US 20020151777A1

(19) United States

(12) Patent Application Publication (10) Pub. No.: US 2002/0151777 A1

Hynynen et al. (43) Pub. Date: Oct. 17, 2002

(54) TRANSMYOCARDIAL REVASCULARIZATION USING ULTRASOUND

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(*) Notice: This is a publication of a continued prosecution application (CPA) filed under 37 CFR 1.53(d).

(21) Appl. No.: **09/523,989**

(22) Filed: **Jan. 31, 2000**

Related U.S. Application Data

(63) Continuation of application No. 09/048,864, filed on Mar. 26, 1998, now abandoned.

(60) Provisional application No. 60/074,969, filed on Feb. 17, 1998.

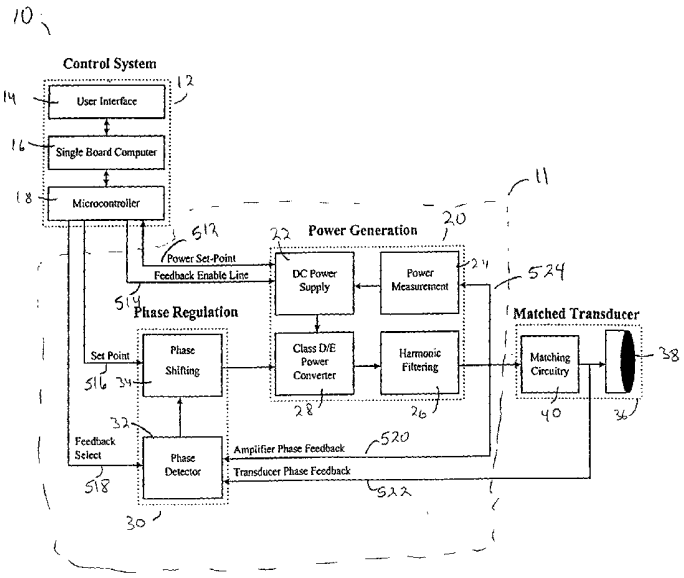
Publication Classification

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

(52) **U.S. Cl.** **600/407**; 600/439

(57) **ABSTRACT**

A method and apparatus for performing transmyocardial revascularization using ultrasound is disclosed. The apparatus includes a phased array ultrasonic device that includes a plurality of ultrasonic transducer elements which are controlled using a feedback control system so that each ultrasonic transducer element produces an ultrasonic wave of particular power and phase in order to achieve constructive interference at a desired acoustic focus. The constructive interference creates high pressure amplitudes for vaporizing the target tissue at the focus. A method is provided for vaporizing target tissue for which a plurality of ultrasonic transducers are focused so as to provide constructive interference within the target tissue. The ultrasonic beams are launched and produce a rapid rise in tissue temperature that will vaporize the target tissue within the focal zone.



Block diagram of the phased array ultrasound driving system.

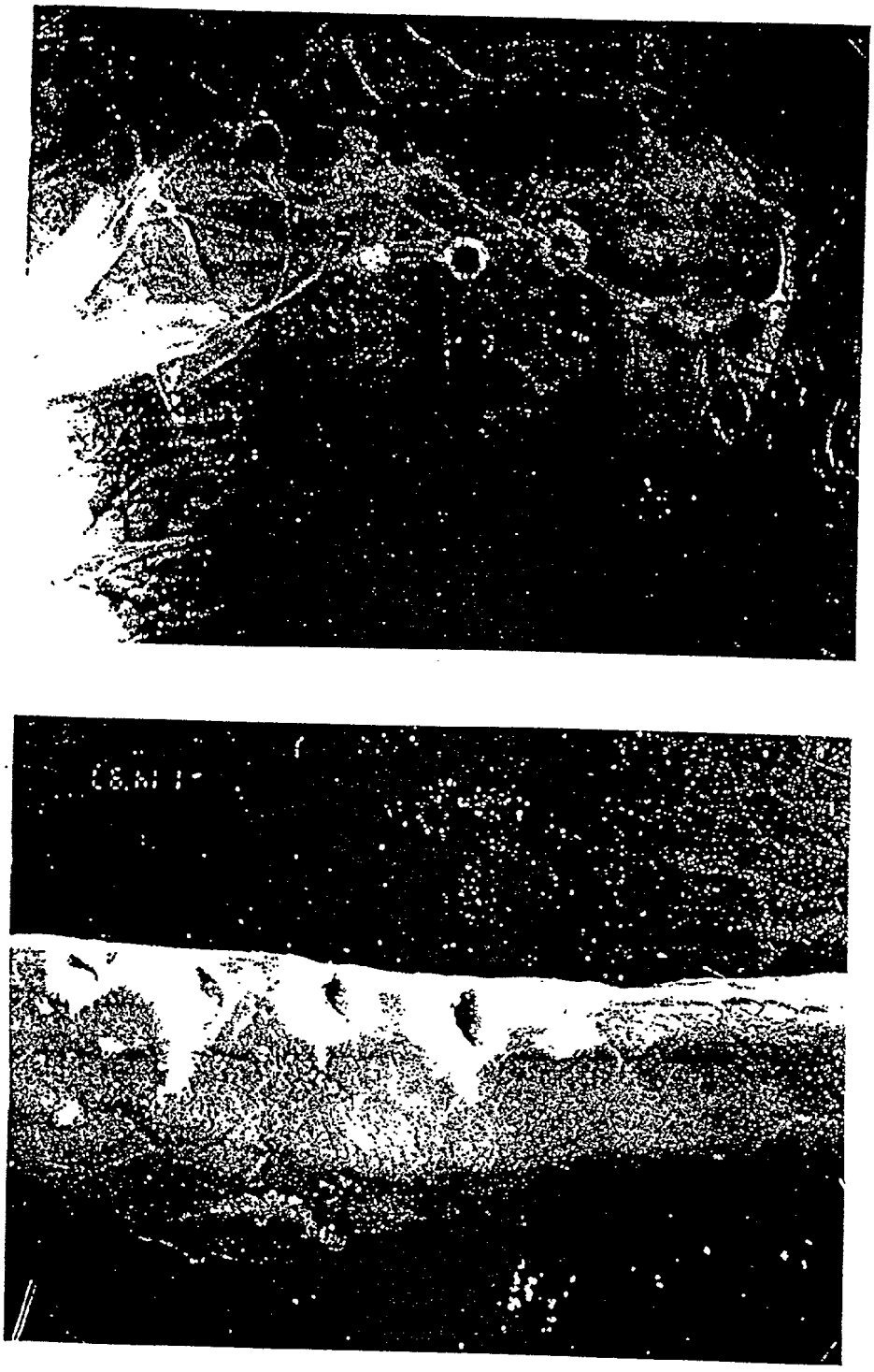
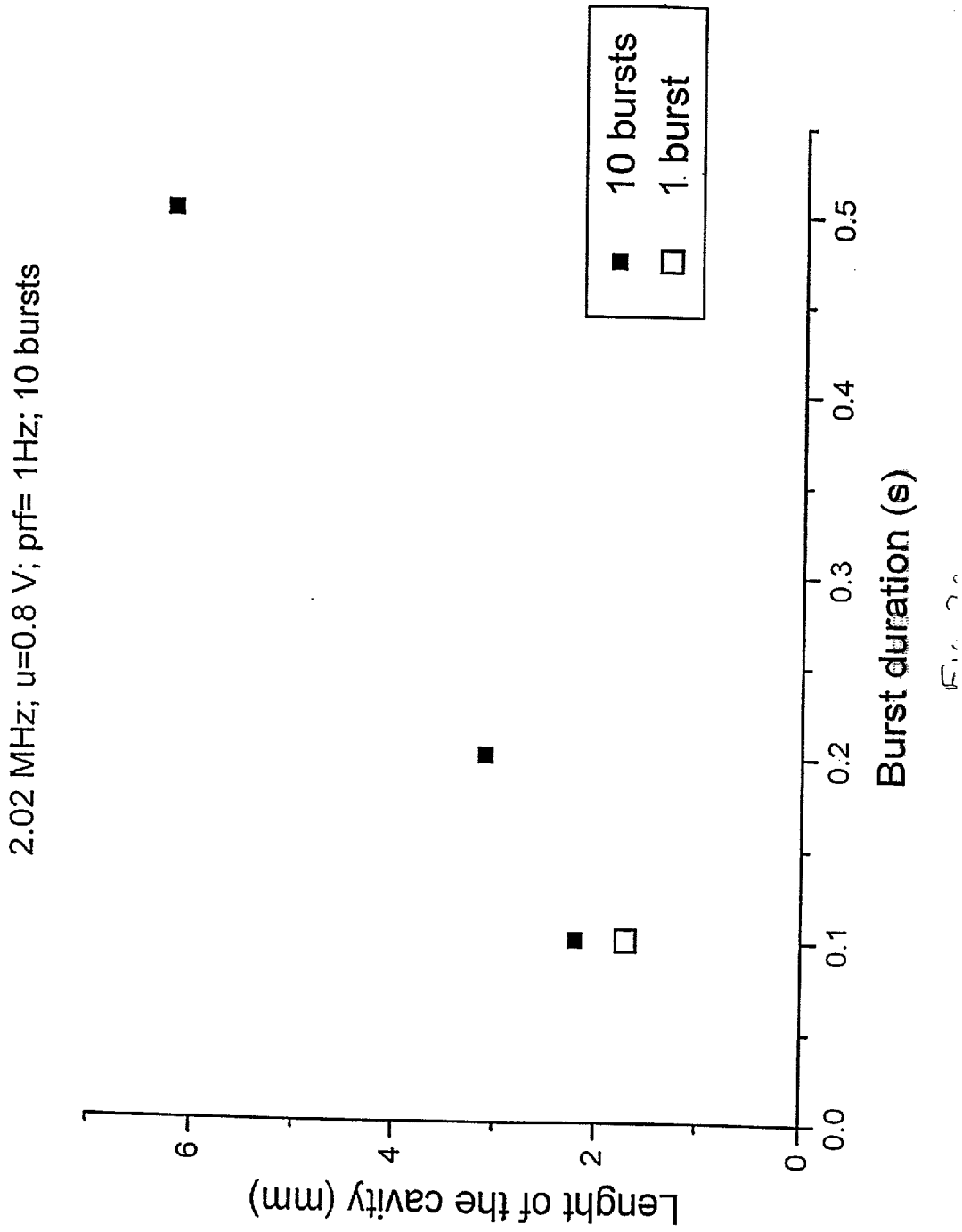


Fig 1


2.02 MHz; u=0.8 V; prf= 1Hz; 10 bursts
10 bursts
1 burst
Length of the cavity (mm)
Burst duration (s)
0
2
4
6
0.0
0.1
0.2
0.3
0.4
0.5

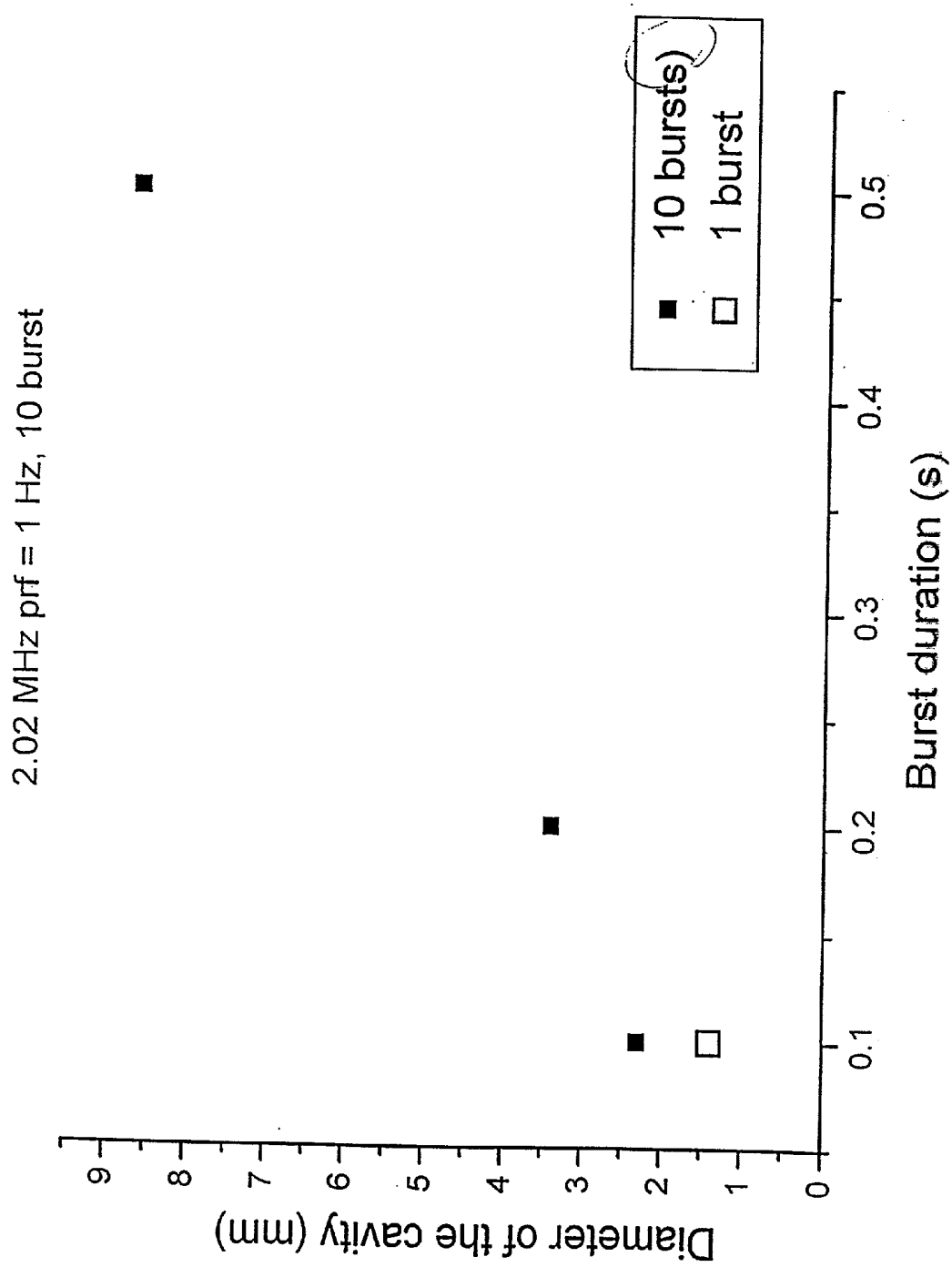
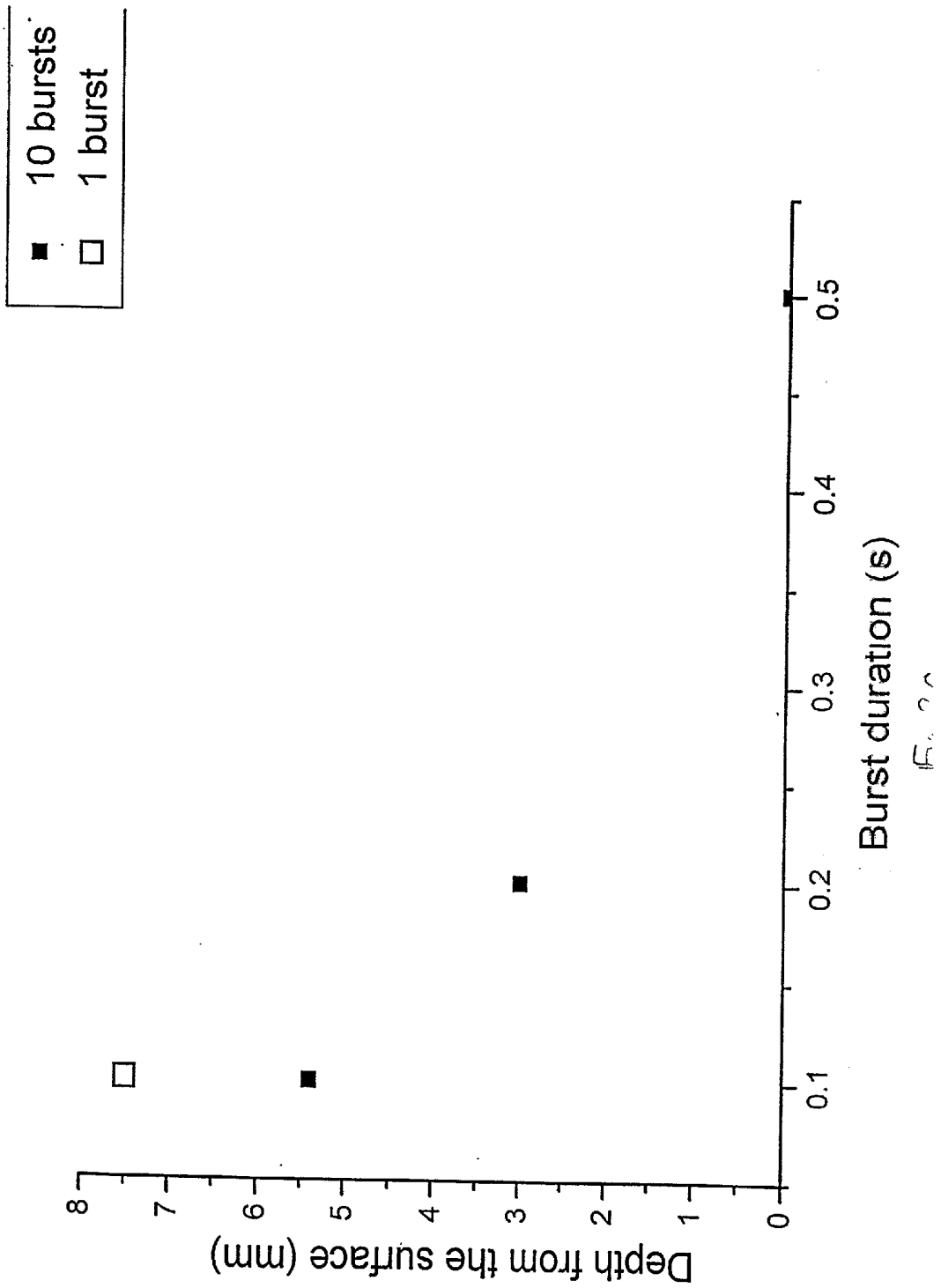

2.02 MHz prf = 1 Hz, 10 burst
10 bursts
1 burst
Diameter of the cavity (mm)
Burst duration (s)
0
1
2
3
4
5
6
7
8
9
0.1
0.2
0.3
0.4
0.5

Fig. 2b


10 bursts
1 burst
Depth from the surface (mm)
0
1
2
3
4
5
6
7
8
0.1
0.2
0.3
0.4
0.5
Burst duration (s)

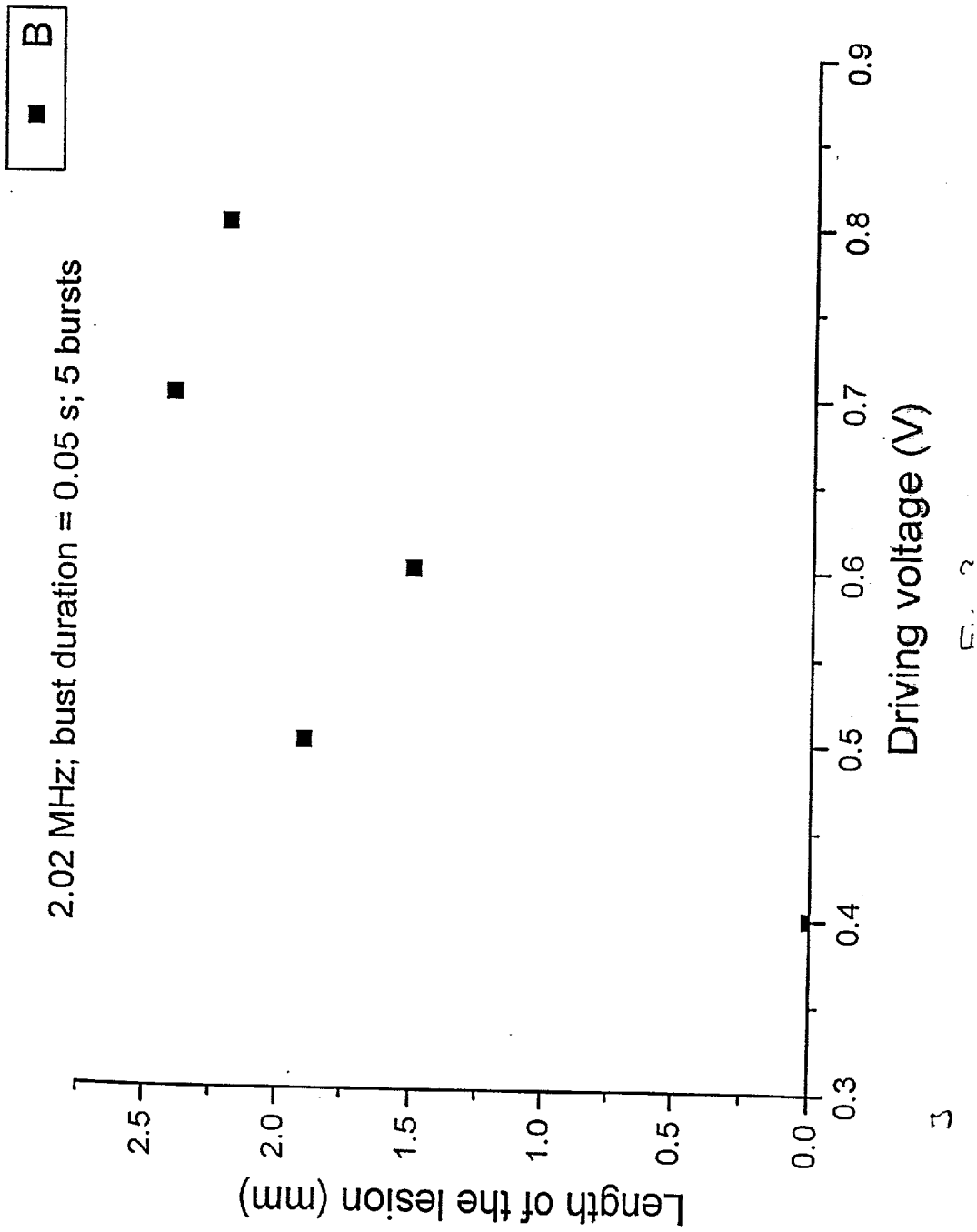
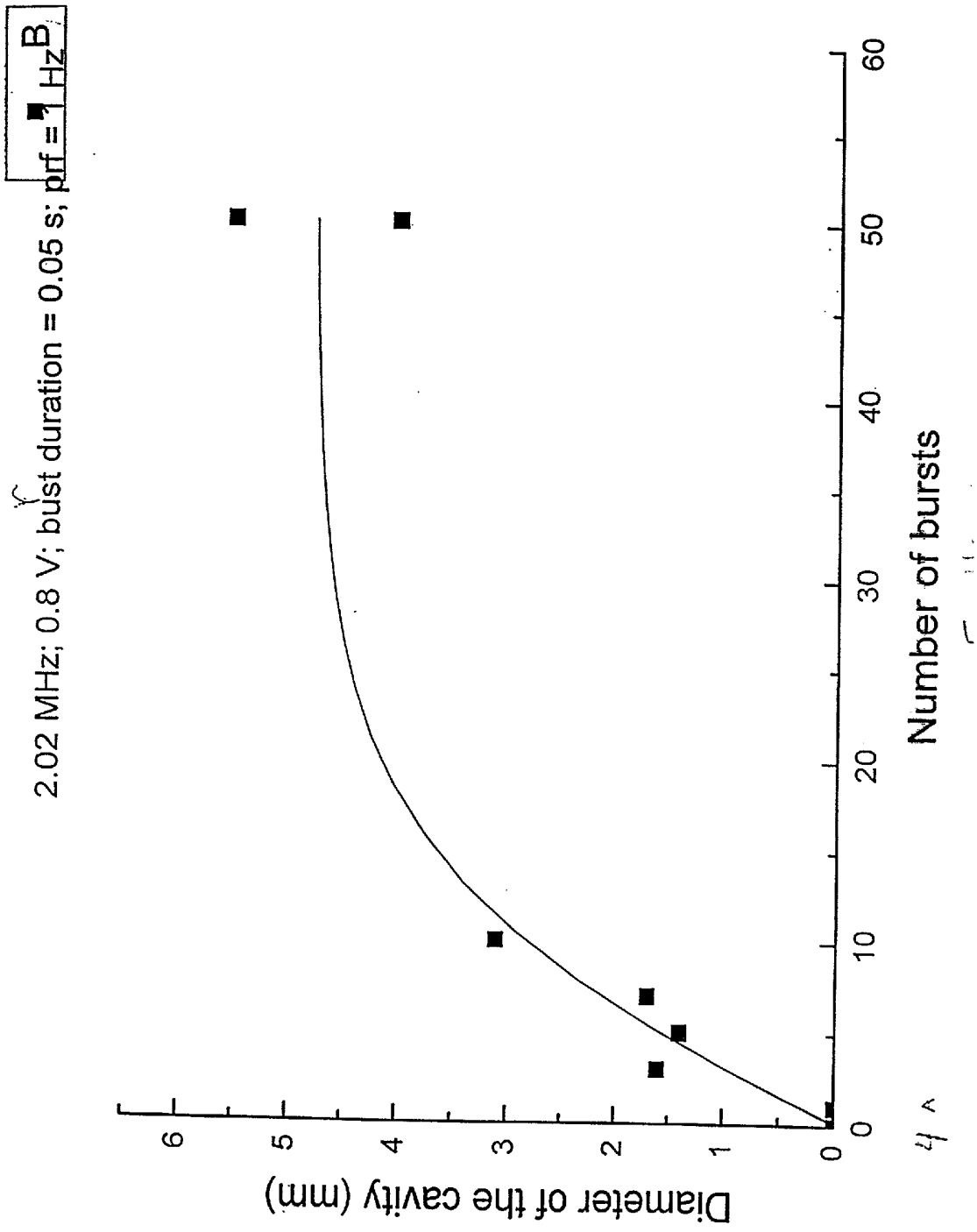

B
2.02 MHz; bust duration = 0.05 s; 5 bursts
Length of the lesion (mm)
0.0
0.5
1.0
1.5
2.0
2.5
0.3
0.4
0.5
0.6
0.7
0.8
0.9
Driving voltage (V)

FIG. 3


2.02 MHz; 0.8 V; bust duration = 0.05 s; prf = 1 Hz
B
Diameter of the cavity (mm)
0
1
2
3
4
5
6
0
10
20
30
40
50
60
Number of bursts

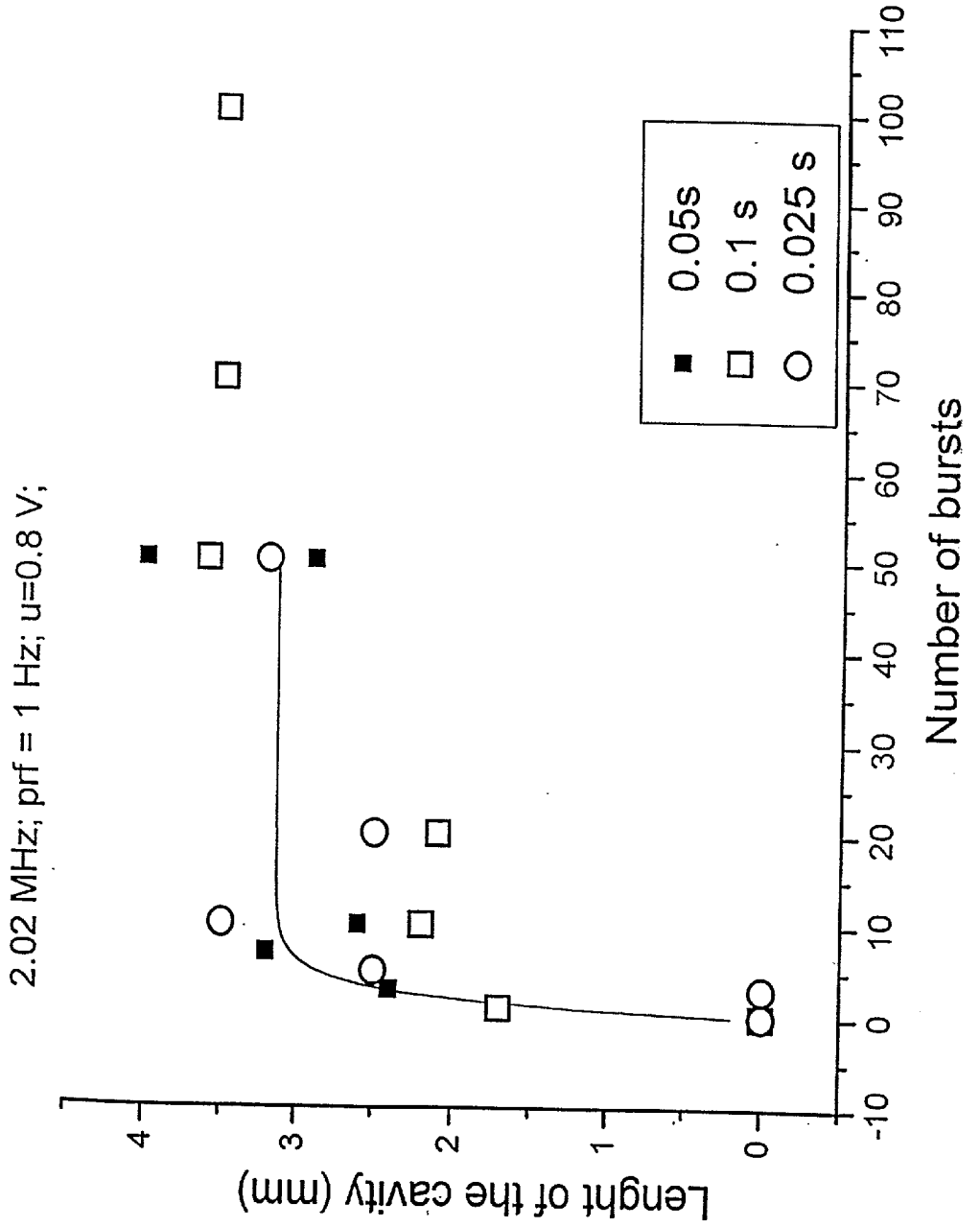

2.02 MHz; prf = 1 Hz; u=0.8 V;
0.05s
0.1 s
0.025 s
Number of bursts
Length of the cavity (mm)
-10
0
10
20
30
40
50
60
70
80
90
100
110
0
1
2
3
4

Fig 4b

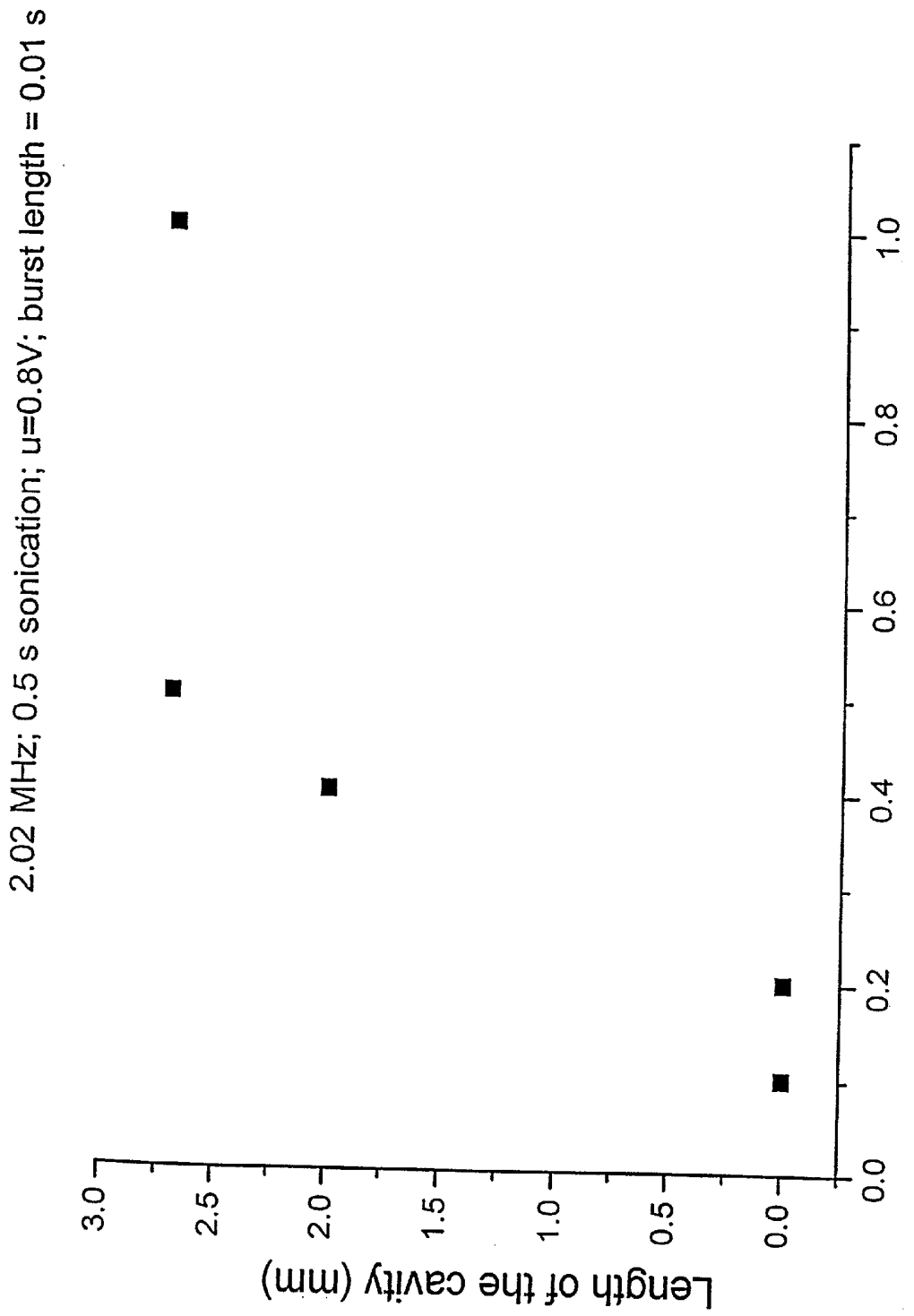

2.02 MHz; 0.5 s sonication; u=0.8V; burst length = 0.01 s
Length of the cavity (mm)
3.0
2.5
2.0
1.5
1.0
0.5
0.0
0.0
0.2
0.4
0.6
0.8
1.0
Duty cycle

Fig 5a

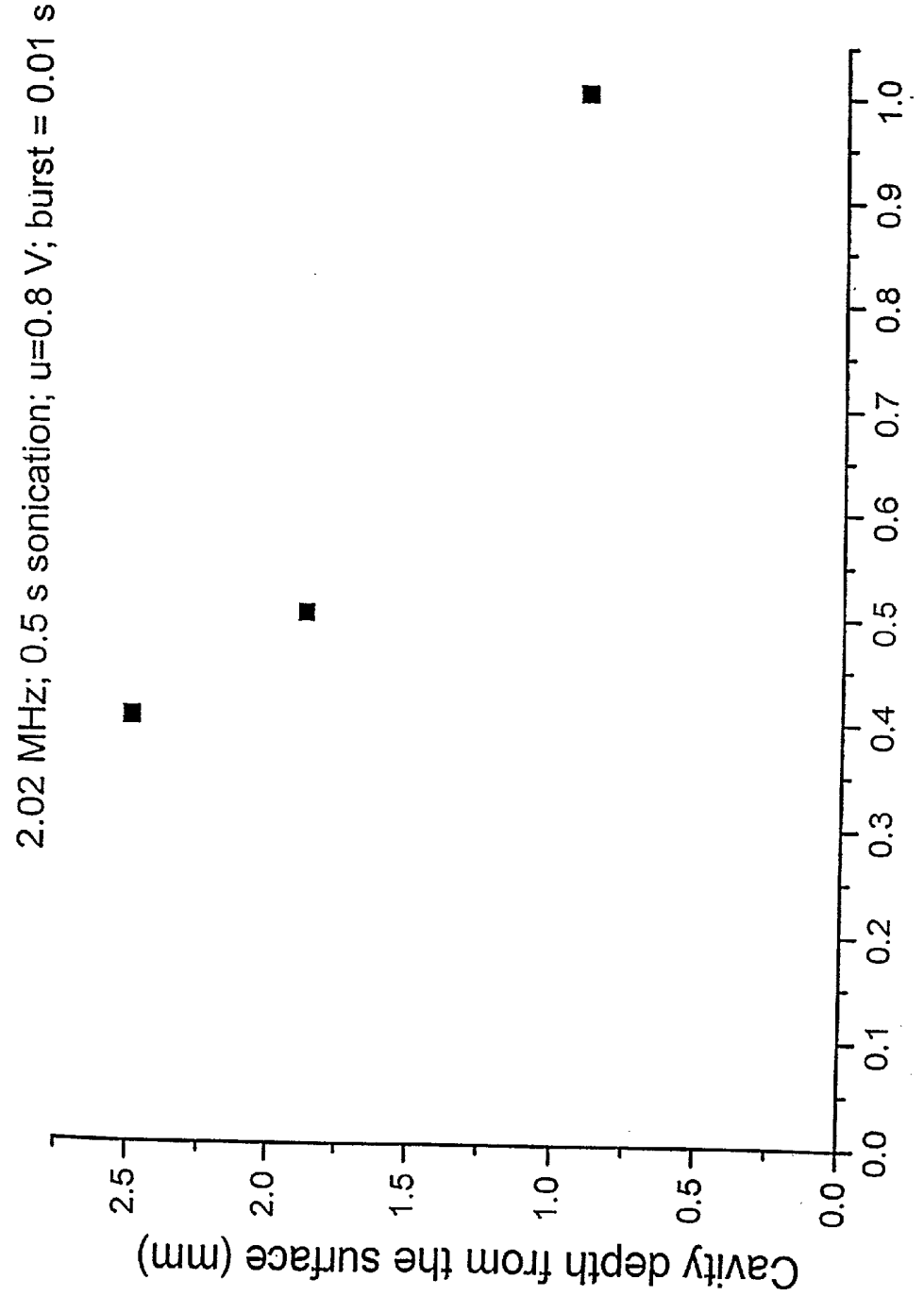

2.02 MHz; 0.5 s sonication; u=0.8 V; burst = 0.01 s
Cavity depth from the surface (mm)
0.0
0.5
1.0
1.5
2.0
2.5
0.0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1.0
Duty cycle

Fig 5b

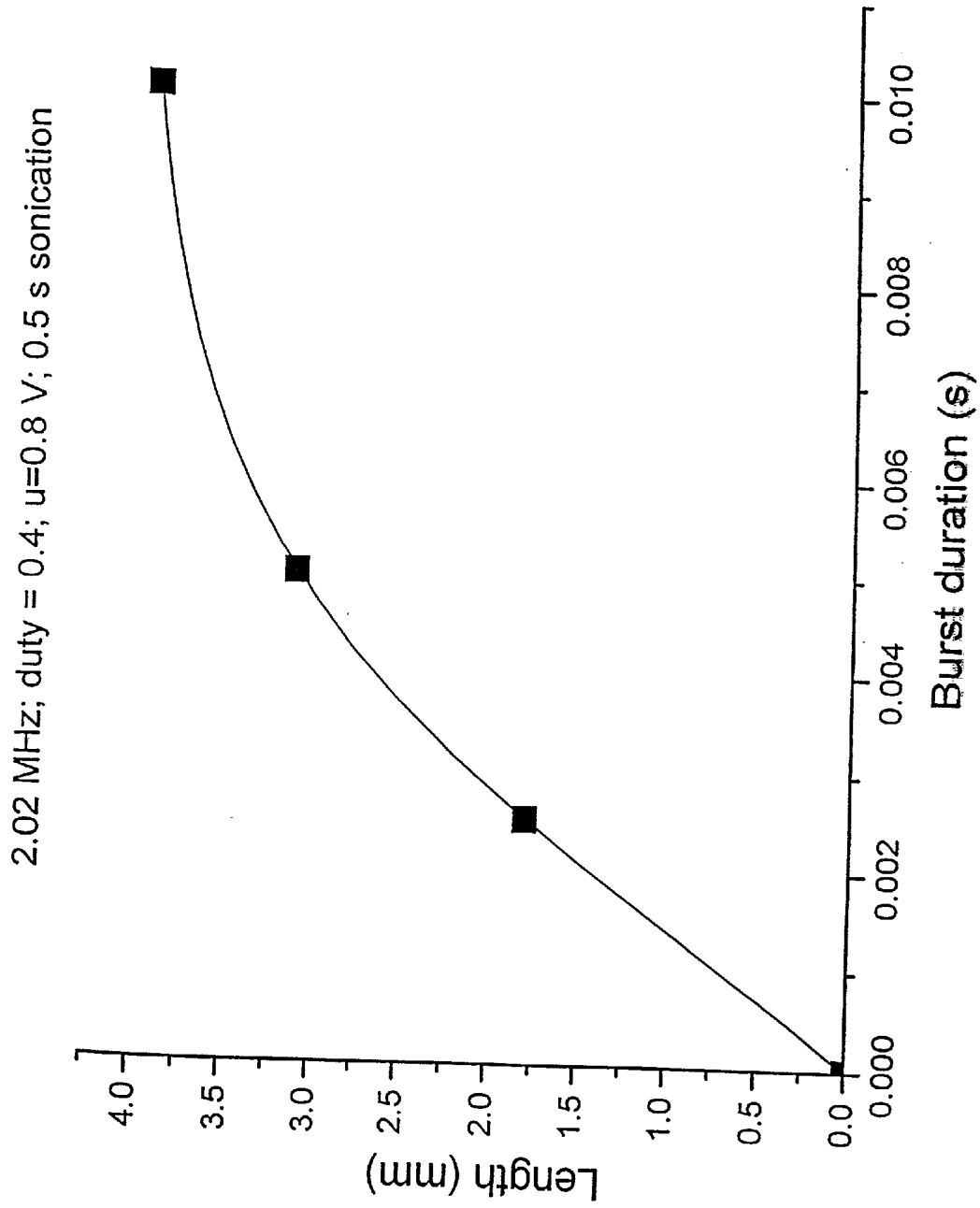

2.02 MHz; duty = 0.4; u=0.8 V; 0.5 s sonication
Length (mm)
4.0
3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
0.000
0.002
0.004
0.006
0.008
0.010
Burst duration (s)

Fig 6a

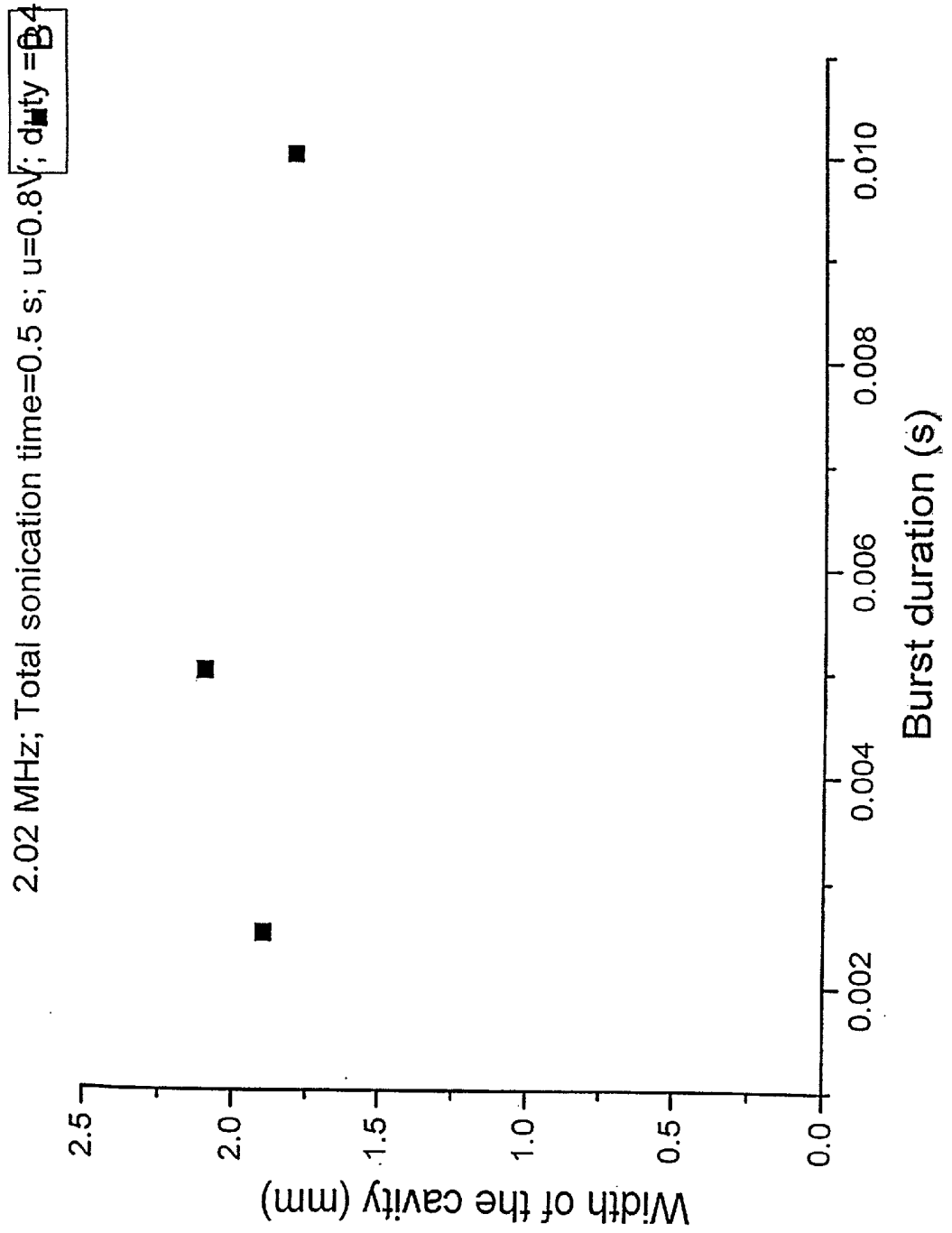

2.02 MHz; Total sonication time=0.5 s; u=0.8V; duty =B4
Width of the cavity (mm)
Burst duration (s)
0.0
0.5
1.0
1.5
2.0
2.5
0.002
0.004
0.006
0.008
0.010

Fig 6b

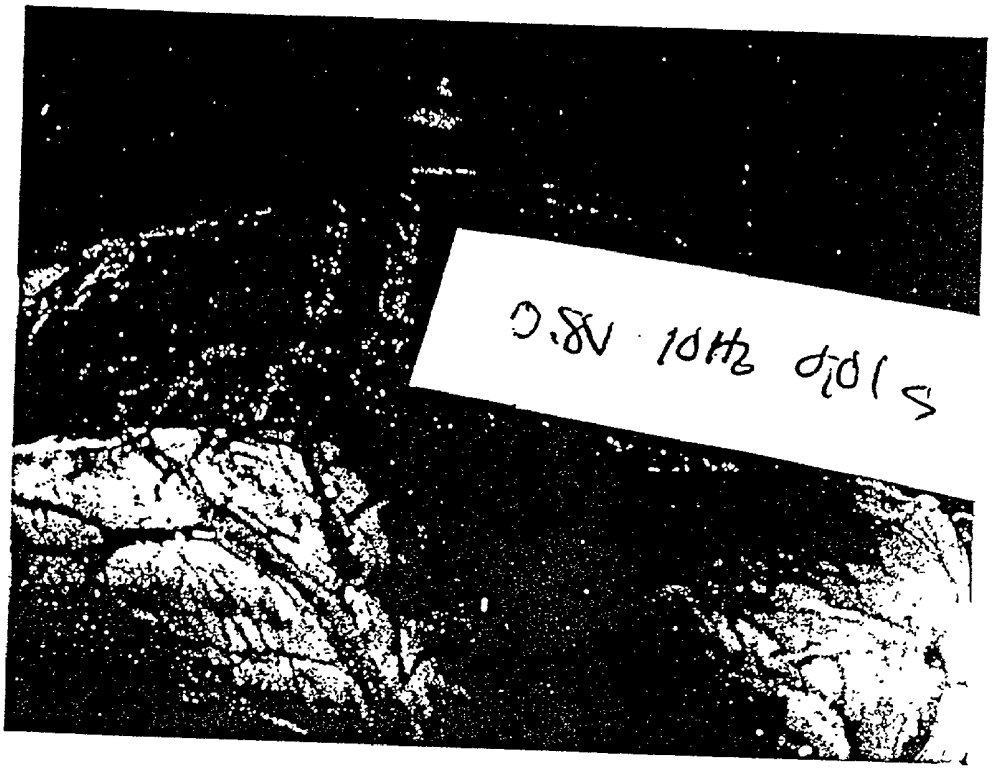
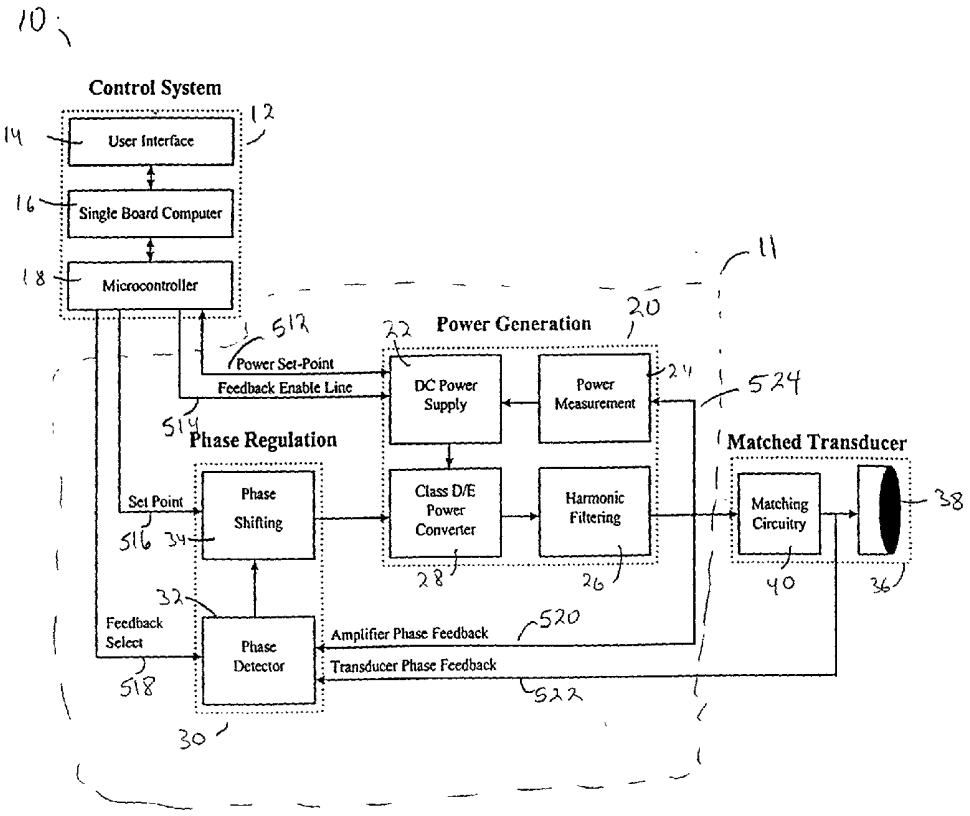
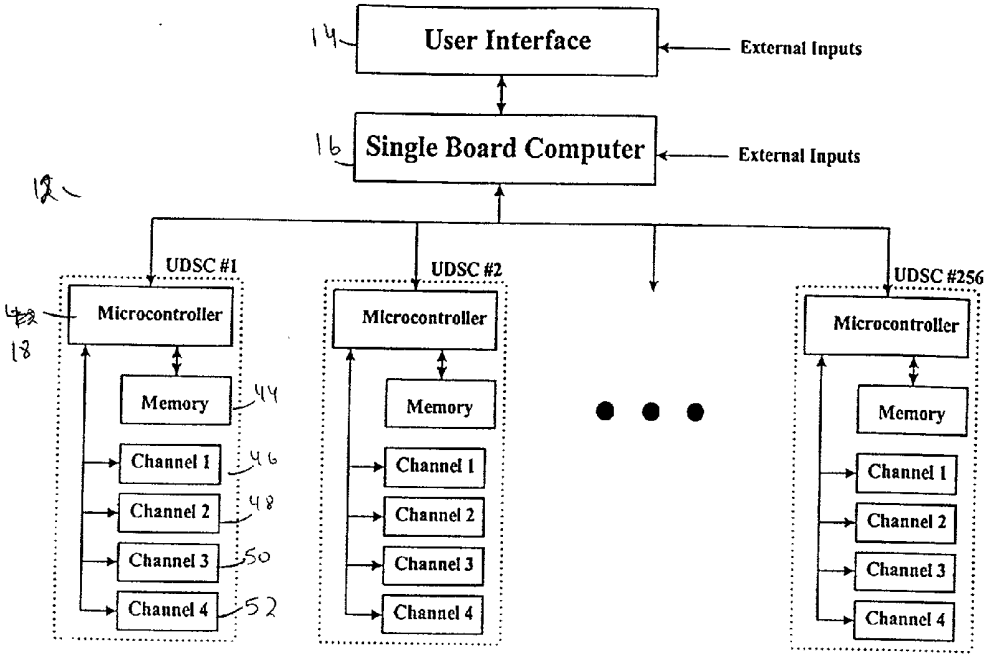


Fig 7



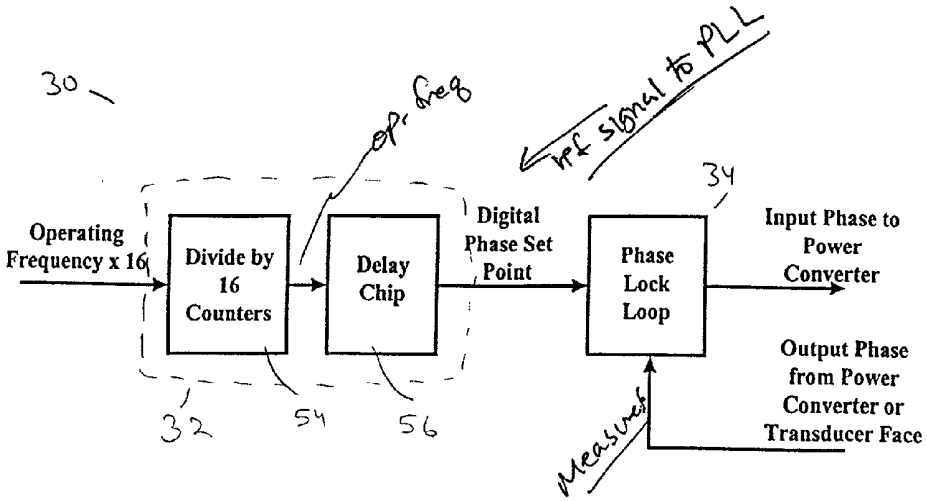
Block diagram of the phased array ultrasound driving system.

Fig 8



Distributed control architecture of the phased array driving system.

Fig 9



Phase regulation system.

Fig 10

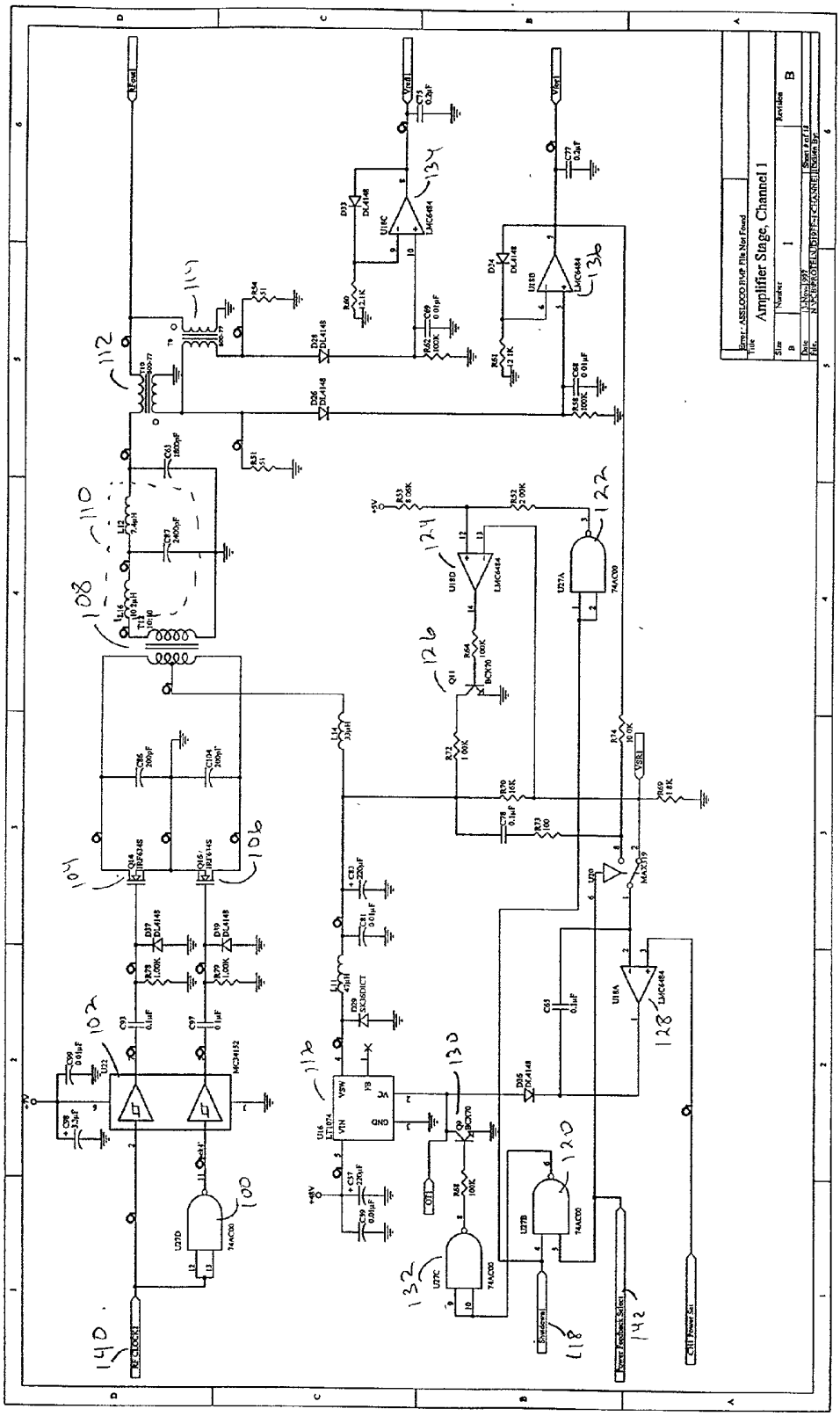

Amplifier Stage, Channel 1
100
102
104
106
108
110
112
114
116
118
120
122
124
126
128
130
132
134
136
140
142

FIG 11

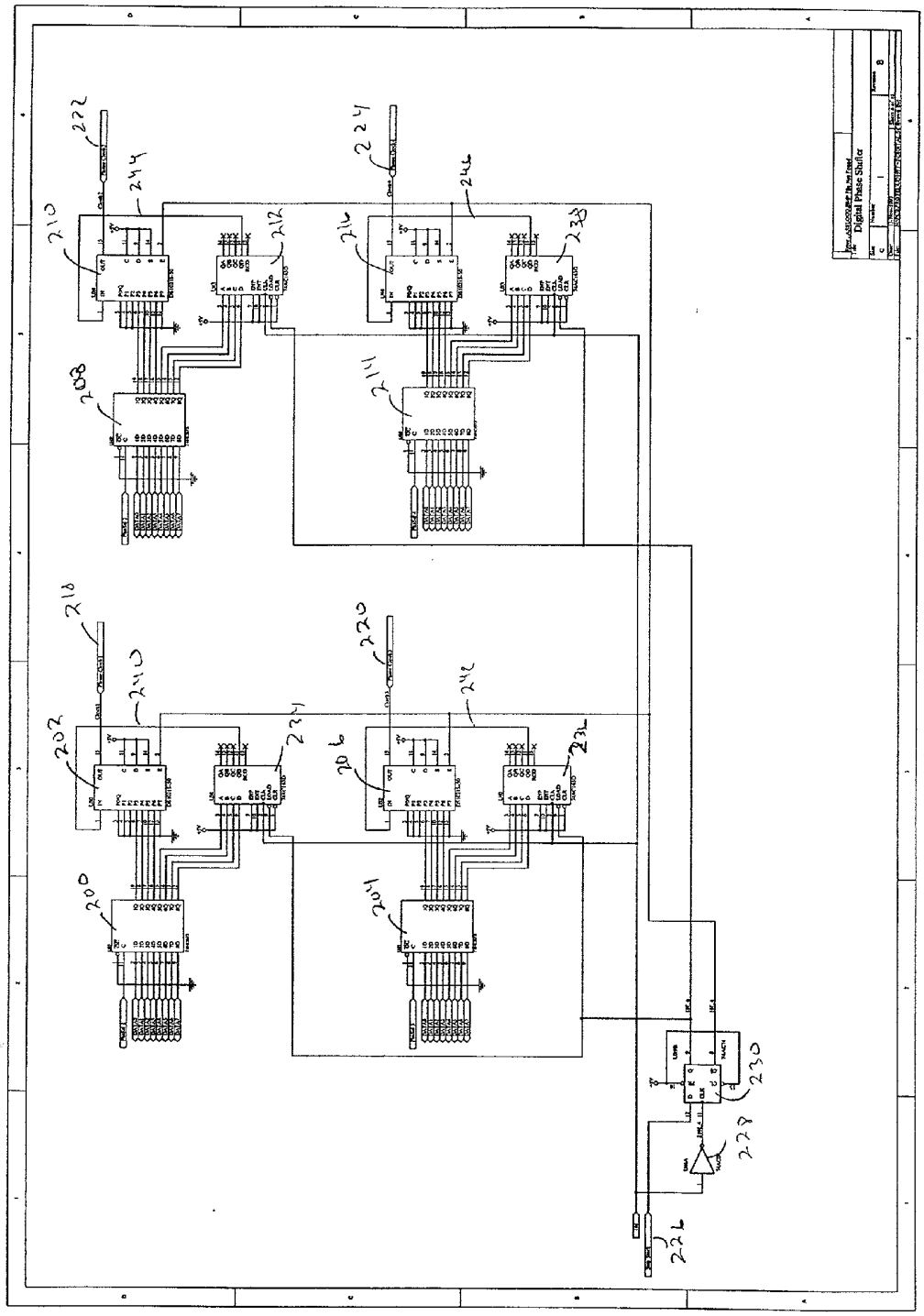


Fig 12

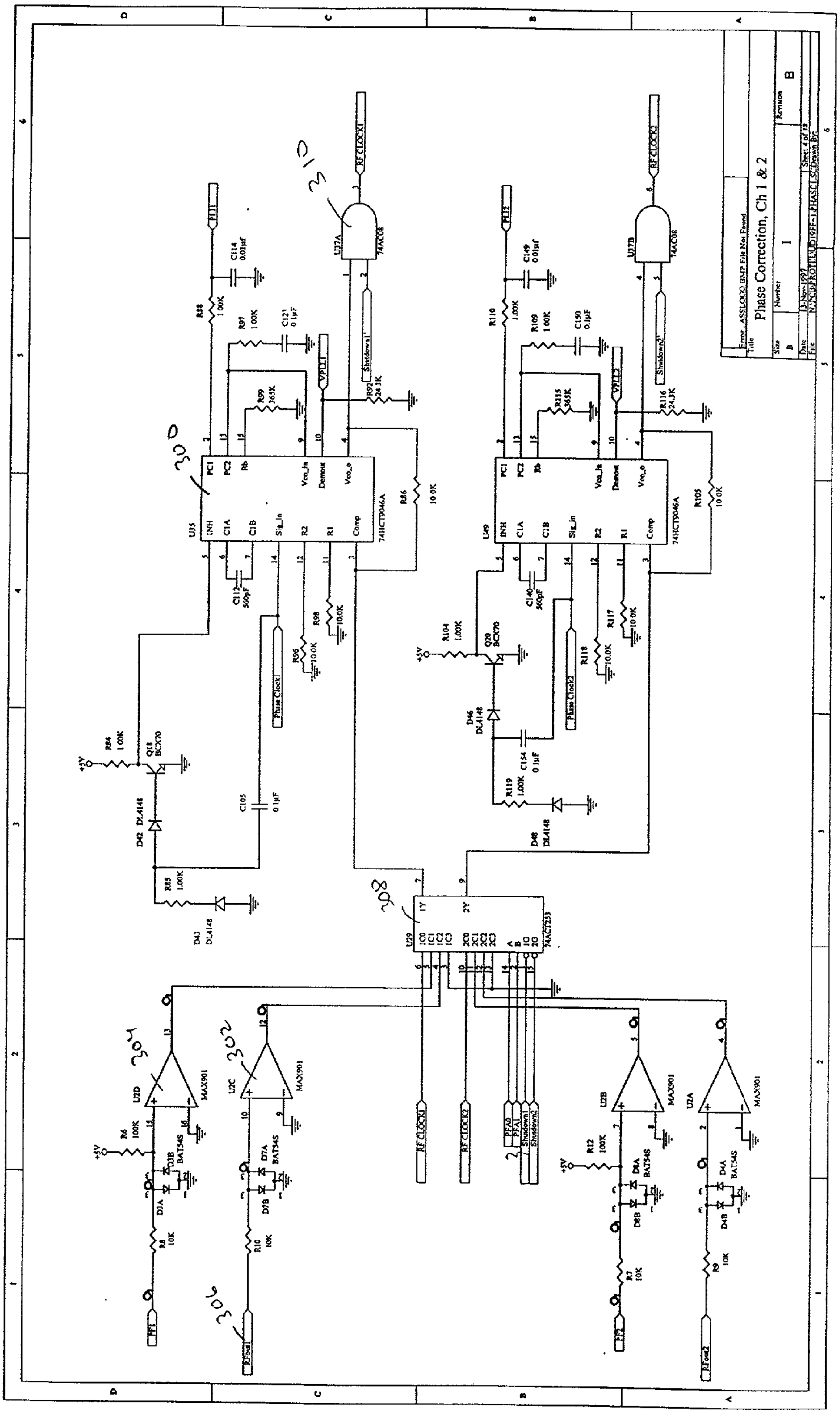
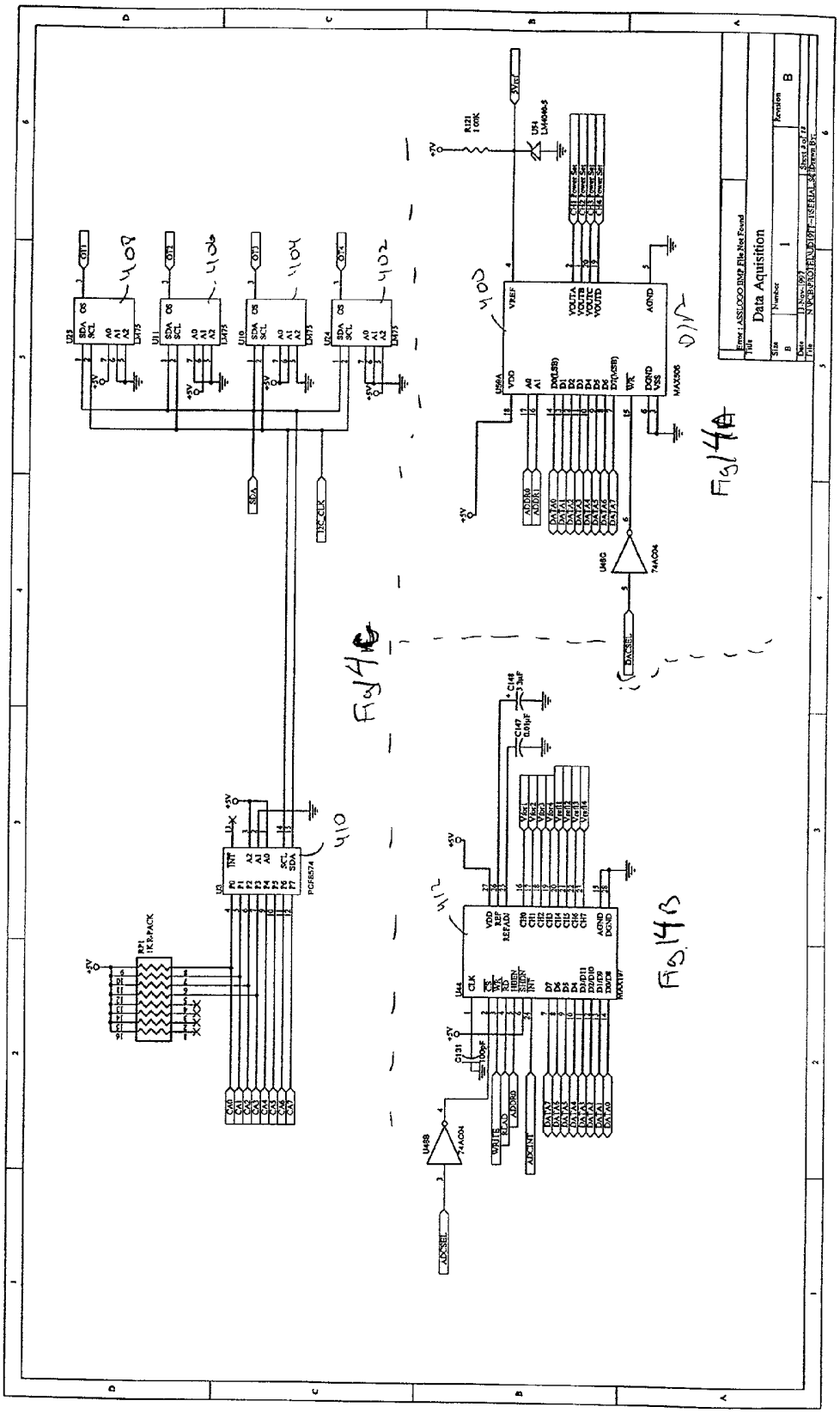

Phase Correction, Ch 1 & 2
74HCT9046A
74HCT9046A
74ACT253
MAX901
RF CLOCK1
RF CLOCK2
Phase Clock1
Phase Clock2
300
302
304
306
308
310

Fig 13


Data Aquisition
Fig 14A
Fig 14B
Fig 14C

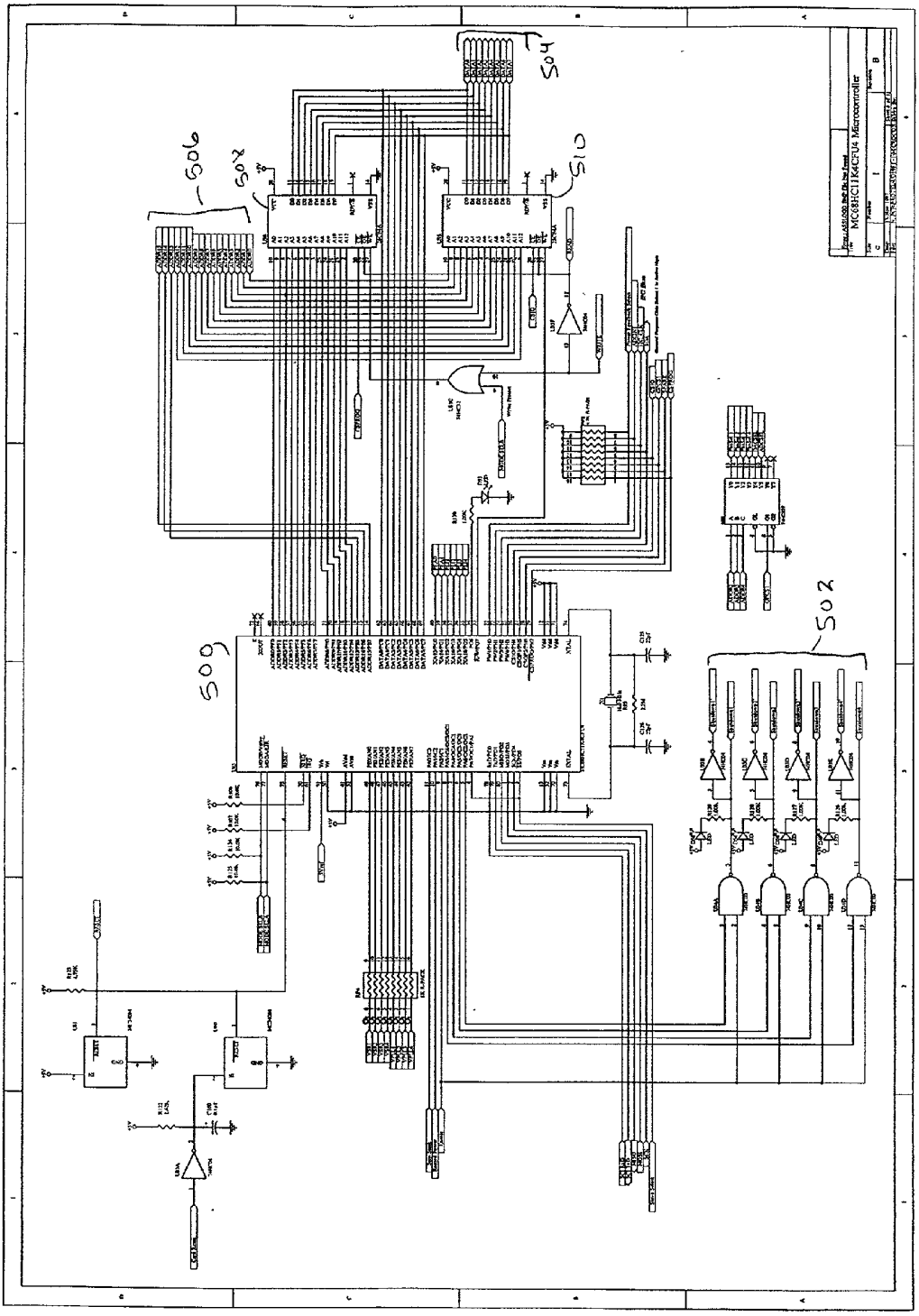


Fig 15

TRANSMYOCARDIAL REVASCULARIZATION USING ULTRASOUND

BACKGROUND OF THE INVENTION

[0001] This invention relates generally to ultrasonic systems used for the vaporization of tissue, and more particularly to a phased array ultrasonic system used for creating channels within organs by ablating tissue.

[0002] Cardiac ischemia is a condition in which oxygenated blood is reduced or cutoff to a section of the heart, usually as the result of cholesterol-laden plaque narrowing the coronary arteries and preventing blood flow. Untreated ischemia may lead to ischemic heart disease often with disabling angina. Angina is severe chest pain caused by insufficient oxygenated blood reaching the heart often during times of exercise or emotional stress. Untreated ischemic heart disease with its associated angina may lead to heart attacks and death or in somewhat less severe cases to a great reduction in the quality of life for the patient.

[0003] There are currently three treatments for the treatment of cardiac ischemic disease and angina. The first therapy is pharmacological. Drugs for reducing cholesterol and for managing the pain of the patient are administrated in conjunction with exercise in order to increase the amount of oxygenated blood reaching the cardiac tissue. The second treatment is balloon angioplasty. In this treatment a catheter is worked into the coronary arteries carrying with it a balloon, when the catheter reaches the portions of the coronary arteries that are clogged with plaque, the balloon is expanded compressing the plaque and opening the coronary artery wider in order to allow greater blood flow. The third current treatment is a coronary graft by-pass operation. The coronary by-pass operation is one where new arteries are grafted around the clogged coronary arteries creating new, unobstructed, blood passageways.

[0004] Recently a new treatment for cardiac ischemic disease has been developed called transmyocardial revascularization (TMR). In TMR tiny channels, approximately 1 mm in diameter, are drilled through the heart muscle to allow oxygenated blood from the left ventricle to flow through these channels into the damaged muscle tissue to bring oxygenated blood to those areas. Currently, TMR utilizes high powered lasers to drill these holes in the cardiac muscle. TMR is an invasive procedure since currently TMR techniques still require the chest to be opened sufficiently to visualize the heart. The laser is then used to drill holes from outside of the heart muscle through the entire heart muscle into the left ventricle. Although current studies show that the outer portion of the drilled channel does heal, more tissue is still damaged than is needed to bring oxygenated blood to the damaged tissues. In addition, the lasers used for TMR are expensive to obtain and to operate. In another method of laser TMR, the laser is threaded into the left ventricle and the channels are drilled into the wall directly. While this method does not destroy more tissue than necessary, it is still invasive, in that the laser is threaded through the circulatory system into the interior of the heart, and in particular to the left ventricle chamber of the heart, in order to be proximate to the target areas.

[0005] While TMR is a new procedure, the use of lasers to vaporize tissue, and the problems associated therewith, are not new. The present invention is superior to using lasers to vaporize tissue, since a laser can destroy more tissue than is necessary, or can perforate tissue causing additional complications, whereas the present invention is more easily controlled.

[0006] Other methods that exist to destroy tissue have other problems as well. For example, direct current cardiac tissue ablation requires a catheter to be inserted into the interior of the heart and 2,000 to 4,000 volts of electricity are applied to the target tissue over several milliseconds. In addition to being invasive, the severe muscle contractions which result, require the patient to be under general anesthesia.

[0007] RF and microwave ablation of cardiac tissue is invasive since it requires a catheter inserted into the interior of the heart. In addition the energy is difficult to focus and the size of target tissue to be ablated is limited due to the lower energy available.

[0008] There are two methods currently used to deliver ultrasonic energy to target tissue. The first is to use a catheter with an ultrasonic transducer or transducer array on the tip. The catheter must be inserted into the interior of the heart and be in close proximity to the target tissue, due to the inability to narrowly focus the beam. Although phased array catheter probes have been discussed in the literature there are none commercially available. In addition, the size of the probe will limit the number of available phased array elements. The fewer the number of elements, the wider the main lobe of the antenna becomes. This will result heating a wider area of tissue and hence cause the collateral destruction of healthy tissue during treatment. In addition more energy will be in the sidelobes of the phased array which will reduce the efficiency and possibly damage collateral tissue as well.

[0009] The second method of delivering ultrasonic energy is the use of an external ultrasonic transducer, having a phased array antenna in conjunction with a hydrophone array. The hydrophone is invasively placed to provide detection of the ultrasonic energy to determine its focus point. The hydrophone measurement provides the necessary feedback to adjust the beam focus properly so as to limit collateral tissue damage. However, the hydrophone array must be placed proximate to the target tissue so as to be effective.

[0010] Vaporization of tissue using ultrasound has not been described in the prior art. Although it has been known generally in the art that small cavities are formed in tissue during ultrasonic exposures with high power. However, there have not been any attempts to control this cavity and use it for tissue removal. In addition, the exposure parameters that cause desired, controlled tissue vaporization have not been known. There is a need for an apparatus to produce the energy required at the appropriate frequency to create tissue vaporization.

[0011] Therefore what is needed is an ultrasonic apparatus capable of producing sufficient pressure at the acoustic focus to vaporize tissue, and an ultrasound phased array with a feedback control system capable of measuring and controlling the power and phase from each individual array element such that TMR channels are created noninvasively within the myocardium by vaporizing tissue at the acoustic focus of the phased array. This will enable tissue to be vaporized without opening the patient's body in order to actually see

the tissue to be vaporized having to invasively thread a catheter or hydrophone array into the patient's body.

SUMMARY OF THE INVENTION

[0012] According to the invention, phased array ultrasonic devices are provided for use in vaporizing tissue non-invasively during medical treatment. The device includes a plurality of ultrasonic transducer elements which transmit ultrasonic waves each having a particular power and phase. The control of an individual ultrasonic transducer element to produce ultrasonic energy having a particular power and phase is needed to achieve constructive interference at the desired acoustic focus, and is achieved by a focusing means that is responsive to a feedback signal. This constructive interference creates high pressure amplitudes for vaporizing the target tissue at the focus. The individual ultrasonic transducer elements are supplied energy by a channel driver element that is responsive to the focusing means.

[0013] To achieve this desired acoustic focus, in one embodiment, the driver element is responsive to a focusing element and feedback means to properly drive the ultrasonic transducer elements. The focusing element comprises a controller that determines an operating parameter of the ultrasonic transducer element. The controller is responsive to the feedback signal and in the preferred embodiment determines the phase and power to be transmitted by each individual ultrasonic transducer and provides a control signal to each channel driver element of the corresponding ultrasonic transducer element. The controller in being responsive to the feedback signal, also provides the necessary control signals to the driver element to adjust the power and phase of each individual ultrasonic transducer element relative to other array elements in order to create the desired acoustic focus.

[0014] Each ultrasonic transducer has a portion of either the signal driving the ultrasonic transducer, or the ultrasonic energy emanating from the ultrasonic transducer, feedback so that its power is measured and its phase determined. These measurements are then provided in a feedback manner to the controller. The controller provides any necessary adjustment to the driver element for the ultrasonic transducer to correct any aberration from the desired operating parameter. In this way, the desired wave front of ultrasonic energy is generated and corrections of the wave front are made automatically to insure that only the desired target tissue volume is heated and vaporized. In addition, the phase and power measurements are made without the need for invasively including a hydrophone array within the patient's body cavity.

[0015] In one aspect of the present invention, the driver element is a Class D/E switching amplifier. The Class D/E amplifier connects the ultrasonic transducer element to a power supply by switching at a particular frequency, and provides a high efficiency power transfer. In a preferred aspect of the present invention, high power MOSFET transistors are used as the switching elements in the Class D/E amplifiers.

[0016] In another aspect of the present invention, the controller comprises a power controller for controlling the level of DC power available to the driver element. The power controller is a switching DC/DC power regulator that provides power to the class D/E amplifier at a power level selected by the switching frequency. By varying the switching power regulator switching frequency, the power level to the Class D/E amplifier may be controlled and fine tuned according to the feedback signal and control inputs.

[0017] In yet another aspect the controller comprises a phase controller. The phase controller comprises a phase shifter that is the combination of a programmable delay chip and a counter. These chips combine to provide the total resolution of phase control of the transmitted ultrasonic wave. In addition, a phase locked loop is used as a phase detector and to ensure coherence between the phase shifter and the signal driving the power converter so that the proper wave is produced.

[0018] In another aspect of the present invention, a feedback means provides a feedback signal that is representative of the output signal. The feedback signal comprises a phase measurement and power measurement from either the input to, or the output from, a corresponding ultrasonic transducer. The feedback signal is feedback to a controller that will adjust a control signal provided to the mean for driving so as to correct the phase and power at the electrical signal provided to the corresponding ultrasonic transducer element.

[0019] A method is provided for vaporizing target tissue in which a plurality of ultrasonic transducers are focused so as to provide constructive interference within the target tissue. The ultrasonic beams are launched and produce fast tissue temperature rise and vaporizes the target tissue within the focal zone.

SUMMARY OF NEW CLAIMS

[0020] In another aspect, the invention features a method for forming a cavity in cardiac tissues in a subject. The methods include focusing an ultrasound beam on the target tissue, where the cavity is to be formed, thereby creating the cavity by vaporizing the target tissue.

[0021] In preferred embodiment the cavity is a channel connecting the left ventricle and tissue in the myocardium.

[0022] In preferred embodiment the method is noninvasive, i.e., the transducer is located outside the body of the subject.

[0023] In preferred embodiment a device described herein is used to form the cavity.

[0024] In preferred embodiment the energy delivered is sufficient to vaporize target tissue.

[0025] The present invention provides a safer and highly efficacious treatment than the prior art. The present invention is much safer than by-pass surgery in that the sternum is not split and the heart itself is not stopped for the duration of the operation. In addition, the present invention may provide a shorter recovery time and is not as costly a procedure to undertake.

[0026] While a preferred embodiment is described, it should be apparent that many modifications and variations are possible, all of which fall within the scope of the Detailed Description and Claims which follow.

BRIEF DESCRIPTION OF THE DRAWINGS

[0027] These and other features and advantages of the present invention will be better understood by reading the following detailed description taken together with the following drawings wherein:

[0028] **FIG. 1** shows a photograph of ultrasonically formed cavities in beef hearts;

[0029] **FIG. 2***a* is graph showing the burst duration on the x-axis and length of the cavity formed on the y-axis for a first set of values;

[0030] **FIG. 2***b* is a graph showing the burst duration on the x-axis and the diameter of the cavity formed on the y-axis for a first set of values;

[0031] **FIG. 2***c* is a graph showing the burst duration on the x-axis and the depth from the surface of the cavity formed on the y-axis for a first set of values;

[0032] **FIG. 3** is a graph showing the driving voltage on the x-axis and length of the cavity formed on the y-axis;

[0033] **FIG. 4***a* is a graph showing the number of bursts on the x-axis and diameter of the cavity formed on the y-axis;

[0034] **FIG. 4***b* is a graph showing the number of bursts on the x-axis and length of the cavity formed on the y-axis;

[0035] **FIG. 5***a* is a graph showing the duty cycle on the x-axis and length of the cavity formed on the y-axis for a second set of values;

[0036] **FIG. 5***b* is a graph showing the duty cycle on the x-axis and depth from the surface of the cavity formed on the y-axis for a second set of values;

[0037] **FIG. 6***a* is a graph showing the burst duration on the x-axis and length of the cavity formed on the y-axis for a third set of values;

[0038] **FIG. 6***b* is a graph showing the burst duration on the x-axis and the width of the cavity formed on the y-axis for a third set of values;

[0039] **FIG. 7** is a photograph of multiple sonications that induced cavities through the cardiac wall;

[0040] **FIG. 8** is a block diagram showing the phased array ultrasound driving system;

[0041] **FIG. 9** is a block diagram showing the control architecture of the phased array driving system;

[0042] **FIG. 10** is a block diagram showing the phase regulation system;

[0043] **FIG. 11** is a schematic diagram showing a single driver element for an ultrasound channel in the phased array ultrasonic system;

[0044] **FIG. 12** is a schematic diagram showing the phase controller circuitry of the phased array ultrasonic system;

[0045] **FIG. 13** is a schematic diagram showing the phase correction circuitry for the phased array ultrasonic system;

[0046] **FIG. 14A** is a schematic diagram showing the data acquisition digital to analog converter supplying the power set point to the driver element in the phased array ultrasonic system;

[0047] **FIG. 14B** shows the measurement system analog to digital converter for measuring the forward and reflected power in a phased array ultrasound system;

[0048] **FIG. 14C** is a temperature sensor for detecting elevated temperatures to protect circuitry for each driving channel of the ultrasound driving system;

[0049] **FIG. 15** is a schematic diagram showing the microcontroller and the circuitry associated with the microcontroller and memory.

DETAILED DESCRIPTION

[0050] In accordance with the current invention, a method and apparatus is described that advantageously creates channels in the left ventricular wall of the heart to improve blood supply to a damaged myocardium. Conventional techniques for creating these channels have included laser energy delivered by a fiber that is placed next to the cardiac wall. A short energy pulse is delivered that vaporizes the tissue. Channels of about one millimeter in diameter are formed to the cardiac wall with this technique

[0051] It has been discovered by the current inventors that ultrasonic energy can be focused and sufficiently controlled to vaporize cardiac tissue and thus create the channels within the myocardium for transmyocardial revascularization. The novel method involves the delivery of ultrasonic energy by a plurality of ultrasonic transducers arranged in a phase array to elevate tissue temperature rapidly at the target location through constructive interference of the ultrasonic waves. Alternatively, the formation of gas bubbles may be utilized to mechanically disintegrate the tissue when the pressure amplitudes are high enough.

[0052] Myocardial revascularization through ultrasound techniques offers the following advantages over conventional laser systems. Ultrasound can be focused through tissue and thus the channel formation does not require physical contact with the transducer. This makes formation of channels of roughly any shape or geometry possible which would theoretically allow more optimal channel networks to be experimentally tested and clinically used. Furthermore, the ability to focus ultrasound allows for a completely non-invasive procedure which may be guided through imaging with MRI, CT or diagnostic ultrasound technology. Finally, ultrasound can be generated with equipment that is potentially less expensive than current laser systems.

[0053] The method of performing transmyocardial revascularization through ultrasonic techniques involves the steps of providing a plurality of ultrasonic transducers in a phased array configuration to deliver ultrasonic energy at a target location within the myocardium, focusing the individual transducers of the array to produce constructive interference of the ultrasonic wave fronts at the target location, and adjusting the power and phase output of the ultrasonic transducers through feedback to provide sufficient ultrasonic energy at the target location to vaporize the cardiac tissue.

[0054] In Vitro Experiments

[0055] In experiments relating to transmyocardial revascularization using ultrasonic energy, ultrasound fields were generated by a focused ultrasound transducer operating at two different frequencies (0.6 MHz and 2.02 MHz). The transducer was 100 mm in diameter with a 80 mm radius of curvature. The RF-signal feeding the transducers was induced by a frequency generator (Wavetek Inc., model 271) and amplified by an RF-amplifier (ENI Inc., model MOA500). A power meter (Hewlett Packard 438A) and dual directional coupler (Werlatone C2625) were used to monitor the forward and reflected power to the transducer matching

network. The electrical impedance of the transducer was matched to the output impedance of the amplifiers by an external matching network. The frequency generator was triggered to give short pulses by a portable PC computer via a parallel port.

[0056] The sonications were performed in degassed, deionized water in a plastic tank the walls of which were lined by rubber mats. The transducer was mounted on a metal arm connected to a mechanical positioning device that allowed the transducer to be positioned in three degrees of freedom with the resolution of 0.01 mm. This resolution was reached by mounting digital calipers on the positioning device. The transducer was aimed to the surface of the water through a hole in a plastic plate that supported the heart.

[0057] The total acoustical power as a finction of the applied electrical power (forward-reflected) was measured using a radiation force technique with a lab balance as the force detector. The absolute intensity in the waterbath was measured using a PVDF membrane hydrophone. The relative intensity distributions were obtained by scanning a thermocouple probe coated with a bead of silicone rubber in the field.

[0058] Fresh beef hearts (3) were obtained within minutes of death. The hearts were removed and placed in saline solution. The sonications were performed within 3-4 hours. The heart was placed on a plastic holder that had an open window immersed in a temperature controlled waterbath in such a way that the tissue was in contact with the water through the window. The water temperature was 37° C. The beam was aimed at the desired depth in to the heart. The sonication was performed and the transducer moved 5 mm before the next sonication. This was repeated five times in each row. Experiments with both frequencies, different pressure amplitudes, burst durations, and numbers and repetition frequencies were performed. After the sonications the tissue was cut along the sonicated line and the dimensions of the created cavities were measured. This was repeated in several rows in each heart.

[0059] Multiple sonications were repeated at different depths with the interval equal to the length of a single cavity. The sonications were performed in the order of their depth in tissue such that first sonication was aimed to the endocardium wall and the last to the epicardium. After the experiments were completed the hearts were fixed in formaldehyde.

[0060] Many of the high amplitude burst sonications at 2.02 MHz disintegrated the cardiac tissue leaving a cavity in the tissue. **FIG. 1** shows a photograph of some of these cavities. The size, location, and to some extent the shape of the cavity was dependent on the sonication parameters. **FIGS. 2***a*, **2***b*, and **2***c* show the effects of the burst duration on the length and diameter of the cavity and its depth from the epicardium. Both the width and length of the cavity increased as a function of burst duration however, the distance from the surface reduced as the burst duration increased. This means that the cavity is forming in front of the focal spot at the longer burst durations. Thus, shorter sonications are required to generate the cavities at the focal depth.

[0061] **FIG. 3** shows that the cavity length is not strongly driving voltage (intensity) dependent above a threshold value that forms the cavity. This is with relatively short sonications and pulse repetition frequency of 1 Hz.

[0062] At the short burst length the number of bursts does not have a strong influence on the cavity length or its diameter after about 5 bursts of 0.05 s in length repeated at 1 Hz rate as shown in **FIGS. 4***a*. And **4***b*.

[0063] Finally, the total sonication time was fixed to 0.5 s and then different sonication parameters were tested. First, the burst length was fixed to 0.01 s and they duty cycle varied. **FIG. 5***a* and **5***b* show that the lower duty cycles did not produce any cavity until at 0.4 the cavity was formed. The length was about the same as with the higher duty cycles. However, the depth of the cavity from the epicardium reduced as the duty cycle increased. Thus, the duty cycle of 0.4 was selected for the next study that evaluated the influence of the burst duration during the 0.5 s sonications. **FIGS. 6***a* and **6***b* a show the length of the lesion to increase up to 0.005 s and then increase only slightly at 0.01 s. The width of the cavity was insensitive to the burst duration under these conditions.

[0064] The lower frequency of 0.5 MHz did not produce cavities at the maximum power output level until continuous wave sonication for 0.5 s was used. The resulting tissue damage was larger, and the tissue was full of small holes but there was not a complete cavity. The shorter burst sonications did not produce observable tissue damage.

[0065] Several sonications with parameters that produced cavities in the previous sonications were selected. These were all performed at the frequency of 2 MHz. These sonications showed that channels through the ventricular wall could be induced as shown in **FIG. 7**.

[0066] The experiments have demonstrated for the first time that ultrasound can be used to generate channels through the ventricular wall. These cavities may offer an alternative to laser induced cavities. It has been also shown that the cavities can be induced deep in the ventricular wall without direct contact of the applicator to the lesion site, allowing different channel geometries to be investigated to optimize the perfusion effects. For example cavities that do not come all the way through the endocardium can be easily formed. These cavities may also prove to be useful for destroying conduction pathways that cause arrhythmia.

[0067] The transducers used here were designed for high power ultrasound experiments and were not optimized for the cardiac sonications. In these experiments a spherically curved transducer was used to focus the beam, however, lenses or phased arrays can also be used for the task. Smaller transducers positioned manually by the surgeon on the epicardium when the heart is exposed can be easily designed and constructed. Transducer geometry to allow the applicator to be positioned via an incision between the ribs is also feasible. Similarly, catheter based applicators delivered onto the heart via blood vessels could be constructed.

[0068] The ultrasound phased array system **10** is shown generally in **FIG. 8**. The ultrasound phased array system **10** generally comprises a control system **12**, controlling a plurality of channel driving systems **11**, that each provide power to a corresponding matched ultrasonic transducer **36**. The channel driving system **11** comprises a power generation system **20** and a phase regulation system **30**. The control system **12** provides a power set point input **512** and a

feedback enable signal **514** to the power generation system **20** and a phase set point input **516** and feedback select signal **518** to the phase regulation system **30**. The power generation system **20** provides an output driving signal to the matched transducer **36** and includes a power feedback input **524**. The phase regulation system **30** includes an amplifier phase feedback signal **520** from the immediate output of the power generation system **20** or alternatively a transducer phase feedback signal **522** after the matching circuitry at the matched transducer input **36** to provide phase correction to the power generation system **20**.

[**0069**] As will be appreciated by one skilled in the art, each matched transducer **36** is a single array element of the ultrasonic phased array **10** and must be individually controlled in both power and phase in order to produce a desired wave form. This is necessary to create acoustic fields of constructive and destructive interference for a variety of phased array shapes and sizes. It is also critical to have individual control of power and phase of array elements in arrays whose elements have various surface area geometries, or to drive an array with non uniform power intensities for each of its elements in order to achieve a desired result. Each matched transducer **36** is driven by a separate power generation system **20** and phase regulation system **30**. One of ordinary skill in the art will recognize that a plurality of ultrasonic transducers, each controlled by a separate power generator system **20**, and phase regulator system **30**, comprise the ultrasonic phased array system **10**. It will be appreciated by one of skill in the art that the phased array may be of any desired orientation and geometry. The problem of various geometries in calculating the appropriate phase and power is a problem well known in the art.

[**0070**] In order for the ultrasound phased array system **10** to create an acoustic focus capable of vaporizing tissue the system must be able to control the power and phase of the ultrasonic energy emanated from each ultrasonic transducer. The control system **12** includes: a user interface **14**, which allows the operator to input user commands; a single board computer **16** for receiving and interpreting commands from the user interface **14** to communicate with the system's micro-controller **18**. The micro-controller **18** determines the power set point input **512** for the power generation system **20**, the phase set point input **516** for the phase regulation system **30**, and enables the feedback enable signal **514** of both the power generation system **20** and the feedback select signal **518** of the phase regulation system **30**.

[**0071**] In one embodiment, the power conversion system **20** comprises a switching DC power regulator **22**, a power measurement system **24**, a Class D/E power converter **28**, and a harmonic filtering system **26**. The DC power regulator **22** provides a regulated DC power to the class D/E power converter **28**. The power measurement system **24** samples the output of the harmonic filtering system **26** and provides feedback to the DC power regulator **22**, which will regulate the DC power available to the Class D/E power converter to the level set by the power set point control signal #.

[**0072**] The Class D/E power converter **28** converts the DC power provided by the DC power regulator **22** to a high power, high frequency square wave. In the preferred embodiment a frequency between 0.5 and 10 MHz and more particularly, between 1.5 and 4 is optimal for vaporization of cardiac tissue. The DC power regulator **22** consists of a DC-to-DC down converter which regulates the DC voltage from 0 V to a constant voltage for the Class D/E stage **28**. Harmonic filtering **26** receives the high frequency signal from the Class D/E power converter **28** and further filters the signal to produce a sinusoidal output signal. This sinusoidal output signal is sampled by the power measurement system **24** to provide a feedback input to the DC power supply **22**, to adjust the power output supplied to the Class D/E power converter **28**, based on the set point provided by the microcontroller.

[**0073**] The phase regulation system **30** comprises a phase shifter **34** and a phase detector **32**. The phase shifter **34** receives a phase set point # from the controller **12** and determines the timing of the switching input control signal # to the power generation system **20**. The phase detector **32** will detect the phase of the feedback signal which is either the amplifier phase feedback signal **520** or the transducer feedback signal #. This provides a closed loop feedback control of the phase of the output signal in order to account for imperfections in the system of the ultrasonic transducer element.

[**0074**] The output from the harmonic filtering system **26** is provided to a matching circuitry **40**, which drives an ultrasonic transducer **38**. Each matched transducer **36** is associated with matching circuitry **40** to provide an impedance match between the harmonic filter system **26** and the ultrasonic transducer **38**. The impedance matching circuitry **40** is preferably adjusted so that maximum power transfer occurs between the driver system **11** and the ultrasonic transducer **38**.

[**0075**] The control system **12** is shown in more detail in **FIG. 9**. In one embodiment, the amplifier system comprises up to 256 ultrasonic driving system cards (UDSC). Each card is capable of driving up to four individual channels with each channel corresponding to one matched ultrasonic transducer **36**. Thus, in one embodiment of the ultrasonic array system **10**, there can be up to 1,024 matched transducer elements **36** in the phased array. Each individual UDSC includes a microcontroller **42** which has a two separate read/write local memory banks **44**: one for protected program storage and one for data storage. Each UDSC drives up to four single channel driving systems **11**. The microcontroller **42** in the present invention is a Motorola 68HC11 microcontroller. In one embodiment the microcontrollers **42** interface with a single board computer **16** over a single data bus. The single board computer **16** is an Intel 486 based single board computer or equivalent. The single board computer **16** reports operational status to, and receives operational commands from, the user interface **14**. It would be known to one skilled in the art that the user interface **14** may be operated manually by a human or operated automatically simultaneously with other devices such as a magnetic resonance imager or positioning system.

[**0076**] In the present embodiment, the user interface **14** inputs data regarding the desired acoustic focus point and calculates the appropriate power and phase for each individual driving system **11** and matched transducer **36** combination in order to achieve the desired acoustic focus point to create vaporization of the target tissue volume. These calculations are conventional and are well known in the art. The user interface **14** transmits the calculated and phase data to the single board computer **16**, that transmits the phase and

power data to the appropriate USDC **12**. The USDC **12** then drives each individual driving system **11** and matched transducer **36** combination to the desired phase and power output.

[**0077**] If it is necessary for the phase and/or power to be changed rapidly during a sonication, e.g. to scan the acoustic focal point of the array, or to create a rapid progression of acoustic focal points, the phase and power data can be downloaded directly to the UDSC's local memory **44** prior to the sonication. The local memory **44** stores the power and phase data for each channel. The single board computer **16** sequences the operation of the microcontroller **18** by directing the microcontroller **18** to execute the stored data.

[**0078**] In one embodiment of the ultrasound phased array system **10**, the power and phase data is stored in a memory stack located within the microcontroller's data memory. This sequence of phase and power data comprises a software implementation of a random-access-memory data list, referred to in this implementation as the control stack. This allows the process to read the data, by retrieving the data from the stack while only keeping track of the stack locations. Preferably once the single board computer directs the microcontrollers that they will be processing stack information, the microcontrollers process subsequent stack data at the direction of a parallel line controlled by the single board computer **16**. This has the advantage of dramatically reducing the communication overhead during sonication, which in turn allows the microcontrollers to more closely monitor the amplifiers while rapidly changing phase and power distribution patterns.

[**0079**] The phase regulation system **30** is shown in greater detail in **FIG. 10**. In one embodiment of the ultrasound phased array system **10** the phase regulation is a combination of both digital counters and delay circuitry. The input master clock operates at 16 times the frequency of the transducer (i.e. 48 MHz for a 3.0 MHz transducer), this input frequency is then provided to a programmable 4-bit divide-by-16 counter **54** which produces 22.5 degrees of frequency independent phase resolution and provides the operating frequency to the delay elements. In a preferred embodiment of the ultrasound phased array system, the finer resolution is provided by an 8-bit programmable delay chip **56** with 0.5 nanosecond resolution. This circuitry provides the ability to create higher degrees of phase resolution. In one embodiment of the ultrasound phased array system, 8 bits are used to control the phase. The first four bits are used to provide the 22.5 degrees of phase resolution using the programmable 4-bit counter **54**. This combination of counters and delay circuitry is effective because it provides increased phase resolution while avoiding ultra high frequency master clock signals and a significant increase in chip count.

[**0080**] As will be discussed in greater detail below, the power generation system **20** implements a switching DC power regulator **22** which provides power to a DC to RF power converter. In the one embodiment of the ultrasound phased array system, a class D/E amplifier is used as the DC to RF power converter. This is also known to those skilled in the art as a sub-optimal Class E amplifier. The Class D/E switching amplifiers are based on the principle of using active switching devices, typically FETs, to drive a harmonic filter such that there is little to no power dissipation in the active switching device. In the preferred embodiment of the ultrasound phased array system the harmonic filter **26** is a low pass filter designed to attenuate the high harmonic components inherent in a switching design. The harmonic filter **26** has a desired cutoff frequency such that the second and third harmonics of the lowest operating frequency would not be significantly transmitted to the matched transducer **36**.

[**0081**] The matching circuitry **40** provides impedance matching between the output of the driving system **11** and the ultrasonic transducer **38**. Impedance matching maximizes the power transfer between the driving system **11** and the transducer **38** and allows for accurate power measurement. In the preferred embodiment of the ultrasound phased array system **10**, the matching circuitry **40** is also capable of matching different impedances to ensure that the same range of power will be delivered to each individual element in the transducer array.

[**0082**] A schematic diagram of a representative amplifier stage channel is shown in **FIG. 11**. The RF clock input **140** and its inverse, created by the inverter **100**, are inputs to a signal conditioning amplifier driver **102**, which provides signal conditioning in the form of providing a square wave output. The square wave outputs from the amplifier driver **102**, which are 180° out of phase with each other, are provided to the inputs of transistors **104** and **106**. Transistors **104** and **106** are preferably power switching MOSFETs and in one embodiment of the present invention are N-channel devices. The output of these devices are connected to opposite terminals of the primary side of transformer **108** which has a center tap connected to the DC switching power regulator **116**. The secondary of transformer **108** is connected to a harmonic filtering system **110** whose purpose is to attenuate the high harmonic components inherent in a switching power supply design. In order to correctly measure and regulate power in the amplifier stage, a dual directional coupler consisting of transformer **112** and **114** provides two output signals representing the forward and reflected power delivered to the load. The forward power from transformer **112** is provided to op amp **136** which provides the forward voltage signal Vfor, and the reflected power is provided from transformer **114** to op amp **134** which provides the reflected voltage signal Vref**1**.

[**0083**] The switching power supply regulator **116**, which in the present embodiment is an LT1074, controls the power available to the switching transistors **104** and **106**. The power regulator **116** receives an input voltage of 48 volts, which it then regulates to an output voltage between 0 v and 48 v. This output voltage which is supplied to the center tap of transformer **108** will determine the power available at the transducer **38**. The output voltage is determined by the power set signal #. If the power feedback select is enabled, the power set signal # is compared to Vfor 1, the forward voltage going to the transducer **38**. If there is a difference between these voltages, an error signal from comparator **128** will adjust the output of the power regulator **11***b* appropriately.

[**0084**] The ability to provide power feedback is critical when utilizing a tuned amplifier such as Class D/E. Class D, Class E, or Class D/E amplifiers will suffer variations in power due to different transducer impedances off resonance. In the preferred embodiment, the power feedback system reduced variation in measured output power from 20% to

less than 1%. This control is critical when using non-uniform array geometries, or if power control is critical for other applications.

[0085] Patient safety and equipment protection are preferably provided by the ability to shut down an amplifier stage if a failure occurs. Shut down of the amplifier stage channel is accomplished when the shut down signal **118** and power feedback select signal **142** are both high. This results in transistor **130** being driven into saturation and grounding the VC input of the switching power regulator **116** thus cutting off all power to the switching transistors **104** and **106**. This could occur for instance if the measured reflected power from the dual power coupler, exceeded a threshold indicating a failure in the ultrasonic transducer element. In addition if an over temperature condition occurs signal OT #, will go low, grounding the VC input to the power regulator **116** also cutting off power to the channel.

[0086] **FIG. 12** is the schematic diagram for the digital phase shifter of the ultrasound phased array system **10**. The digital phase shifter outputs, as shown in **FIG. 12**, are the phase clock inputs **218**, **220**, **222**, **224** that drive the phase correction circuits in **FIG. 13**. The UDSC microcontroller provides eight bits of phase data to the inputs. Four bits of the data are provided to the four bit counters **234**, **236**, **238**, and **240**, and four bits of the data are provided to the digital delay chips **202**, **206**, **210**, and **214**. The 4-bit counters **234**, **236**, **238**, and **240** provide the first four bits of phase information which, via lines **240**, **242**, **244**, and **246**, will turn on digital delay chips **202**, **206**, **210**, and **216**, which provide a second 4 bits of phase data, after the preset count of the 4-bit counters **234**, **236**, **238**, and **240** is concluded. The 8-bit delay chip where bits **0**, **1**, and **7** are hardwired, resulting in 1.08 degrees of phase resolution at 1.5 MHz. The phase clock output **218**, **220**, **222**, **224** is provided after both delay functions have been achieved. As can be seen in **FIG. 12**, there are four channels of digital phase shifters per circuit card, and in the preferred embodiment of the invention there would be one digital phase shifter for each channel of the ultrasound phased array system.

[0087] **FIG. 13** is a schematic diagram of an embodiment of the automatic phase detection/correction circuitry for the ultrasound phased array system **10**. The output signal from the amplifier stage, RF out, is provided to the phase locked loop **300** via the comparator **302** and multiplexer **308**. The phase locked loop **300** will synchronize the RF out signal with the phase clock signal provided from the digital phase shifter. This output is provided to gate **310** such that if the shutdown signal input to **310** goes low there will be no driving signal for the amplifier and that channel will be effectively shut off. The output from the gate **310**, RF clock, which drives the Class D/E amplifier shown in **FIG. 11**, is also fed back and is selected via multiplexer **308** in order to provide necessary feedback to ensure synchronization of the signals within phase locked loop **300**. This will provide correction for the inherent non-linearities in the class D/E amplifier, as well as any aberrations caused by other sources.

[0088] The preferred embodiment of the phase regulation system **30** described above allows the non-linear Class D, Class E, or Class D/E amplifiers to be used. These amplifiers typically have almost 50% variation in phase depending upon the power output. By providing phase feedback at either the amplifier output or the transducer face. This phase variation is reduced to less than 3%.

[0089] The preferred embodiment of phase regulator system **30** described above also advantageously increases the peak acoustic intensities at the acoustic focus point. There are several sources of phase errors within the embodiments described. The first is the matching network **40**, which will cause a phase shift to occur between the amplifier output voltage and the transducer **38**. A second source of phase error is created by transducer elements being different shapes or sizes. By providing phase feedback measurements from the transducer face, an increase of 25% in acoustic intensity at the acoustic focus is achieved over no phase feedback. In addition, phase feedback measurements from the amplifier output result in an 18% increase in acoustic intensity.

[0090] **FIGS. 14A, 14B**, and **14**C provide the schematic diagrams for the data acquisition system of the ultrasound phased array system **10**. In **FIG. 14**A, the digital to analog converter **400** accepts data lines, data **0** through data **7**, and address lines ADDR**0** and ADDR**1** to produce the power set voltages for each of the channels used in the ultrasonic phased array. These outputs, CH Power set, are provided to the amplifier stage shown in **FIG. 11** and provide the set point to the DC switching power regulator **116**.

[0091] In **FIG. 14B** the analog to digital converter **412** accepts inputs of forward and reflected power from each of the channels in the ultrasonic phased array system and converts that analog data to digital data and stores that data in memory, where it is retrieved by the single-board computer **16**.

[0092] In **FIG. 14**C, temperature sensors **402**, **404**, **406**, **408** detect elevated temperatures to protect circuitry for each driving channel of the ultrasound driving system.

[0093] **FIG. 15** is a schematic diagram of one embodiment of the microcontroller and its associated circuitry. Microcontroller **500** has associated with it memory **508**, **510**. The address lines **506** and data lines **504** provide the read/write address and data to be stored in the memory. In addition control signals are generated in the microcontroller **500**, to control the phased array ultrasonic system electronic circuitry.

1. An ultrasonic phased array system for selectively vaporizing bodily tissue, comprising:

a plurality of ultrasonic transducer elements, each capable of producing an ultrasonic wave;

a feedback means for providing a feedback signal responsive to a corresponding ultrasonic transducer element;

a focusing element responsive to the feedback means for focusing said plurality of ultrasonic transducer elements to produce constructive interference of said ultrasonic waves at a selected portion of said human body tissue,

a channel driver element responsive to said focusing element for driving said plurality of ultrasonic transducers to generate said ultrasonic waves.

2. An ultrasound phased array system as in claim 1 wherein the focusing element comprises:

a controller for determining at least one operating parameter for a corresponding ultrasonic transducer element,

the controller being responsive to the feedback means for adjusting the channel driver element so as to correct any aberrations in the output ultrasonic wave from the at least one determined operating parameter.

3. The apparatus of claim 2 wherein the feedback signal comprises a phase measurement of the output ultrasonic wave from the corresponding ultrasonic transducer.

4. The apparatus of claim 2 wherein the feedback signal comprises a power measurement of the output ultrasonic wave from the corresponding ultrasonic transducer.

5. The apparatus of claim 2 wherein the feedback signal comprises a phase measurement and a power measurement of the output ultrasonic wave from the corresponding ultrasonic transducer.

6. The apparatus of claim 1 wherein the feedback means provides the feedback signal from the input to the ultrasonic transducer.

7. The apparatus of claim 1 wherein the feedback means provides the feedback signal from the output from the ultrasonic transducer.

8. An ultrasound phased array system as in claim 1 wherein the channel driver element comprises a switching amplifier.

9. An ultrasound sound phased array as in claim 8 wherein the switching amplifier is a Class D/E amplifier.

10. An ultrasound sound phased array as in claim 9 wherein the class D/E switching amplifier comprises at least 2 MOSFET transistors.

11. Am ultrasound sound phased array as in claim 8 wherein the driver element further comprises a resonant circuit in series with the switching amplifier for producing a substantially single frequency sinusoidal output.

12. An ultrasound sound phased array as in claim 2 wherein the controller comprises a phase controller for controlling the phase of the corresponding ultrasonic transducer.

13. An ultrasound sound phased array as in claim 12 wherein the phase controller comprises a phase shifter and a phase detector.

14. An ultrasound phased array system as in claim 13 wherein the phase shifter comprises a digital counter and a digital delay circuit.

15. An ultrasound phased array as in claim 13 wherein the phase detector is a phase locked loop.

16. An ultrasound sound phased array as in claim 2 wherein the controller comprises a power controller for controlling the power of the corresponding ultrasonic transducer.

17. An ultrasound sound phased array as in claim 16 wherein the power controller comprises a switching DC-DC power regulator.

18. An ultrasound phased array system as in claim 2 wherein at least one operating parameter is a power output parameter of the output ultrasonic wave.

19. An ultrasound phased array system as in claim 2 wherein at least one operating parameter is a phase output parameter of the output ultrasonic wave.

20. An ultrasound phased array system as in claim 2 wherein at least one operating parameter is a power output parameter and a phase output parameter of the output ultrasonic wave.

21. An ultrasound phased array system for focusing an ultrasonic beam on a target tissue volume for performing vaporization of the target tissue comprising:

a plurality of ultrasonic transducer elements, each producing an output ultrasonic wave,

a means for feedback for providing a feedback signal

the feedback signal comprising a phase measurement and a power measurement from a corresponding ultrasonic transducer element,

a controller for determining a desired phase and a desired power for a corresponding ultrasonic transducer element and for providing a control signal,

the controller being responsive to the feedback signal for correcting the control signal so as to correct any aberrations in the output ultrasonic wave from the desired phase and the desired power,

a means for power conversion responsive to the control signal and electrically connected to a corresponding ultrasonic transducer element, for converting a DC power supply to a high frequency signal for electrically driving the ultrasonic transducer to produce an output ultrasonic wave of the desired power and phase,

whereby the output ultrasonic waves from the plurality of ultrasonic transducers combine constructively at the desired acoustic focus point for vaporizing the target tissue.

22. An ultrasound phased array system as in claim 21 wherein a means for power conversion comprises a switching amplifier.

23. An ultrasound sound phased array as in claim 22 wherein the switching amplifier is a Class D/E amplifier.

24. An ultrasound sound phased array as in claim 23 wherein the class D/E switching amplifier comprises at least 2 MOSFET transistors.

25. An ultrasound sound phased array as in claim 21 wherein the power conversion means further comprises a resonant circuit in series with the switching amplifier for producing a substantially single frequency sinusoidal output.

26. An ultrasound sound phased array as in claim 21 wherein the controller comprises a phase controller for controlling the phase of the corresponding ultrasonic transducer.

27. An ultrasound sound phased array as in claim 21 wherein the phase controller comprises a phase shifter and a phase detector.

28. An ultrasound phased array system as in claim 27 wherein the phase shifter comprises a digital counter and a digital delay circuit.

29. An ultrasound phased array as in claim 27 wherein the phase detector is a phase locked loop.

30. An ultrasound sound phased array as in claim 21 wherein the controller comprises a power controller for controlling the power of the corresponding ultrasonic transducer.

31. An ultrasound sound phased array as in claim 30 wherein the power controller comprises a switching DC-DC power regulator.

32. The apparatus of claim 21 wherein the feedback means provides the feedback signal from the input to the ultrasonic transducer.

33. The apparatus of claim 21 wherein the feedback means provides the feedback signal from the output from the ultrasonic transducer.

34. A method for selectively vaporizing human body tissue, the method comprising the steps of:

providing a plurality of ultrasonic transducers which are each capable of launching an ultrasonic wave;

focusing said plurality of ultrasonic waves to produce constructive interference of said beams within human body tissue;

launching said waves to produce a vaporization of said human body tissue.

35. The method of claim 34 wherein the step of focusing further comprises providing a feedback signal from at least one of the ultrasonic transducer elements, and

adjusting the focusing element of at least one ultrasonic transducer.

36. The method of claim 34 wherein a feedback signal comprises a phase measurement.

37. The method of claim 34 wherein the feedback signal comprises a power measurement.

38. The method of claim 35 wherein the feedback signal comprises a phase measurement and a power measurement.

39. The method of claim 35 wherein the feedback signal is provided from the input to the ultrasonic transducer element.

40. The method of claim 35 wherein the feedback signal is provided from the output from the ultrasonic transducer element.

41. The method of claim 35 wherein the step of adjusting the focusing element comprises adjusting the phase of the ultrasonic waves of at least one of the ultrasonic transducers.

42. The method of claim 35 wherein the step of adjusting the focusing element comprises adjusting the power of the ultrasonic waves of at least one of the ultrasonic transducers.

43. The method of claim 35 wherein the step of adjusting the focusing element comprises adjusting the phase and power of the ultrasonic waves of at least one of the ultrasonic transducers.

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公开(公告)号	US20020151777A1	公开(公告)日	2002-10-17
申请号	US09/523989	申请日	2000-01-31
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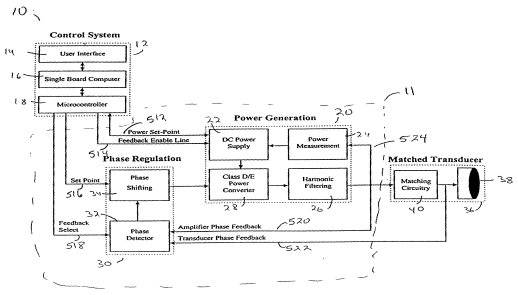
IPC分类号	A61B17/00 A61B17/22 A61B18/00 A61B8/00		
CPC分类号	A61B17/22004 A61B2018/00642 A61B2018/00392 A61B2017/00247		
优先权	60/074969 1998-02-17 US		
其他公开文献	US6511444		
外部链接	Espacenet USPTO		

摘要(译)

公开了一种使用超声进行心肌血运重建的方法和装置。该装置包括相控阵超声装置，该装置包括多个超声换能器元件，这些超声换能器元件使用反馈控制系统控制，使得每个超声换能器元件产生特定功率和相位的超声波，以便在期望的声学焦点处实现相长干涉。 。相长干涉产生高压振幅，用于在焦点处蒸发目标组织。提供了一种用于蒸发靶组织的方法，其中多个超声换能器被聚焦，从而在靶组织内提供相长干涉。超声波束被发射并且产生组织温度的快速升高，其将使聚焦区域内的目标组织蒸发。



Block diagram of the phased array ultrasound driving system.