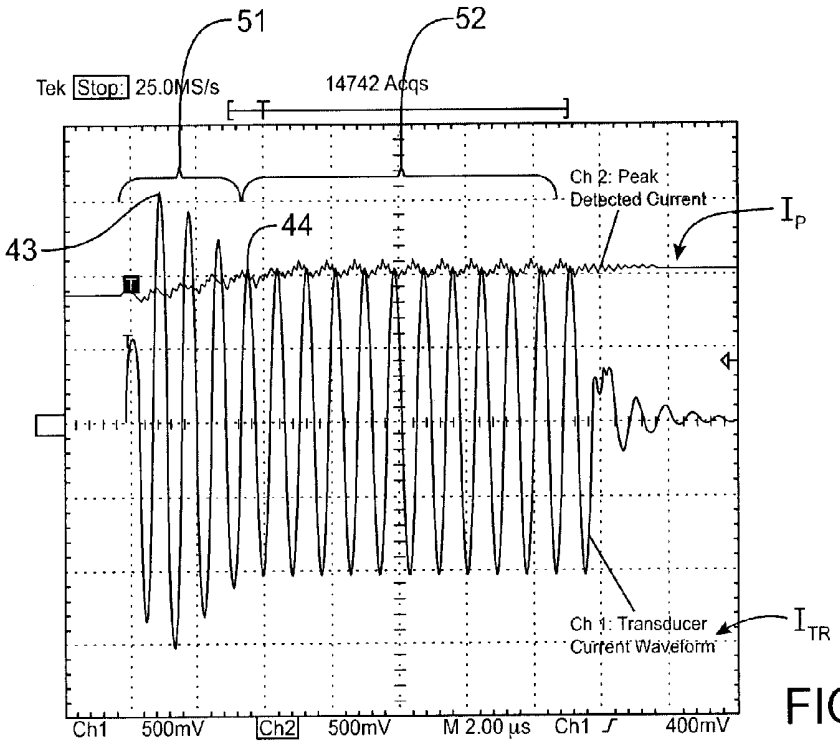
51
52
Tek Stop: 25.0MS/s
14742 Acqs
Ch 2: Peak
Detected Current
I_P
43
44
Ch 1: Transducer
Current Waveform
I_{TR}
Ch1 500mV Ch2 500mV M 2.00 µs Ch1 ƒ 400mV

FIG. 5

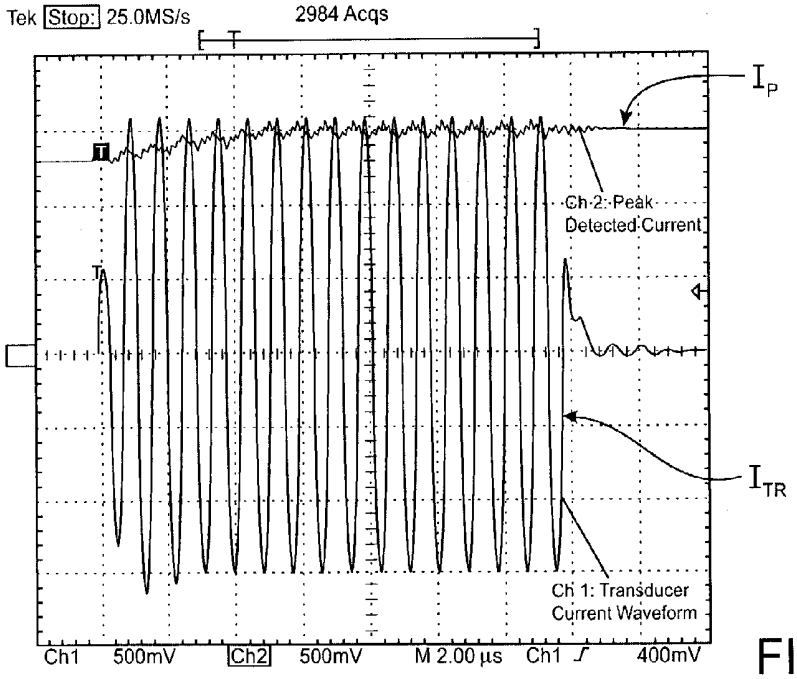
Tek Stop: 25.0MS/s
2984 Acqs
I_P
Ch 2: Peak
Detected Current
I_{TR}
Ch 1: Transducer
Current Waveform
Ch1 500mV Ch2 500mV M 2.00 µs Ch1 ƒ 400mV

FIG. 6

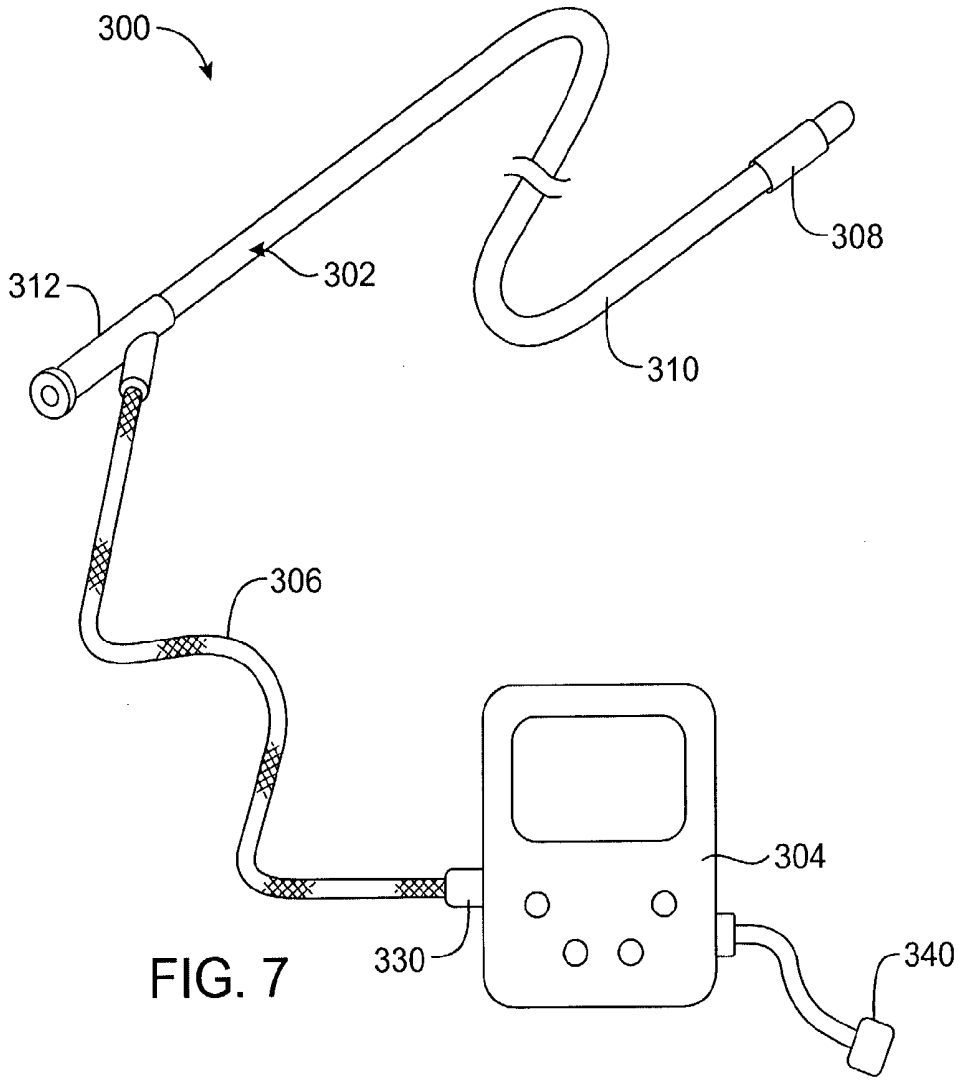

FIG. 7

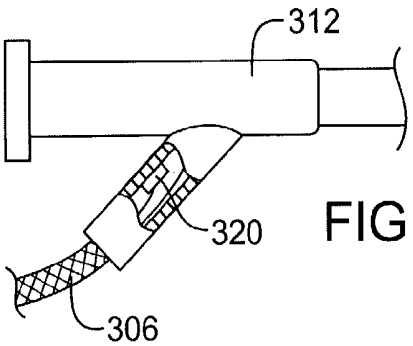

FIG. 8

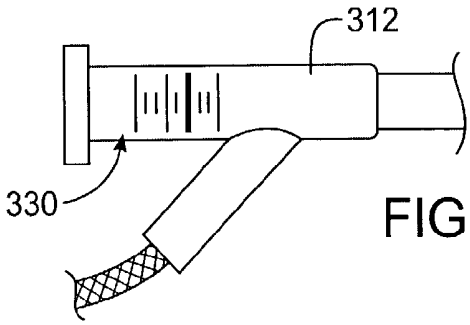

FIG. 9

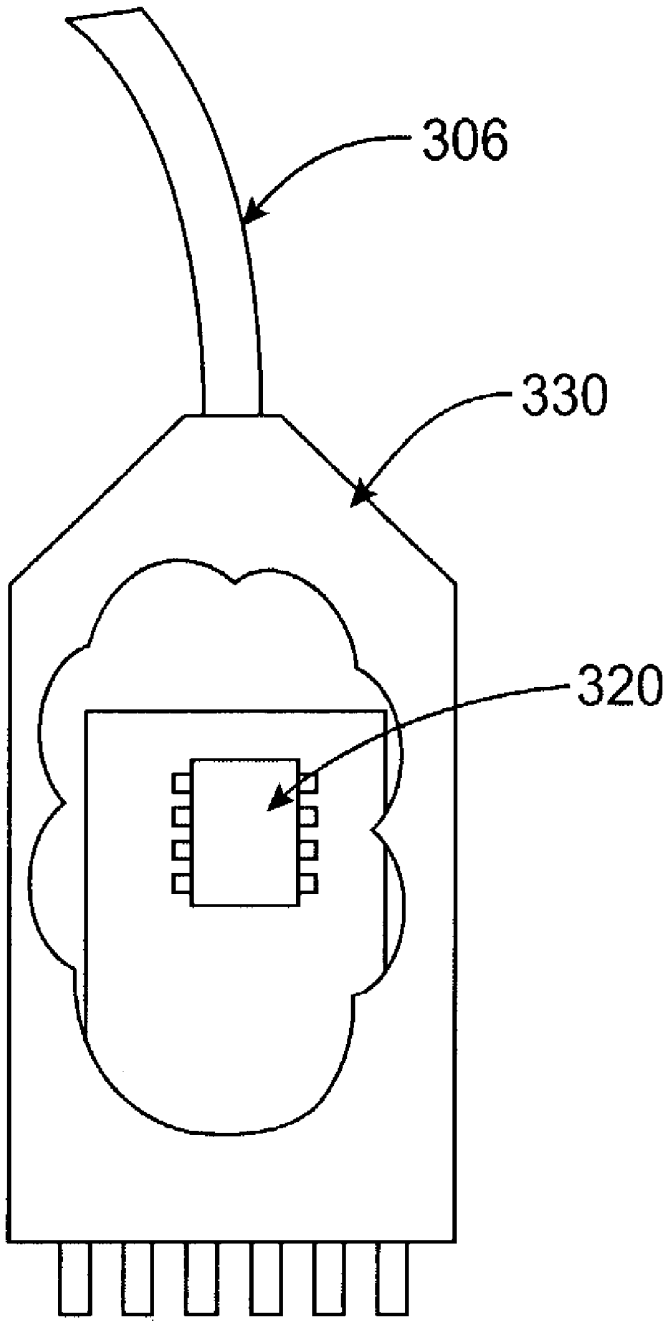

FIG. 10

METHOD AND APPARATUS FOR DETECTION OF ULTRASOUND TRANSDUCER FAILURE IN CATHETER SYSTEMS

BACKGROUND OF THE INVENTION

[0001] The present invention relates to catheter-based therapeutic ultrasound systems in general and to systems for detecting ultrasound transducer failure in catheter systems in particular.

[0002] Catheter systems employing high-output therapeutic ultrasound transducers can fail during operation for a variety of reasons, including the presence or development of microscopic fractures or other defects in the ceramic of the transducer. Subsequent to the development of such fractures, at the high drive energies typically applied, numerous harmonic vibration modes may develop among the now-independently vibrating elements of the transducer. As a result, much of the drive energy delivered to the transducer is converted into heat, not into acoustic energy as desired. Heat results from frictional losses between the microscopic regions of the ceramic. Such unintended heating not only reduces the generation of ultrasonic energy, but if sufficient heat is transferred to surrounding tissue it may also cause serious complications such as bums, or if applied within the vasculature, thrombus formation and burning of the arterial wall. Thus, a strong need exists to be able to detect transducer failure in high-output therapeutic ultrasound transducers.

[0003] A variety of approaches currently exist for detecting transducer failure in ultrasound systems, each suffering from various limitations when applied to catheter-based systems, as follows. First, a temperature-sensing device, such as a thermocouple or thermistor, can be attached directly to the ultrasonic transducer to provide feedback of transducer temperature. In such systems, the temperature-sensing device may be incorporated into a circuit that produces a voltage proportional to the temperature of the sensor. When this voltage exceeds a pre-set maximum value, a separate circuit detects this condition and either reduces the amplitude of the drive signal to the transducer or inhibits its operation entirely.

[0004] This first approach has numerous limitations, particularly when applied within an intravascular ultrasound catheter. The inclusion of a temperature measurement device and subsequent electrical wiring and connections into the catheter increases both manufacturing complexity and cost. The inclusion of such components further requires a significant amount of space, regardless of the state of their own miniaturization. In the case where a plurality of transducers are used, an independent temperature sensor is required for each transducer, further adding to the overall cost/complexity of the system. Additionally, the inclusion of a temperature sensing device adjacent each transducer element would not necessarily detect local overheating should a transducer fail at a point opposite the location of the sensor.

[0005] In a second approach, transducer impedance is monitored to detect a change in impedance away from desired operating characteristics. Unfortunately, in many instances, transducer failure may not result in a measurable change of impedance. For example, at high drive levels used during normal operation, slight changes in the phase between the driving voltage and current may be observed, but detection of the resulting impedance change may not be reliable, in particular when only one of multiple transducers has failed.

[0006] In a third approach, an ultrasonic receiving element (which may either be separate from, or fabricated as part of, the transmitting element) is used to detect a reduction in acoustic emissions, and thus is used to detect transducer failure. This third approach, however, suffers from significant cost and complexity in the form additional of receiving and detection circuitry to process the returned ultrasound signal. Moreover, the inclusion of such components requires a significant amount of space, regardless of the state of their own miniaturization. Furthermore, in the case where a plurality of transducers are used, an independent ultrasonic receiving element would be required for each transducer, further adding to the overall cost and complexity of the system.

[0007] In a fourth approach, non-invasive systems for the detection of temperature increases within the body are used. Such systems may include techniques adopted primarily for the localization and control of hyperthermia treatment of tumors. However, since such systems typically involve temperature estimation through the analysis of data obtained from non-invasive ultrasound imaging, MRI, or CT imaging, they are all costly and generally incompatible with the cardiac or peripheral catheterization laboratory setting.

[0008] For these reasons, it would be desirable to provide additional and improved methods and systems for detecting transducer failure during use of high-output therapeutic ultrasound devices, particularly those used in intravascular and other interventional procedures. Such methods and systems should require minimum modification of and/or addition to the design of and fabrication procedures for existing ultrasonic transducers and catheter-based transducer systems, should be capable of reliably detecting transducer failure, should be relative simple and inexpensive to implement, and should require very little extra space or weight in the deployed system. At least some of these objectives will be met by the inventions described hereinafter.

BRIEF SUMMARY OF THE INVENTION

[0009] The present invention provides improved methods, systems, and apparatus for detecting transducer failure in medical ultrasound systems, particularly high-output therapeutic ultrasound systems where the transducer is remotely located in the vasculature or other body locations. The present invention is based at least partly on the recognition that power consumption in a properly operating ultrasonic transducer is very predictable, particularly in high-output transducers as defined below. Thus, any deviations in observed power consumption, particularly current consumption, from a predicted or calculated consumption pattern will provide an indication that the transducer has failed or is at significant risk of failure. In such cases, a signal or alert may be provided to the user and/or the system may be automatically shut down.

[0010] The present invention is particularly suitable for use with high-output therapeutic intravascular ultrasound systems such as those described in U.S. Pat. Nos. 5,725,494; 5,728,062; 5,735,811; 6,221,038; 5,846,218; 6,287,272; 6,464,660; 5,931,805; 6,228,046; 6,210,393; 6,372,498;

6,296,619; and 6,464,680, each of which is assigned to the assignee of the present application and each of which is incorporated herein by reference. By high-output transducer, it is meant that the transducer (or the combined transducers in multiple transducer systems) will have a peak acoustic output of at least about 1000 watts, usually at least about 100 watts. Typically, the peak acoustic output will correspond to a peak current consumption of at least about 5 amps, usually at least about 20 amps. The methods, systems, and apparatus, of the present invention are not limited to such high-output systems, but will find their greatest use with such systems.

[0011] In a first aspect of the present invention, methods for detecting failure of an ultrasound transducer in a remotely positioned therapeutic device comprise determining a first operational range, typically a power or current range, for the transducer based on data stored in or on the device. Operation of the transducer is then monitored by observing the operation over a first time period, and a failure is detected if the transducer operates outside of the determined first operational range during at least a predetermined portion of the first time period. As described in more detail below, the data stored in or on the device will preferably be obtained by testing the actual device which is incorporated into the catheter or other system. By testing the actual device, an operational characteristic of that particular device (as opposed to that class of device or devices fabricated in the same way as the particular device) can be precisely determined. By then observing the actual operation of the device, typically by measuring power or current consumption, deviations from the expected operational characteristics of the particular device being used may then be assessed.

[0012] Preferably, this method for detecting failure of the ultrasound transducer additionally includes a second phase or stage. By observing the operation of the transducer during the first time period, the actual operating characteristics of the device at the time during which it is being used may be determined. That is, any variations in the expected operation based on aging of the transducer, environmental conditions, or the like, may be taken into account, and a second expected operational range may then be calculated. Typically, the second operational range will be narrower than the first operational range so that operation during a second time period, which is usually continuous with the first time period, may then be assessed more rigorously. Typically, the second operational range will be based on the observed average cordial power or current consumption during the first time period. The range is then determined by placing upper and lower limits around the observed average, typically being 95% to 105% of the average, although such "window" may vary depending on the device and other factors. The operation of the transducer may then be assessed during such second time period, which may last as long as the entire remainder of the operation of the device, and any variations or deviations outside of the operational range may indicate a transducer or system failure. Particular limits or constraints on the deviations may vary so that some minimum time of operation outside of the second operational range may be required before a system failure is indicated.

[0013] In further preferred aspects of this first method, the data stored in or on the device is an actually measured current or power consumption, and the first operational range is calculated relative to this first value. Because of the operational characteristics of the transducer, the first operational range in some instances may actually be higher than the measured current or power consumption. For example, the first operational range may have a current value which is from 110% to 130% of the measured or test current value which is provided on the catheter itself.

[0014] The duration of the first time period will typically be relatively short, usually being from five seconds to thirty seconds, more typically being about 15 seconds measured from the time the transducer is initially energized. Failure of the transducer during the first time period may be indicated or detected when the transducer operates outside of the first operational range for some minimum time period ranging from a fraction of a second to a few seconds, typically being from about one second to five seconds.

[0015] The therapeutic ultrasound system will often operate in a series of bursts where the system is alternately energized and de-energized. During each burst, the transducer will be energized over a plurality of current waveform cycles. In such instances, observing the operation of the transducers will typically comprise measuring the peak current value after the first several current waveform cycles have passed, typically after at least four current waveform cycles have passed.

[0016] In a second aspect of the present invention, failure of an ultrasound transducer in a remotely positioned therapeutic device may be detected without the need to store or obtain power or current consumption characteristics of the particular device which is being used. Instead, such methods rely on measuring peak cycle current during operation of the device, typically by monitoring the current delivered to the device from an ultrasound generator. The difference between the peak current measured at an early cycle and the peak current measured at a subsequent or later cycle is then calculated. It has been found that the peak current value at an early cycle, typically the second or third cycle, and more typically the second cycle, should be higher than that observed at subsequent cycles, typically the fifth cycle or a later cycle. Thus, if the calculated difference between the measured cycle falls below an expected minimum value, typically at least 25% of the early peak current cycle value, then failure of the transducer is indicated.

[0017] In a further aspect of the present invention, a therapeutic ultrasound controller for use in combination with a catheter having a high-output therapeutic ultrasound transducer comprises means for measuring peak current delivered to the transducer. The means for determining a first expected peak current operational range for the transducer is further provided, typically based on a value received from an electronic memory in the catheter itself. Means for comparing the measured peak current value with the first determined peak current range is further provided, or measured peak current value which falls outside of the first determined peak current range indicates transducer failure. The system will usually further comprise means for determining a second expected peak current operational range based on the peak current measured during the first operational period, typically on the average peak current during the first operational period. Means are then provided for comparing the measured peak current value with the second determined

peak current range, wherein a measured peak current value which falls outside of the second peak current range indicates a transducer failure.

[0018] In a fourth aspect of the present invention, a therapeutic ultrasound controller for use in combination with a catheter having a high-output therapeutic ultrasound transducer comprises means for measuring peak current to the transducer and means for comparing the measured peak current of an early current cycle with that of a later cycle, typically being the difference between the second or third peak current cycle with the fifth or later peak current cycle. Usually, the peak current cycles will be monitored in each burst of the transducer operation, where a difference of less than 25% between the peak current value indicates a failure of the transducers.

[0019] In yet another aspect of the present invention, an intravascular catheter comprises a catheter body, a high-output therapeutic ultrasound transducer operatively disposed on the catheter body, and data on or in the catheter body representing a measured operational range of the transducer. The data may be incorporated on the catheter body itself, on an attached hub, on an attached electrical connector, or on any other component or system of the catheter. A high-output therapeutic ultrasound transducer will typically have a peak acoustic power output of at least about 1000 watts, usually at least about 100 watts. The data may be incorporated in an electronic memory device which is in or on any portion of the catheter body, catheter hub, transducer assembly, electrical connector, or the like. Suitable electronic memory devices include flash memory, electrically-erasable memory (EEPROM), radio frequency identification tags (RFID's), and the like. Alternatively, the data may comprise indicia printed or otherwise embossed on to the catheter body or any related portion thereof. Indicia may be machine readable, e.g., being in the form of barcode, or may be human readable. In the latter case, an operator reading the operational data of the catheter can manually input such data into the catheter power supply or controller related to the power supply for practicing the methods of the present invention.

[0020] In a still further aspect of the present invention, methods for fabricating intravascular catheters comprise providing an intravascular catheter having a catheter body and a high-output therapeutic ultrasound transducer operatively disposed on or in the catheter body. A power consumption characteristic of the transducer during operation is then measured during or after the time of fabrication. Information representing the power consumption is then embedded in data in or on the catheter body in a readable form. Usually, measuring will comprise measuring current consumption of the transducer, typically where the current is measured with the transducer immersed in water and under nominal excitation conditions. Embedding may then comprise storing the data in an electronic memory disposed in or on the catheter body. Alternatively, embedding may comprise printing indicia setting for the measured value, where the indicia may be machine readable, e.g., in the form of barcode, or may be human readable. As described previously, the data encoded may represent any value which may be related to an expected operational range of the transducer based on the measured power consumption characteristic. For example, the data may be a peak power or current consumption value where the expected operational range is then calculated from the value. Alternatively, the data may represent the expected range itself, multiple expected ranges, etc.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] **FIG. 1** is an illustration of peak operating current of an ultrasound catheter over an extended period of time.

[0022] **FIG. 2** is an enlarged view of a small portion of the instantaneous and peak operating currents of the catheter of **FIG. 1**, also showing the excitation voltage applied to the transducer to generate this current.

[0023] **FIG. 3A** is a system for generating the excitation voltage to, and detecting and monitoring peak current in an ultrasound transducer in a catheter system.

[0024] **FIG. 3B** is an alternate system for generating the excitation voltage to, and detecting and monitoring peak current in an ultrasound transducer in a catheter system.

[0025] **FIG. 3C** is another alternate system for generating the excitation voltage to, and detecting and monitoring peak current in an ultrasound transducer in a catheter system.

[0026] **FIG. 4** is a flowchart of the operations of the present transducer failure detection system.

[0027] **FIG. 5** is an illustration of both instantaneous and peak current waveforms generated by a properly functioning ultrasound transducer, corresponding to **FIG. 2**.

[0028] **FIG. 6** is an illustration of both instantaneous and peak current waveforms generated by a degraded transducer.

[0029] **FIG. 7** illustrates a system comprising a high-output therapeutic ultrasound catheter in combination with a therapeutic ultrasound controller in accordance with the principles of the present invention.

[0030] **FIG. 8** illustrates a first configuration of the hub of the catheter of **FIG. 7**, shown with an electronic memory module incorporated in a side branch of said hub.

[0031] **FIG. 9** illustrates a second configuration of the hub of the catheter of **FIG. 7** shown with a barcode identifying the transducer characteristics of the catheter.

[0032] **FIG. 10** illustrates a configuration of the electrical connector of the catheter of **FIG. 7** shown with an electronic memory module incorporated within the body of said connector.

DETAILED DESCRIPTION OF THE INVENTION

[0033] The present invention sets forth a method and system that can reliably and quickly detect the degradation or failure of an ultrasound transducer in a catheter system, such as a catheter system adapted to deliver therapeutic ultrasound energy to a patient. Advantageously, the present invention can also detect the degradation or failure of a single ultrasound transducer in a catheter system having a plurality of ultrasound transducer elements.

[0034] As will be explained, the present invention detects transducer degradation or failure by measuring the peak current through the transducer(s) over time. Deviation of this measured operating current outside of preferred current ranges during particular periods of time (and for particular

lengths of time) results in a failure detection condition. As will be explained, these preferred current ranges correspond to pre-stored "test" characteristics that are particular to the individual catheter in use.

[0035] **FIG. 1** is an illustration of peak operating current (I_P) of an ultrasound catheter as measured over an extended period of time.

[0036] In accordance with the present invention, a memory device is provided and is used to store a "test" current value (I_T) therein. Preferably, this memory device is provided within the body or hub or electrical connector of the catheter, as will be explained. Test current value I_T preferably corresponds to an experimentally determined (or expected) peak operating current value for the particular catheter in use. This I_T value is preferably determined during the manufacture of the particular catheter in use. As such, each catheter may have its own (i.e., different) I_T current value stored therein. In preferred aspects, this peak operating current I_T is typically between 4.0 and 8.0 A when measured in room temperature water for a catheter incorporating a multi-element transducer.

[0037] It has also been experimentally determined by the present inventors that peak operating current for such an ultrasound catheter is typically higher when measured in-vivo (due to changes in transducer impedance from temperature and acoustic loading). For example, in-vivo peak current typically ranges from 0.5 A to 1.5 A higher than the peak current observed with the transducers in water. Accordingly, the actual measured peak operating current I_P is thus typically between 0.5 A and 1.5 A above the stored test current I_T.

[0038] In accordance with the present invention, therefore, the present system detects whether actual peak operating current I_P is within a first range **20** during a first period of time T1 (i.e., transducer failure is determined to have occurred if I_P exceeds upper limit **22** or falls below lower limit **24** during time T1). Should I_P exceed upper limit **22**, this would indicate failure due to transducer fracture or degradation, or an electrical short circuit. Conversely, should I_P fall below lower limit **24**, this would indicate failure due to a transducer or an electrical connection which has been broken by excessive bending or mishandling of the catheter prior to use.

[0039] In preferred aspects, therefore, upper limit **22** is preferably equal to I_T plus approximately 1.5 A; and lower limit **24** is preferably equal to I_T plus approximately 0.5 A.

[0040] In various preferred aspects, lower limit **24** is preferably approximately equal to 110% of I_T and upper limit **22** is preferably approximately equal to 130% of I_T.

[0041] Transducer degradation during operation due to microscopic breakdown of the ceramic causes a rise in steady-state peak current, although this increase may be subtle, especially in the case of breakdown of a single transducer element in a multi-element catheter. In such a case, simply monitoring peak current against fixed limits such as would be suggested by the above described monitoring in first range **20**, i.e., between upper limit **22** (I_T+1.5 A) and lower limit **24** (I_T+0.5 A) may not be sensitive enough to detect this transducer degradation. For example, in the case of a multi-element transducer operating at, or near lower limit **24** of this range (i.e., operating at or near I_T+0.5 A) which suffers a single element breakdown, the measured current I_P may rise significantly, but still remain within the 'normal' range (i.e., below upper limit **22**).

[0042] It has also been experimentally determined by the present inventors, that although the in-vivo peak current I_P may be highly variable with respect to in-vitro current levels, it does remain quite stable during normal operation in a given in-vivo setting, typically varying less than +/−5% (i.e., about +/−0.25 amperes) from an initial I_P value.

[0043] In accordance with the present system, therefore, a determination is also made whether the peak current I_P has increased or decreased by more than about 5% or 0.25 A from the average of the peak operating current I_P measured during time period T1, after time period T1 has passed. In preferred aspects, T1 is approximately 15 seconds in duration.

[0044] During time period T1, an average peak current intensity I_{AVG} (being the average of I_P) is determined. After time T1, (i.e., any time after the start of time period T2), the present system detects whether actual peak operating current I_P remains within a second range **30**. Range **30** is preferably centered at the value determined for I_{AVG}. In accordance with preferred aspects, range **30** has an upper limit **32** and a lower limit **34**, as shown. In one preferred aspect, transducer failure is determined to have occurred if I_P exceeds upper limit **32** or falls below lower limit **34** during time T2.

[0045] In one preferred aspect, upper limit **32** will be about 5% or 0.25 A greater than I_{AVG}, and lower limit **34** will be 0.25 A lower than I_{AVG} As can be seen, therefore, range **30** will be much narrower than range **20**. As such, a smaller variance in I_P during time T2 will result in a failure detection condition. An advantage of range **30** being narrower than range **20** is that should only one of a plurality of transducers fail, the overall operating current for the multi-transducer system would only increase by a small amount. Such a small increase would nevertheless result in I_P exceeding upper limit **32**.

[0046] An advantage of detecting transducer failure during time period T2 is that the present system is essentially comparing its measured current I_P to its own initial operating conditions. As such, failure detection during time period T2 (i.e., with I_P rising above upper limit **32** or falling below lower limit **34**) results in detection limits which are particular to the individual catheter in use and the in-vivo conditions to which it is exposed.

[0047] In an optional preferred aspect of the invention, small deviations of I_P outside of range **30** are permitted, provided however, that I_P returns to a value within range **30** within a short period of time T3. In preferred aspects, T3 is limited to a pre-determined duration of less than 15 seconds. This optional "temporal filter" feature of the invention is advantageous, as follows.

[0048] Certain events, such as the injection of x-ray contrast media into the artery, can cause significant changes in the acoustic environment that temporarily affects the impedance, and thus the peak current, of the transducer. Accordingly, if I_P remains outside of range **30** for longer than a desired period of time, a conclusion can be made that one or more of the transducers are defective, and the system can then be shut down. Conversely, allowing I_P to briefly exit range **30** permits short duration events (such as the injection

of x-ray contrast media into the artery) without triggering a transducer "failure detection" condition.

[0049] Referring next to **FIG. 2**, an enlarged (i.e., close up) view of the waveforms giving rise to a small portion of the peak operating current I_P of the catheter of **FIG. 1** is shown. The waveform shown in **FIG. 2** is exemplary of peak operating current I_P and the underlying excitation voltage waveforms of I_P at all times (i.e., during any of time periods T1, T2 or T3).

[0050] As can be seen in the enlarged view of **FIG. 2**, the line representing peak operating current I_P on **FIG. 1** is actually comprised of the detected peak values of the instantaneous transducer current (I_{TR}), from a series of repeating excitation bursts (for example, B1 and B2). **FIG. 2** also shows the excitation voltage applied (V_{EX}) to the catheter resulting in the instantaneous transducer current (I_{TR}) and detected peak current (I_P). V_{EX} and I_{TR} are shown contemporaneously. In other words, waveform cycles **51** of I_{TR} occur when waveform cycles **41** of V_{EX} occur; and, waveform cycles **52** of I_{TR} occur when waveform cycles **42** of V_{EX} occur, as follows.

[0051] It is well known that an ultrasound transducer can be modeled as a resonant circuit having a certain quality factor Q, with the value of Q being dependent on many variables in the design and construction of the transducer. As can be seen in **FIG. 2**, for each excitation burst (B1 or B2), several initial waveform cycles of V_{EX} are required prior to generating a steady-state condition in the transducers, this number of cycles being approximately equal to the Q of the resonant circuit, which for example in **FIG. 2** is approximately 4. Specifically, for each excitation burst B1 or B2, the instantaneous transducer current I_{TR} is demonstrated by initial waveforms **51** of decreasing amplitude, prior to achieving steady-state waveforms **52**.

[0052] In accordance with an optional preferred aspect of the present invention, therefore, I_P is therefore preferably calculated after 4 or even 5 waveform cycles of each excitation burst. (i.e., I_P is calculated only during waveforms **52**). Accordingly, degradation of the described transducers during operation is preferably detected by only measuring the peak current of the fourth or subsequent cycles of each excitation burst.

[0053] Referring next to **FIG. 3A**, a system **100** is provided for accomplishing the above method. A catheter **180** that may comprise a plurality of transducers **150**, **160** and **170** is provided. Catheter **180** has an internal memory device **120** (which may optionally comprise an EEPROM) incorporated therein. Memory device **120** preferably stores information that may include test current (I_T) data recorded during manufacture of the catheter. As stated above, test current I_T preferably comprises the steady-state peak current amplitude that was experimentally determined (in water) for the particular catheter **180** being used.

[0054] System **100** also preferably comprises a current-detecting transformer **140** that produces a current in its secondary winding **144** proportional to the current in its primary winding **142**. Primary winding **142** is connected in series between the ultrasound power amplifier **130** and transducers **150**, **160** and **170** (in catheter **180**). Therefore, the current passing from current-detecting transformer **140** through load resistor **110** creates a voltage signal that is also proportional to the transducer current. In a preferred aspect, the voltage across load resistor **110** is scaled and peak-detected by detection circuit **101** which, in a preferred aspect, has a peak acquisition delay equal to approximately four or five periods of the transmit waveform, corresponding, as stated above, to the number of waveform cycles required to achieve steady-state operation. In various preferred aspects, detection circuit **101** is preferably adapted to produce a voltage proportional to the peak current with an accuracy of better than +/−1% for peak currents ranging from 2.5 to 20 amperes.

[0055] The peak-detected current signal is then preferably digitized by an analog-to-digital converter **190**, and the result is read by computer **105** for processing. Preferably, processing of the peak current signal in computer **105** includes reading test current I_T data (which may be recorded during manufacture of catheter **180**, and stored in an EPROM memory device **120** incorporated into catheter **180**), and processing test current I_T data in accordance with the presently set forth method, as described herein.

[0056] System **100** optionally comprises separate frequency generation and timing hardware **125**, also preferably under control of computer **105**, which preferably generates the signal to be amplified by power amplifier **130** and also optionally provides a timing signal to analog-to-digital converter **190** to initiate its sampling/data conversion cycle immediately following each transmit burst (e.g., burst B1). This timing offers the advantage of avoiding sampling the peak-detected signal either during the transmit cycle such as B1 (which could result in erroneous information due to internal electrical noise), or significantly after the transmit cycle has ended such as immediately before transmit burst B2 (which would result in under-reading the peak current due to unavoidable droop in the peak detection circuitry).

[0057] In accordance with the present invention, the software operating on computer **105** executes an algorithm to determine the condition of transducers **150**, **160** and **170** during operation, as detailed by the flowchart of **FIG. 4**. Specifically, upon connection of catheter **180** to system **100**, computer **105** reads information from the EPROM device **120** located in catheter **180**. This information preferably includes information about the catheter type and configuration, transducer characteristics including resonant frequency and efficiency, and operating characteristics including peak current levels measured during manufacturing test (i.e., test current, I_T). Analysis to determine if transducer failure has occurred is preferably carried out as follows, in accordance with the preferred method described herein.

[0058] At step **200**, a determination is made as to whether the catheter is connected. At step **202**, the data in memory device **120** are read by computer **105**. At step **204**, the computer **105** configures frequency generator and timing circuitry **125** and power amplifier **130** to produce the appropriate excitation waveforms for the catheter, and catheter operation is commenced. At step **206**, measurement of I_P is started. Such measurement is carried out over time period T1 (step **208**). Determination is made continually during time period T1 (at step **210**) whether I_P has moved out of range **20**.

[0059] In various optional preferred aspects, temporal filtering is implemented by steps **210**, **212**, **214**, and **216** to allow brief excursions of I_P out of range **20**. If I_P has exited

range **20**, a determination is made at step **216** whether such deviation was for at least as long as time period T**3**. If so, a transducer failure conclusion is made at step **218**. This is advantageous, because as described previously, certain events such as the injection of x-ray contrast media into the artery can cause significant changes in the acoustic environment that temporarily affects the impedance, and thus the peak current, of the transducer. Accordingly, if I_P remains beyond desired limits longer than the specified time T**3**, computer **105** can then determine that one or more of the transducers are defective and appropriate action may then be taken, for example shutting off the excitation signal to the transducer and notifying the operator of the failure.

[**0060**] After the passage of time period T**1**, I_{AVG} is calculated from the I_P measurements obtained during T**1** at step **220**. Thereafter, at step **222**, range **30** is determined, and at step **224**, I_P is measured during time period T**2**. At step **226**, a determination is made whether I_P has exited range **30**.

[**0061**] Again, temporal filtering is incorporated to allow brief excursions of I_P out of range **30**. This filtering is implemented by steps **226**, **228**, **230**, and **232**. If I_P has exited range **30**, a determination is made at step **232** whether such deviation was for at least as long as time period T**3**. If so, a transducer failure conclusion is made at step **218** and appropriate action may be taken.

[**0062**] In accordance with a second aspect of the present method, transducer failure can also be detected as follows. Referring to **FIG. 5**, which illustrates instantaneous transducer current I_{TR} during a single burst (such as B**1** or B**2** in **FIG. 2**) and the detected peak current I_P for a properly functioning transducer, it can be seen that transducer current I_{TR} reaches a peak at about the second cycle **43** of the waveform, and then settles down to a steady level at and beyond the fifth cycle **44**. As can be seen, the amplitude of second cycle peak **43** is normally about 25-30% higher than the steady-state current at or beyond the fifth cycle **44**.

[**0063**] This feature of the properly operating transducer's waveform is not seen in **FIG. 6** (which illustrates the current waveforms I_{TR} and I_P for a degraded transducer) in which little or no peaking occurs (i.e., the transducer current amplitude remains approximately constant from near the second cycle peak throughout the transmit waveform).

[**0064**] In accordance with an optional aspect of the present invention, the amplitude of second cycle peak **43** (of I_{TR}) is thus compared to the amplitude of the fifth cycle peak **44** to determine whether or not the transducer is functioning properly, or has degraded.

[**0065**] Specifically, should the value of fifth cycle peak **44** rise above a predetermined percentage, for example 65% to 75% of the value of second cycle peak **43**, the present system concludes that transducer failure has occurred.

[**0066**] Referring to **FIG. 3B**, an optional system for accomplishing this optional preferred aspect is provided as follows. A second peak detector **102** is incorporated into system **100**. Preferably, second detector **102** has a response time such that the value of the maximum (i.e., second cycle peak **43**) is held and digitized. Software in computer **105** then compares the digitized values of the second cycle peak **43** and the fifth cycle peak **44** from detectors **102** and **101**.

[**0067**] Preferably, both absolute minimum and maximum values for each of current cycle peaks **43** and **44** (and allowable ratios between cycle peaks **43** and **44**) could be stored in memory device **120** in catheter **180**. An advantage of pre-storing these values in the particular memory device **120** for each individual catheter **180** is that the present system is able to accommodate catheters having different characteristics, each having unique pre-stored values. Since comparisons between measured values and pre-stored values are made with the software in computer **105**, the present invention advantageously compensates for various transducer configurations and manufacturing variances.

[**0068**] An advantage of using this second aspect of the preferred method for transducer failure detection is that the requirement of separating transducer operation and monitoring into two time periods T**1** and T**2** (referring to **FIG. 1**) may not be required. This is because in-vivo conditions causing transducer current I_{TR} to vary from test current I_T affect the entire waveform equally and the characteristic peaking of a working transducer would not be lost. A larger peak current operating range (such as range **20**) could be maintained for detection of non-transducer related failures (e.g., electrical short or open circuits) while the ratio of cycle peaks **43** and **44** would be used to detect degraded transducer element(s). This could eliminate the need to rely on the large operating range **20** for the detection of transducer degradation during the time period TI thus improving sensitivity during the initial operating period, as well as allowing simplification of the monitoring algorithm.

[**0069**] Another advantage of using this second aspect of the preferred method for transducer failure detection is that a "transient filter" (i.e., allowable I_P excursions out of range **20** for less than time period T**3**) as described above, may not be required. Alternatively, if such a transient filter is used, T**3** could be of a shorter length, due to the fact that if current changes due to a temporary change in acoustic load, the entire waveform is changed equally and the characteristic peaking (at cycle peak **43**) of a working transducer would not be lost. This could allow for more rapid software detection of a degraded transducer.

[**0070**] Referring to **FIG. 3C**, another optional system for accomplishing this optional preferred aspect is provided wherein circuitry performs a simple comparison between second cycle peak **43** and fifth cycle peak **44**, and provides a suitable output when fifth cycle peak **44** reaches a set percentage of the second cycle peak **43**. Specifically, a comparator **103** can be used to compare the peak signals received from second cycle peak current detector **102** and the fifth cycle peak current detector **101**. Comparator **103** could operate independently of the software to shut down transducer operation, if transducer failure is detected. As such, the present system need not require computer functions dedicated to monitoring transducer function. Alternatively, such a system could be used as a backup that would still operate in the event of a computer failure.

[**0071**] Referring now to **FIG. 7**, a system **300** constructed in accordance with the principles of the present invention comprises a high-output therapeutic ultrasound catheter **302** connected to a therapeutic ultrasound controller **304** by a cable **306**. The high-output therapeutic ultrasound catheter **302** includes an ultrasound transducer assembly **308** at or near the distal end of catheter body **310**. A hub assembly **312** is located on the proximal end of the catheter body **310**. The catheter **302** is typically an intravascular catheter intended

for treatment of the coronary arteries or other portions of a patient's vasculature. Specific examples of high-output therapeutic intravascular catheters are provided in the patents and pending applications of the assignee of the present application, as listed and incorporated by reference hereinabove.

[0072] The catheter **302** is provided with data representing a measured operational range of the transducer of assembly **308**. The data will be stored or otherwise made available on the catheter **302**, i.e., either on or in the catheter body **310**, the transducer assembly **308**, in or on the hub **312**, or most usually in or on the catheter electrical connector **330** that plugs into the controller **304**. Referring to **FIG. 10**, the most common way for incorporating the ultrasound data with the system **300** is by providing an electronic memory module **320**, shown mounted within the electrical connector **330**. The memory module **320** can take a variety of conventional forms, typically being a flash memory or EEPROM which will retain the data even in a non-powered configuration. The electronic memory module may be connected to the controller through or by conventional wiring or other data transmission elements within the cable **306**. In addition to conventional wiring, it would be possible to provide optical connections between the memory module **320** and the controller **304**. The data in the memory module **320** represents the measured operational range of the ultrasonic transducer, either in the form of an average or peak operational value, the calculated operational range, or any other data upon which the expected operational range may be determined or read by the controller **304**. The memory module could alternatively be located in the hub **312**, as shown in **FIG. 8**.

[0073] As an alternative to the electronic memory module **320**, the hub **312** or electrical connector **330** may be provided with printed, embossed, or otherwise physically marked indicia, typically in the form of a barcode **330**, as shown in **FIG. 9**. The barcode **330** may incorporate the same information as stored in the memory module **320**, but will typically be read by an external scanner **340** which may optically be connected to the controller **304**. In additional to such machine readable data, the hub, catheter body, or electrical connector body may also incorporate human readable data, typically simple number or alphanumeric patterns, which may then be transferred by the end user of the controller using a keyboard or other interface. A variety of other approaches for incorporating the operational data of the transducer into or onto the catheter will also be available, although it is generally believed that the electronic memory provides the most efficient approach since the controller may automatically read the data from the electronic memory at the beginning of any treatment protocol.

[0074] The above-described examples of method and associated apparatus can advantageously be extended to function with a variety of single- and multiple-transducer and catheter configurations to allow rapid and reliable detection of transducer failure during operation. Detection of such failure provides a necessary level of patient safety by terminating ultrasound transmission in the event of transducer failure before excessive heating can occur.

What is claimed is:

1. A method for detecting failure of an ultrasound transducer in a remotely positioned therapeutic device, said method comprising:

determining a first operational range for the transducer based on data stored in or on the device; and

observing operation of the transducer over a first time period, wherein a failure is detected if the transducer operates outside the determined first operational range.

2. A method as in claim 1, further comprising:

determining a second operational range for the transducer based on the observed operation during the first time period, wherein the second operational range is narrower than the first;

observing operation of the transducer during a second time period extending after the first time period, wherein a failure is detected if the transducer operates outside of the determined second operational range.

3. A method as in claim 1 or **2**, wherein determining the first operational range comprises calculating a range based on a value provided by the data stored on or in the device.

4. A method as in claim 3, wherein the value is a test current and the calculated range is above the test current value.

5. A method as in claim 4, wherein the first operational range is a current from 110% to 130% of the test current value.

6. A method as in claim 1 or **2**, wherein the first time period is from five seconds to thirty seconds measured from the time the transducer is initially energized.

7. A method as in claim 6, wherein the failure of the transducer during the first operational period is detected when the transducer operates outside the determined first operational range for a minimum time period.

8. A method as in claim 7, wherein the minimum time period is fifteen seconds.

9. A method as in claim 1 or **2**, wherein observing operation of the transducer comprises measuring the peak current value of a plurality of sequential excitation bursts and calculating the peak current value after at least four current waveform cycles of each excitation burst.

10. The method of claim 9, wherein the peak current is calculated after at least five current waveform cycles of each excitation burst.

11. A method as in claim 2, wherein determining the second operational range comprises calculating an average power consumption value of the transducer during the first operational range, wherein the second operational range is from 95% to 105% of the calculated average power consumption during the first period.

12. A method as in claim 2, wherein the failure is detected only if the transducer operates outside of the determined second operational range for a minimum time period.

13. A method as in claim 12, wherein the minimum time period is 15 seconds.

14. A method for detecting failure of an ultrasound transducer in a remotely positioned therapeutic device, said method comprising:

measuring peak current resulting from individual cycles of the excitation voltage to the transducer during operation; and

calculating the difference between peak current of an early cycle with peak current of a later cycle, wherein a calculated difference below an expected minimum value indicates transducer failure.

15. A method as in claim 14, wherein the difference between the second cycle peak current and the fifth or subsequent cycle peak current is calculated.

16. A method as in claim 15, wherein the expected difference is at least 25% of the second cycle peak current.

17. A therapeutic ultrasound controller for use in combination with a catheter having a high-output therapeutic ultrasound transducer, said controller comprising:

means for measuring peak current delivered to the transducer;

means for determining a first expected peak current operational range for the transducer; and

means for comprising the measured peak current value with the first determined peak current range, wherein a measured peak current value which falls outside of the first determined peak current range indicates a transducer failure.

18. A therapeutic ultrasound controller as in claim 17, wherein the determining means receives a value from an electronic memory in the catheter.

19. A therapeutic ultrasound controller as in claim 17 or **18**, further comprising:

means for determining a second expected peak current operational range based on the peak current measured during a first operational period; and

means for comprising the measured peak current value with the second determined peak current range, wherein a measured peak current value which falls outside of the second peak current grange indicates a transducer failure.

20. A therapeutic ultrasound controller for use in combination with a catheter having a high-output therapeutic ultrasound transducer, said controller comprising:

means for measuring peak current to the transducer; and

means for comparing the measured peak current of an early cycle with the measured peak current of a later cycle.

21. A therapeutic ultrasound controller as in claim 20, wherein the comparing means compares the peak current of a second cycle in a burst with the peak current of a fifth or later cycle in the same burst, wherein a difference of less than 25% of the second cycle peak current indicates a failure of the transducer.

22. An intravascular catheter comprising:

a catheter body;

a high-output therapeutic ultrasound transducer operatively disposed on the catheter body; and

data on the catheter body representing a measured operational range of the transducer.

23. An intravascular catheter as in claim 22, wherein the high-output therapeutic ultrasound transducer has a power output of at least 100 watts.

24. An intravascular catheter as in claim 22, further comprising an electronic memory device, wherein the data are stored in the device.

25. An intravascular catheter as in claim 24, wherein the electronic memory device is selected from the group consisting of flash memory, RFID's, and EEPROM's.

26. An intravascular catheter as in claim 25, wherein the data comprises indicia printed on the catheter body.

27. An intravascular catheter as in claim 22, wherein the printed data comprises machine readable code.

28. An intravascular catheter as in claim 22, wherein the printed data comprises human readable information.

29. A method for fabricating an intravascular catheter, said method comprising:

providing an intravascular catheter having a catheter body and a high-output therapeutic ultrasound transducer operatively disposed on the catheter body;

measuring a power consumption characteristic of the transducer during operation; and

embedding the data in or on the catheter body in a readable form.

30. A method as in claim 29, wherein measuring comprises measuring current consumption.

31. A method as in claim 30, wherein current is measured with the transducer immersed in water and under nominal excitation parameters.

32. A method as in claim 29, wherein embedding comprises storing the data in an electronic memory disposed in or on the catheter body.

33. A method as in claim 29, wherein embedding comprises printing indicia setting forth the measured value on the current catheter body.

34. A method as in claim 33, wherein the indicia are machine readable.

35. A method as in claim 33, wherein the indicia are human readable.

* * * * *

专利名称(译)	用于检测导管系统中的超声换能器故障的方法和设备		
公开(公告)号	US20040230116A1	公开(公告)日	2004-11-18
申请号	US10/436966	申请日	2003-05-12
[标]申请(专利权)人(译)	PHARMASONICS		
申请(专利权)人(译)	PHARMASONICS INC.		
当前申请(专利权)人(译)	PHARMASONICS		
[标]发明人	COWAN MARK W CORL PAUL D REYNOLDS BYRON J		
发明人	COWAN, MARK W. CORL, PAUL D. REYNOLDS, BYRON J.		
IPC分类号	A61B17/22 A61B8/00		
CPC分类号	A61B17/2202		
外部链接	Espacenet USPTO		

摘要(译)

用于检测超声导管系统中的超声换能器故障的方法和系统包括提供存储装置或其他数据存储元件或导管主体，其具有至少一个设置的超声换能器。存储器装置存储测试电流幅度值，该测量电流幅度值与至少一个超声换能器的实际操作峰值电流有关。计算在第一时间段期间的平均实际操作峰值电流幅度，并且可选地还可以计算在第二时间段内针对至少一个超声换能器的实际操作峰值电流。如果实际操作峰值电流幅度在第一时间段内超过适合的优选范围，或者实际操作峰值电流幅度在第二时间段内超过第二优选范围，则发生换能器故障。