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(54) **NON-INVASIVE ULTRASONIC BODY CONTOURING**

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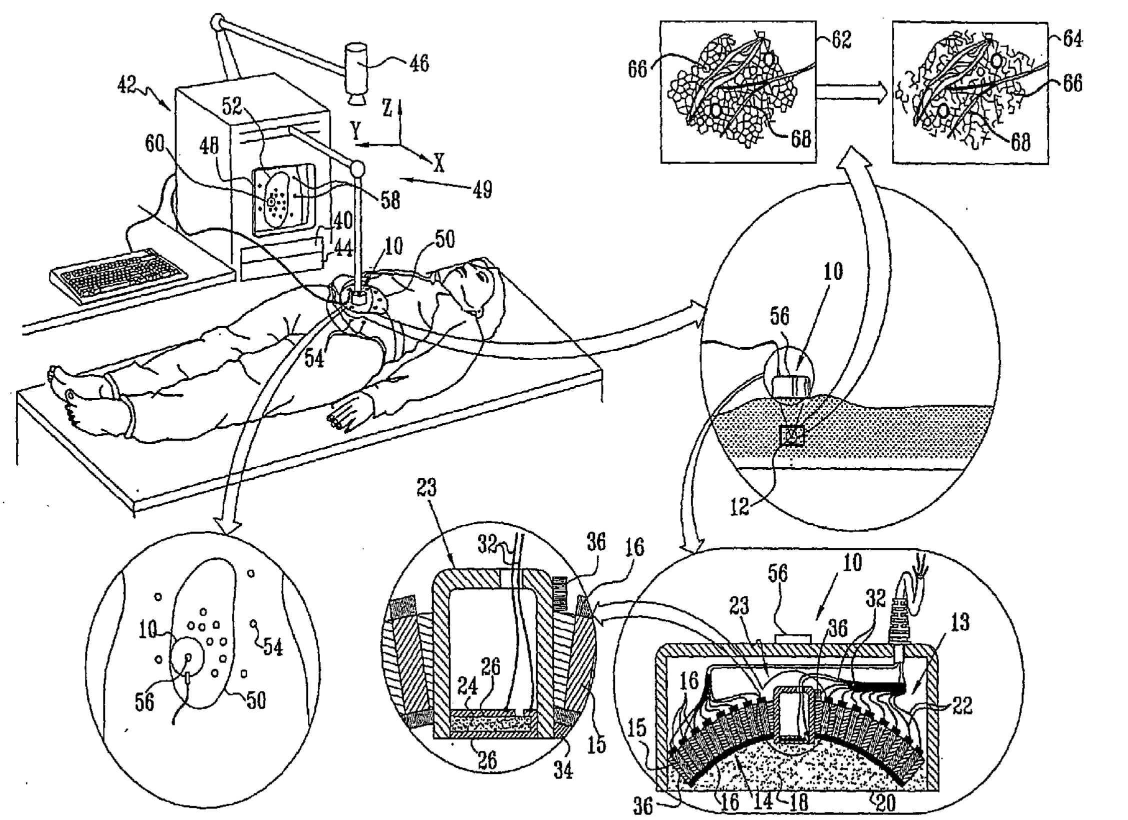
(57) **ABSTRACT**

An apparatus for lysing adipose tissue, the apparatus comprising a power source and modulator assembly configured to supply modulated electrical power; an ultrasonic therapeutic transducer connected to said power source and modulator assembly and configured to convert the modulated electrical power to ultrasonic energy directed at a target volume in a region of a body containing adipose and non-adipose tissue, so as to selectively generally lyse the adipose tissue and generally not lyse the non-adipose tissue; an ultrasonic imaging sub-system configured to identify changes in the target volume resulting from the ultrasonic energy; and a lipolysis control computer configured to control said power source and modulator assembly based on the changes identified by said ultrasonic imaging sub-system.



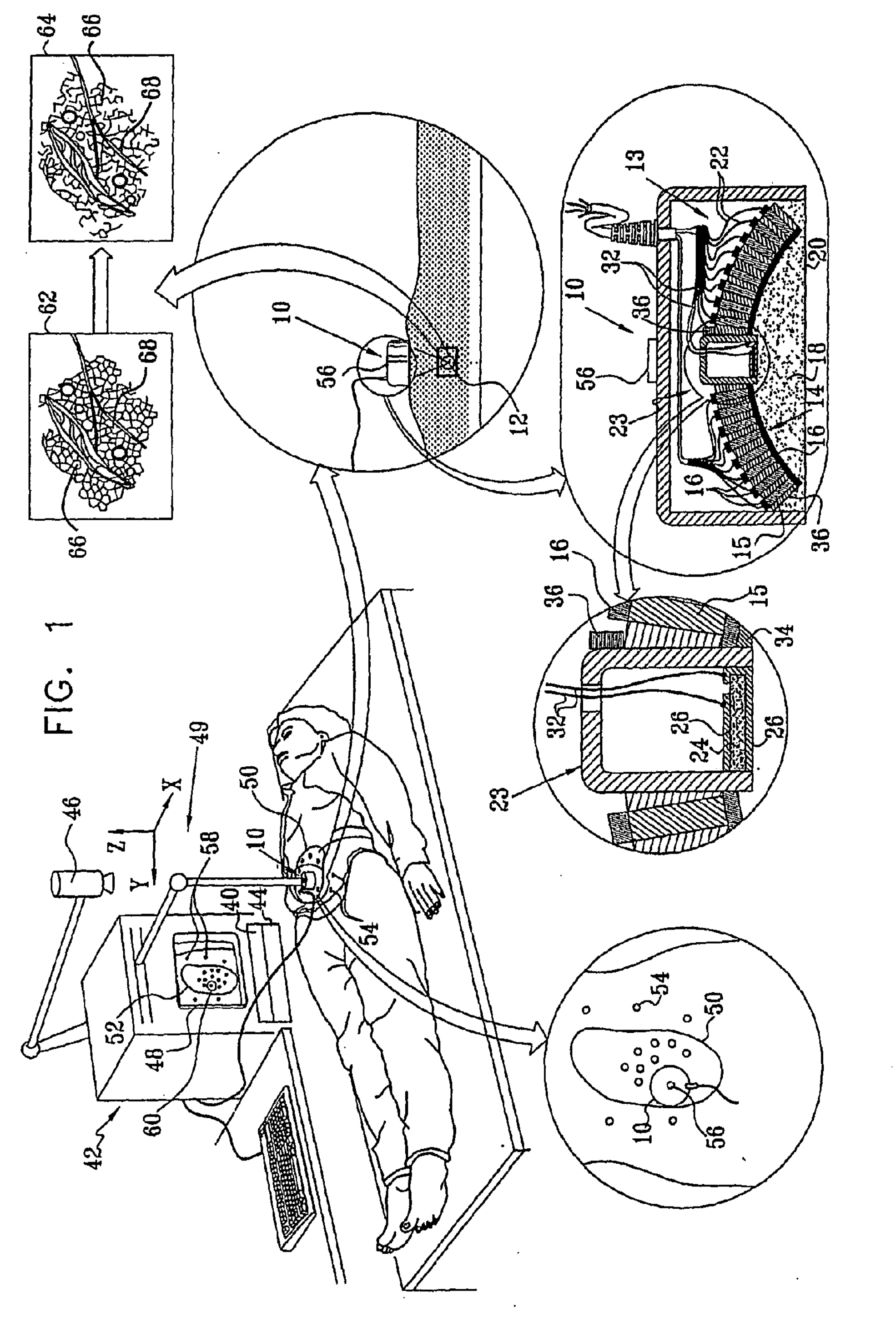
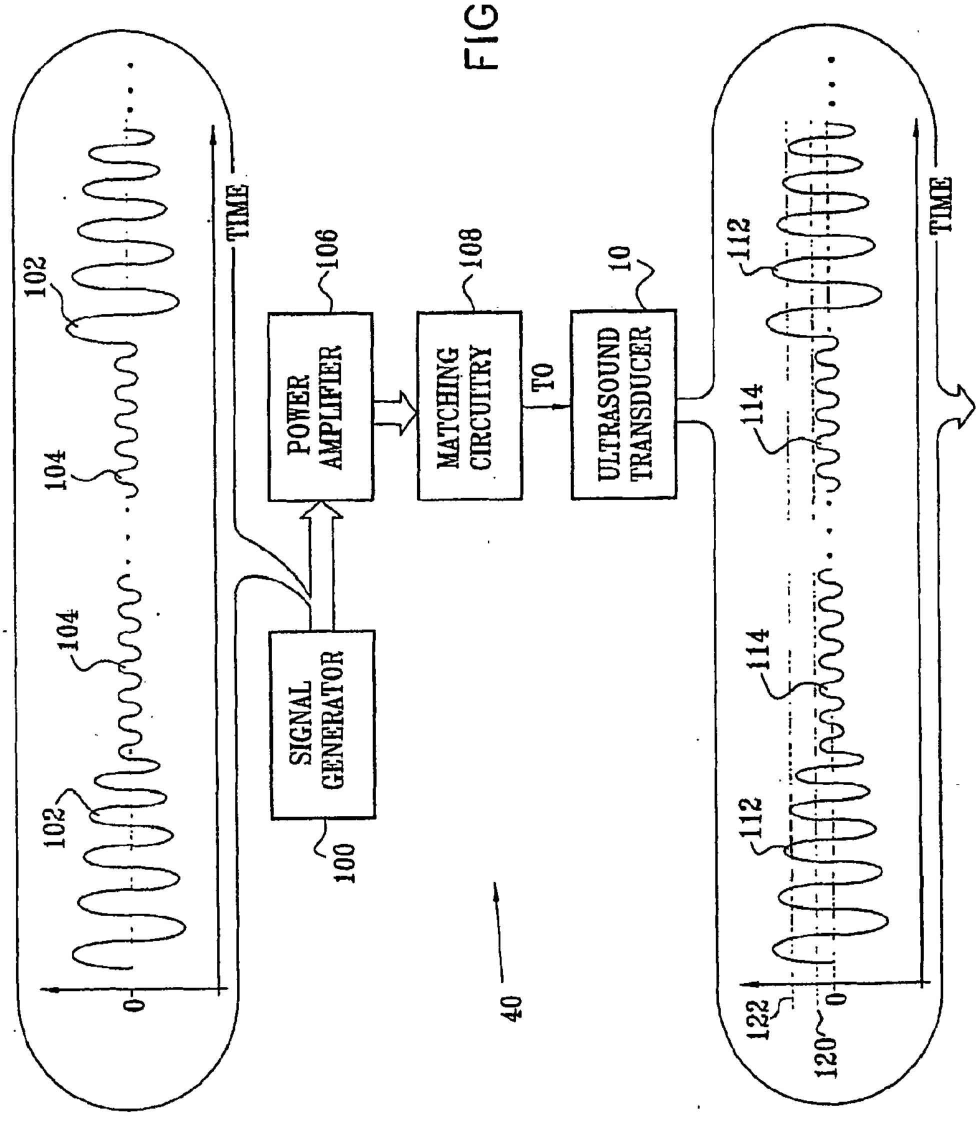


FIG. 1

FIG. 2



SIGNAL GENERATOR
POWER AMPLIFIER
MATCHING CIRCUITRY
TO
ULTRASOUND TRANSDUCER
TIME
TIME
0
0
100
102
104
106
108
10
112
114
120
122
40

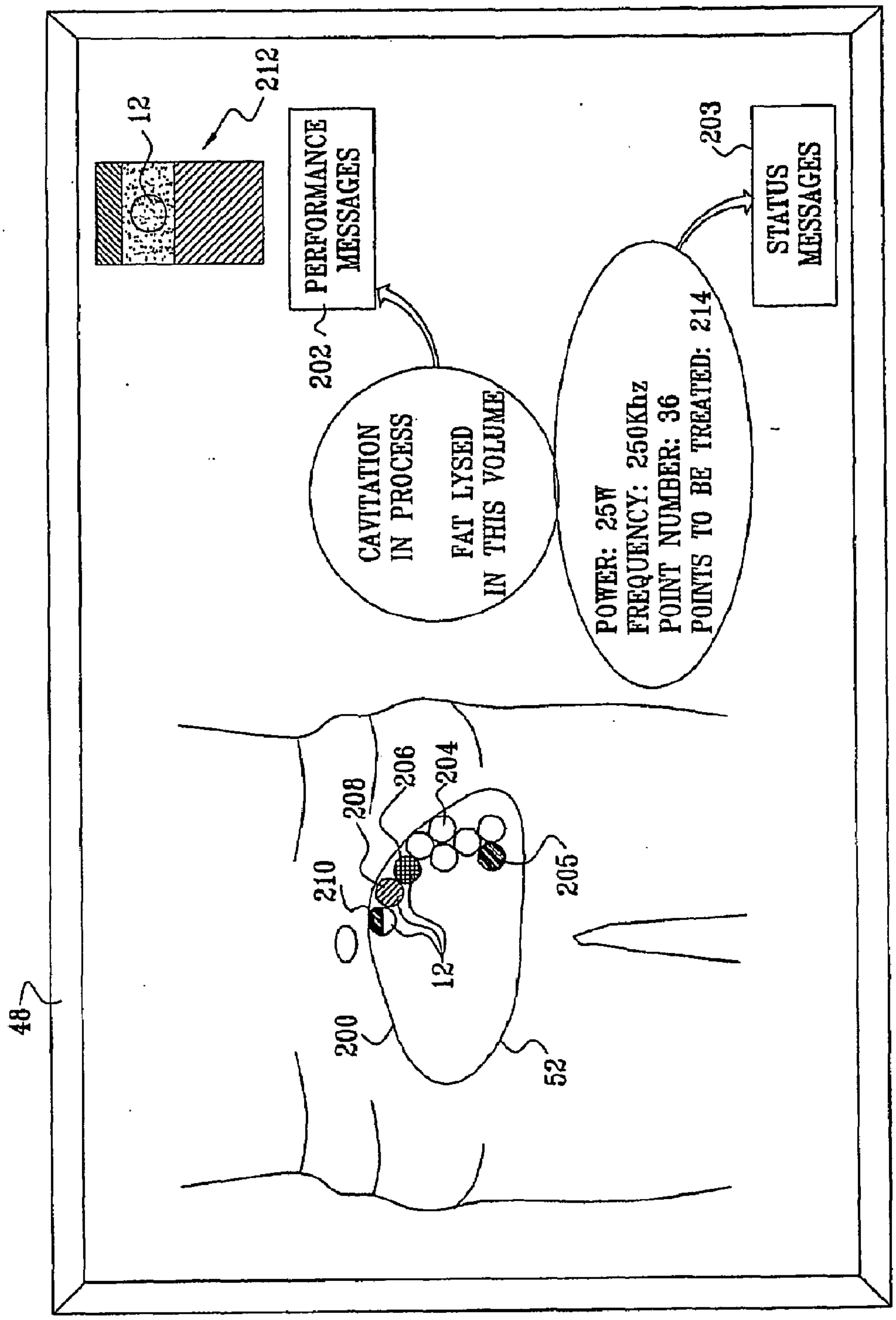

48
12
212
PERFORMANCE MESSAGES
202
CAVITATION IN PROCESS
FAT LYSED IN THIS VOLUME
POWER: 25W
FREQUENCY: 250Khz
POINT NUMBER: 36
POINTS TO BE TREATED: 214
203
STATUS MESSAGES
210
208
206
204
205
12
200
52

FIG. 3A

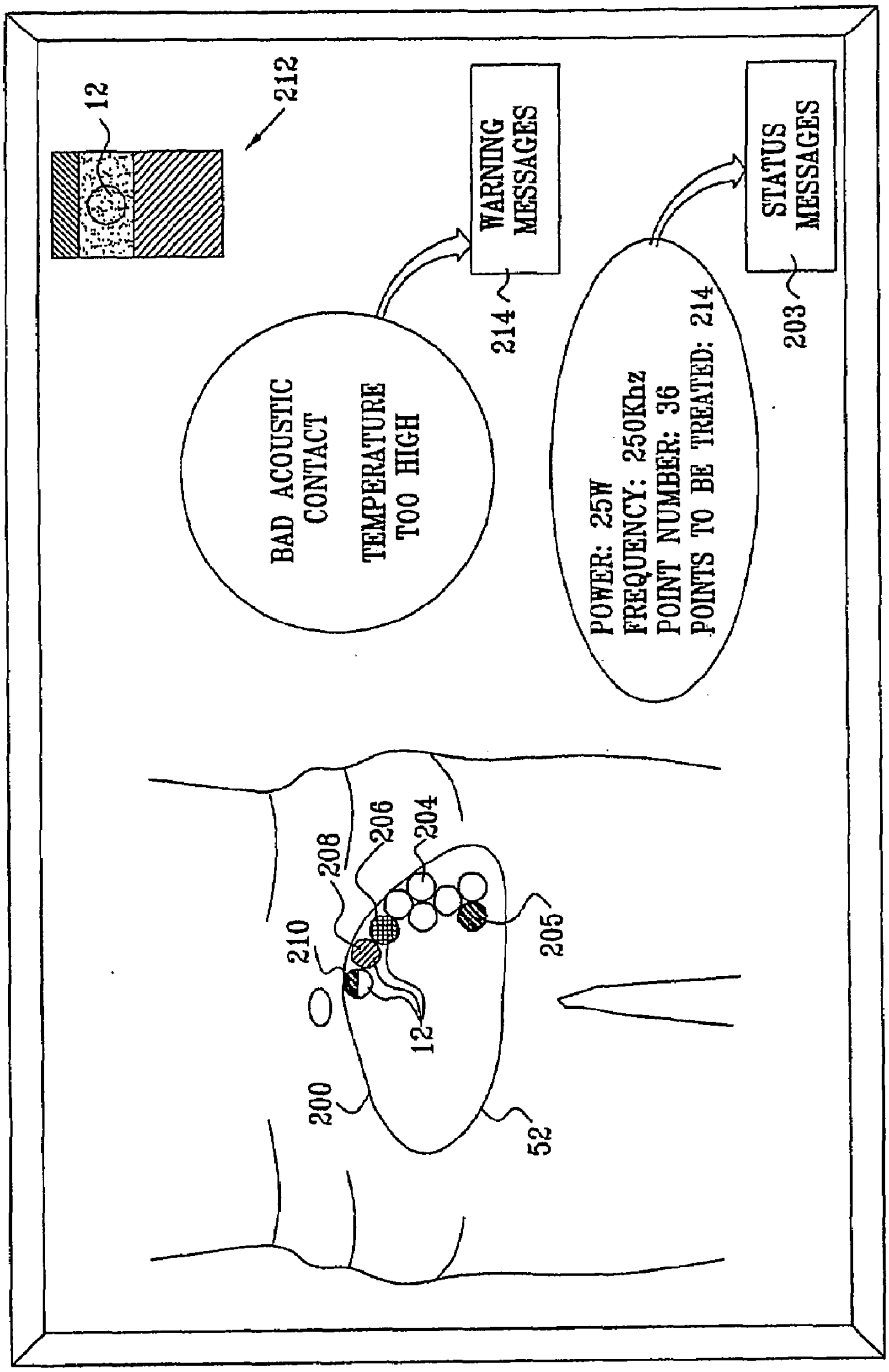
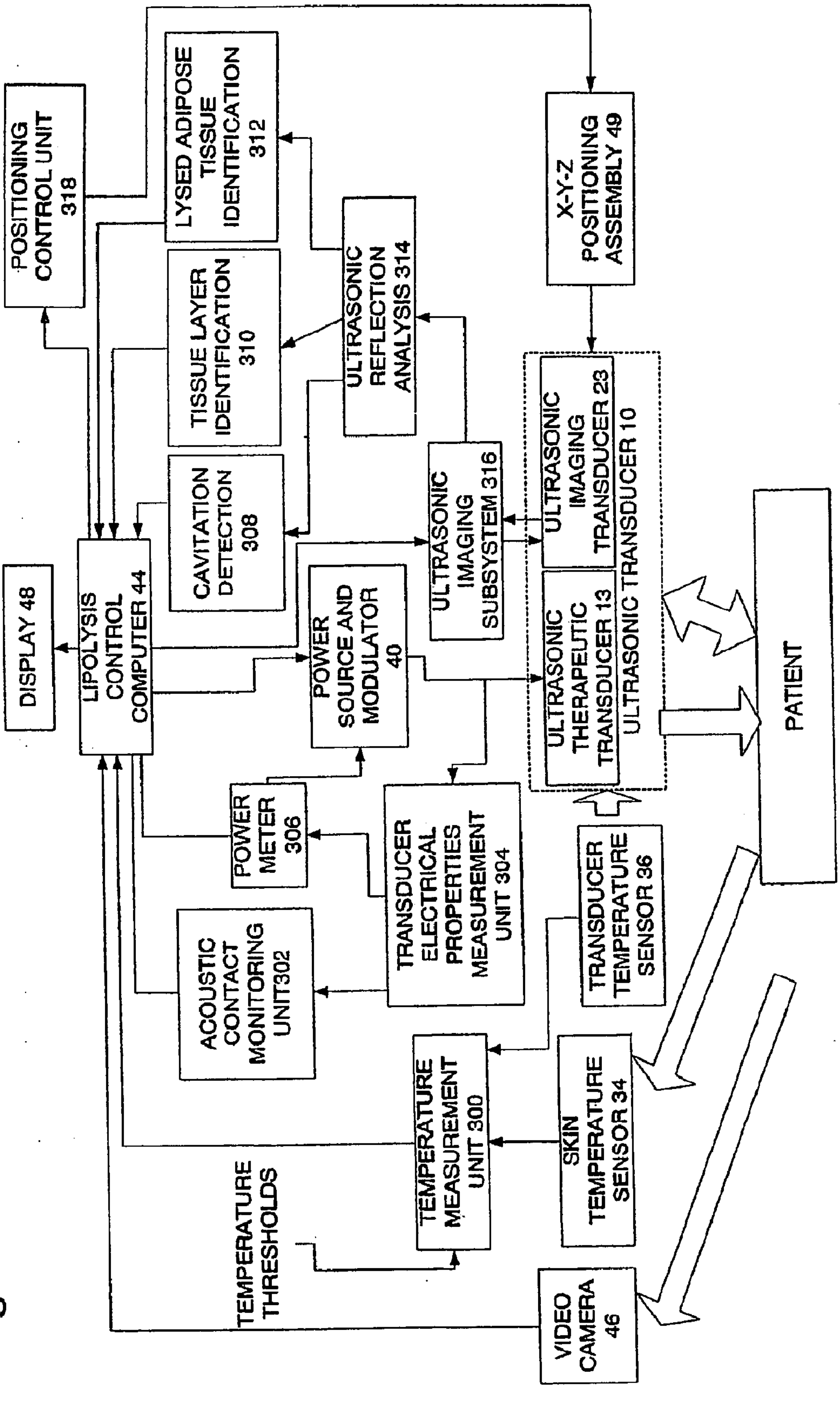

12
212
WARNING MESSAGES
214
BAD ACOUSTIC CONTACT
TEMPERATURE TOO HIGH
STATUS MESSAGES
203
POWER: 25W
FREQUENCY: 250Khz
POINT NUMBER: 36
POINTS TO BE TREATED: 214
208
206
204
210
205
12
200
52

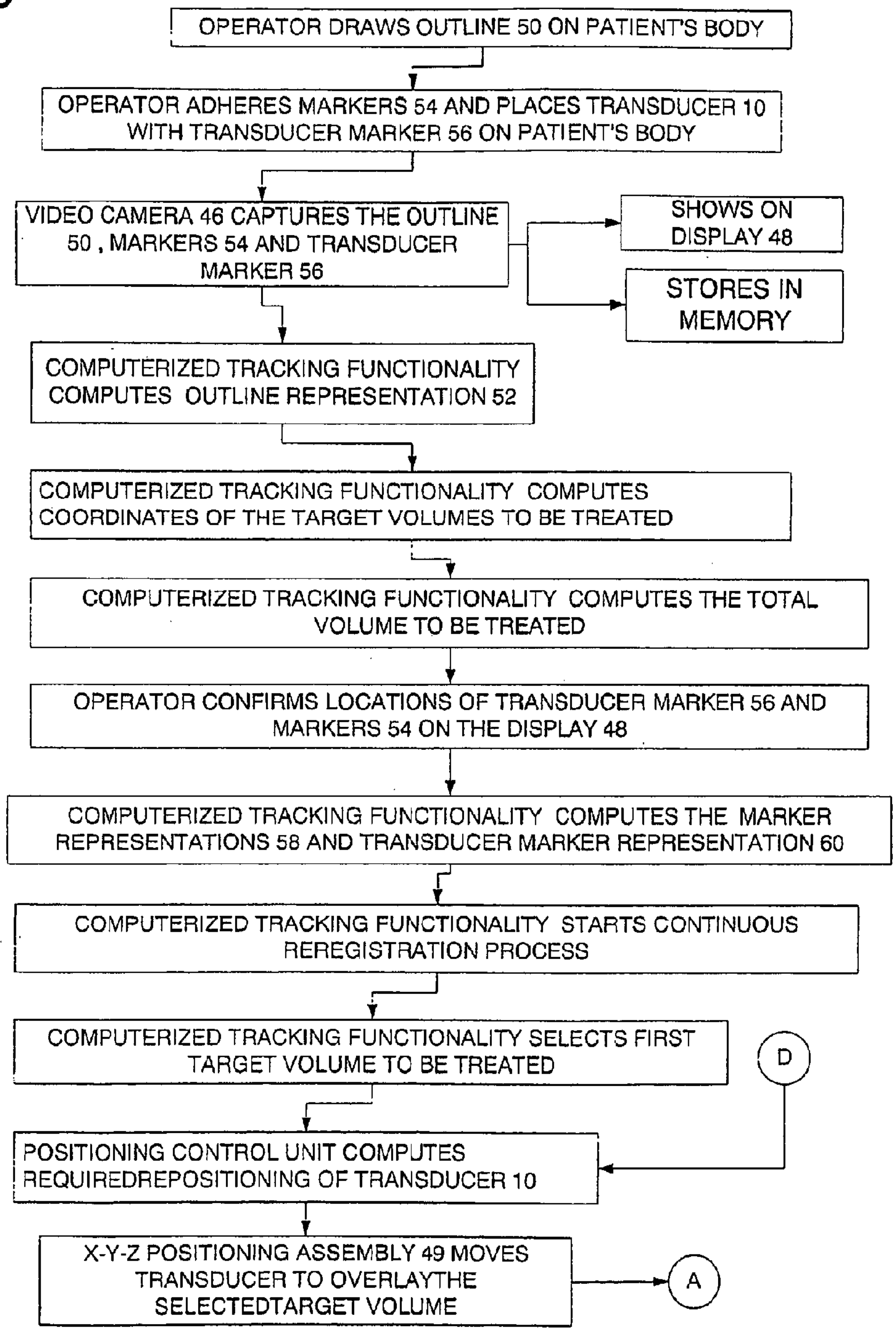
FIG. 3B

Fig. 4



POSITIONING CONTROL UNIT 318
LYSED ADIPOSE TISSUE IDENTIFICATION 312
X-Y-Z POSITIONING ASSEMBLY 49
TISSUE LAYER IDENTIFICATION 310
ULTRASONIC REFLECTION ANALYSIS 314
ULTRASONIC IMAGING TRANSDUCER 23
ULTRASONIC TRANSDUCER 10
DISPLAY 48
LIPOLYSIS CONTROL COMPUTER 44
CAVITATION DETECTION 308
ULTRASONIC IMAGING SUBSYSTEM 316
POWER SOURCE AND MODULATOR 40
ULTRASONIC THERAPEUTIC TRANSDUCER 13
PATIENT
POWER METER 306
TRANSDUCER ELECTRICAL PROPERTIES MEASUREMENT UNIT 304
TRANSDUCER TEMPERATURE SENSOR 36
ACOUSTIC CONTACT MONITORING UNIT302
TEMPERATURE MEASUREMENT UNIT 300
SKIN TEMPERATURE SENSOR 34
TEMPERATURE THRESHOLDS
VIDEO CAMERA 46

Fig. 5A


OPERATOR DRAWS OUTLINE 50 ON PATIENT'S BODY
OPERATOR ADHERES MARKERS 54 AND PLACES TRANSDUCER 10 WITH TRANSDUCER MARKER 56 ON PATIENT'S BODY
VIDEO CAMERA 46 CAPTURES THE OUTLINE 50 , MARKERS 54 AND TRANSDUCER MARKER 56
SHOWS ON DISPLAY 48
STORES IN MEMORY
COMPUTERIZED TRACKING FUNCTIONALITY COMPUTES OUTLINE REPRESENTATION 52
COMPUTERIZED TRACKING FUNCTIONALITY COMPUTES COORDINATES OF THE TARGET VOLUMES TO BE TREATED
COMPUTERIZED TRACKING FUNCTIONALITY COMPUTES THE TOTAL VOLUME TO BE TREATED
OPERATOR CONFIRMS LOCATIONS OF TRANSDUCER MARKER 56 AND MARKERS 54 ON THE DISPLAY 48
COMPUTERIZED TRACKING FUNCTIONALITY COMPUTES THE MARKER REPRESENTATIONS 58 AND TRANSDUCER MARKER REPRESENTATION 60
COMPUTERIZED TRACKING FUNCTIONALITY STARTS CONTINUOUS REREGISTRATION PROCESS
COMPUTERIZED TRACKING FUNCTIONALITY SELECTS FIRST TARGET VOLUME TO BE TREATED
D
POSITIONING CONTROL UNIT COMPUTES REQUIREDREPOSITIONING OF TRANSDUCER 10
X-Y-Z POSITIONING ASSEMBLY 49 MOVES TRANSDUCER TO OVERLAYTHE SELECTEDTARGET VOLUME
A

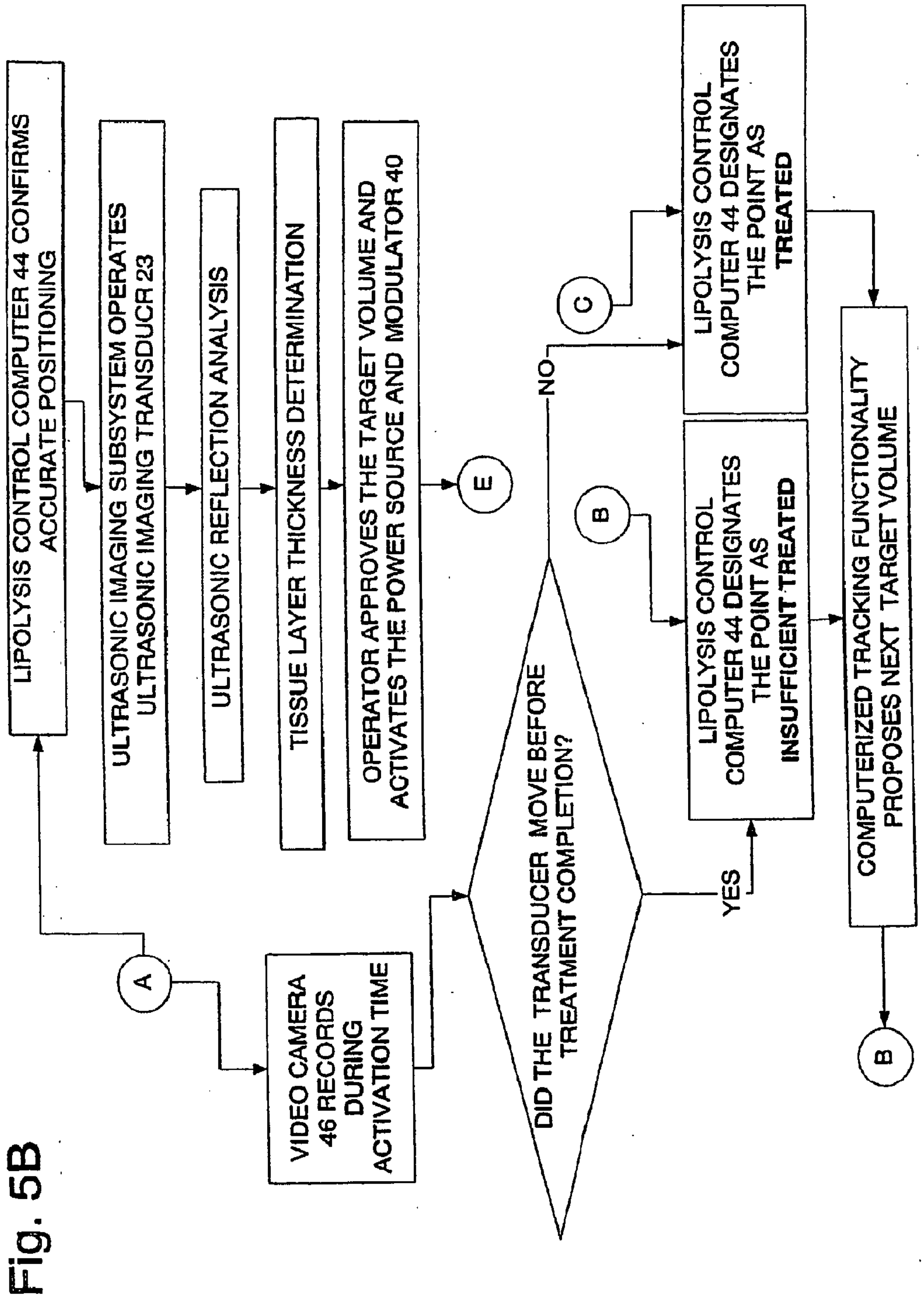

A
LIPOLYSIS CONTROL COMPUTER 44 CONFIRMS ACCURATE POSITIONING
ULTRASONIC IMAGING SUBSYSTEM OPERATES ULTRASONIC IMAGING TRANSDUCR 23
ULTRASONIC REFLECTION ANALYSIS
TISSUE LAYER THICKNESS DETERMINATION
OPERATOR APPROVES THE TARGET VOLUME AND ACTIVATES THE POWER SOURCE AND MODULATOR 40
E
VIDEO CAMERA 46 RECORDS DURING ACTIVATION TIME
DID THE TRANSDUCER MOVE BEFORE TREATMENT COMPLETION?
YES
NO
B
LIPOLYSIS CONTROL COMPUTER 44 DESIGNATES THE POINT AS INSUFFICIENT TREATED
C
LIPOLYSIS CONTROL COMPUTER 44 DESIGNATES THE POINT AS TREATED
COMPUTERIZED TRACKING FUNCTIONALITY PROPOSES NEXT TARGET VOLUME
B

Fig. 5B

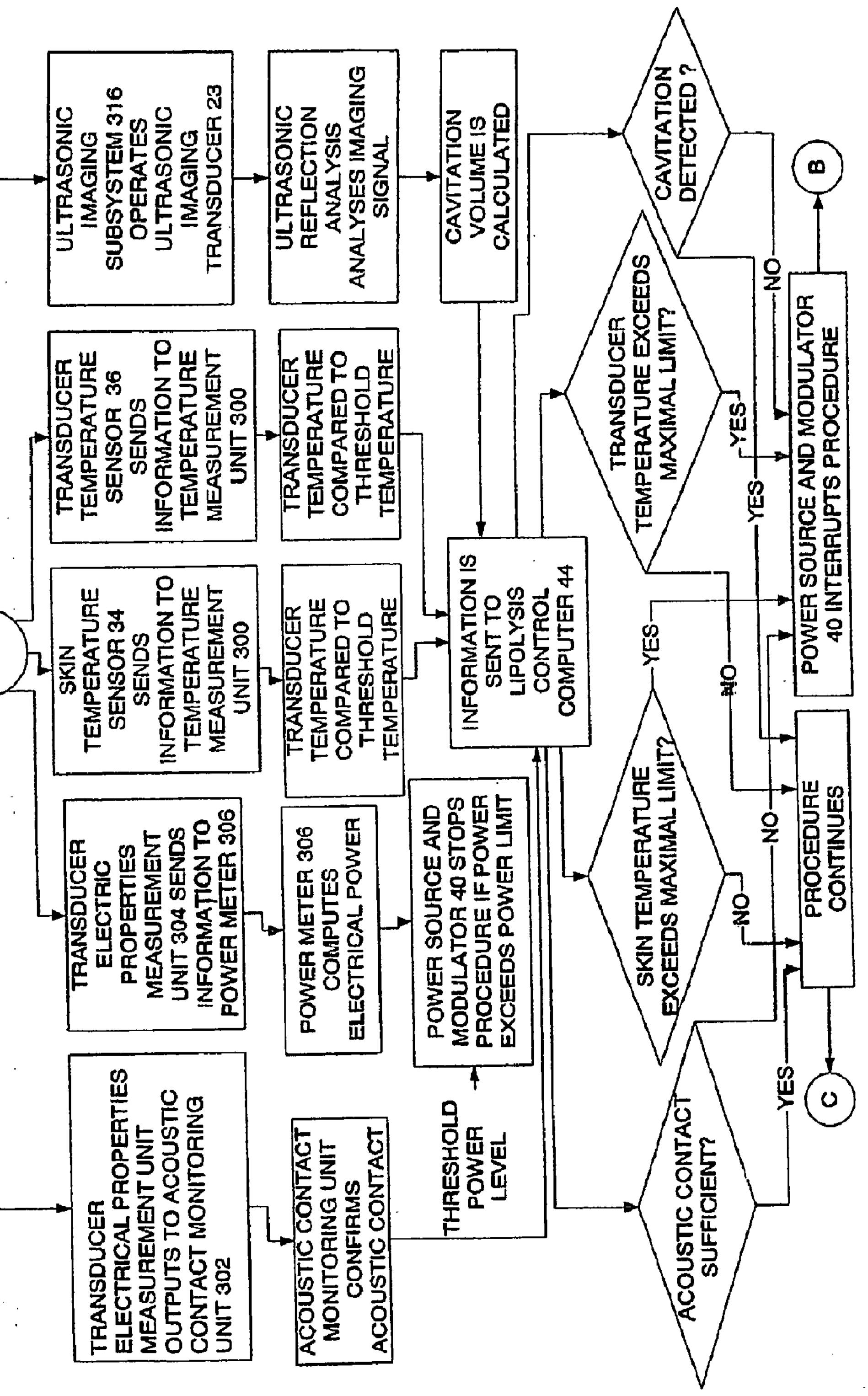

E
TRANSDUCER ELECTRICAL PROPERTIES MEASUREMENT UNIT OUTPUTS TO ACOUSTIC CONTACT MONITORING UNIT 302
ACOUSTIC CONTACT MONITORING UNIT CONFIRMS ACOUSTIC CONTACT
THRESHOLD POWER LEVEL
TRANSDUCER ELECTRIC PROPERTIES MEASUREMENT UNIT 304 SENDS INFORMATION TO POWER METER 306
POWER METER 306 COMPUTES ELECTRICAL POWER
POWER SOURCE AND MODULATOR 40 STOPS PROCEDURE IF POWER EXCEEDS POWER LIMIT
SKIN TEMPERATURE SENSOR 34 SENDS INFORMATION TO TEMPERATURE MEASUREMENT UNIT 300
TRANSDUCER TEMPERATURE COMPARED TO THRESHOLD TEMPERATURE
TRANSDUCER TEMPERATURE SENSOR 36 SENDS INFORMATION TO TEMPERATURE MEASUREMENT UNIT 300
TRANSDUCER TEMPERATURE COMPARED TO THRESHOLD TEMPERATURE
ULTRASONIC IMAGING SUBSYSTEM 316 OPERATES ULTRASONIC IMAGING TRANSDUCER 23
ULTRASONIC REFLECTION ANALYSIS ANALYSES IMAGING SIGNAL
CAVITATION VOLUME IS CALCULATED
INFORMATION IS SENT TO LIPOLYSIS CONTROL COMPUTER 44
ACOUSTIC CONTACT SUFFICIENT?
SKIN TEMPERATURE EXCEEDS MAXIMAL LIMIT?
TRANSDUCER TEMPERATURE EXCEEDS MAXIMAL LIMIT?
CAVITATION DETECTED ?
YES
NO
YES
NO
YES
NO
YES
YES
NO
PROCEDURE CONTINUES
POWER SOURCE AND MODULATOR 40 INTERRUPTS PROCEDURE
C
B

Fig. 5C

NON-INVASIVE ULTRASONIC BODY CONTOURING

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 12/071,382, filed Feb. 20, 2008, which is a continuation of U.S. patent application Ser. No. 10/021,238, now U.S. Pat. No. 7,347,855, filed Oct. 29, 2001.

FIELD OF THE INVENTION

[0002] The present invention relates to lipolysis generally and more particularly to ultrasonic lipolysis.

BACKGROUND OF THE INVENTION

[0003] The following U.S. patents are believed to represent the current state of the art: U.S. Pat. Nos. 4,986,275; 5,143,063; 5,143,073; 5,209,221; 5,301,660; 5,431,621; 5,507,790; 5,526,815; 5,884,631; 6,039,048; 6,071,239; 6,113,558; 6,206,873.

SUMMARY OF THE INVENTION

[0004] There is provided, in accordance with an embodiment, an apparatus for lysing adipose tissue, the apparatus comprising: a power source and modulator assembly configured to supply modulated electrical power; an ultrasonic therapeutic transducer connected to said power source and modulator assembly and configured to convert the modulated electrical power to ultrasonic energy directed at a target volume in a region of a body containing adipose and non-adipose tissue, so as to selectively generally lyse the adipose tissue and generally not lyse the non-adipose tissue; an ultrasonic imaging sub-system configured to identify changes in the target volume resulting from the ultrasonic energy; and a lipolysis control computer configured to control said power source and modulator assembly based on the changes identified by said ultrasonic imaging sub-system.

[0005] In some embodiments, said ultrasonic imaging sub-system comprises an ultrasonic imaging transducer and an ultrasonic reflection analyzer.

[0006] In some embodiments, the changes identified by said ultrasonic imaging sub-system comprise cavitation in the target volume.

[0007] In some embodiments, the changes identified by said ultrasonic imaging sub-system comprise lysis of adipose tissue in the target volume.

[0008] In some embodiments, said ultrasonic therapeutic transducer comprises a director configured to vary a focus of the ultrasonic energy directed towards the target volume.

[0009] In some embodiments, the varying of the focus comprises changing a volume of said target volume.

[0010] In some embodiments, the varying of the focus comprises changing a distance of said target volume from said ultrasonic therapeutic transducer.

[0011] There is further provided, in accordance with an embodiment, a method for selectively lysing adipose tissue, the method comprising: generating a time-varying electrical signal having a series of relatively high amplitude portions separated in time by a series of relatively low amplitude portions; converting the electrical signal to a corresponding ultrasonic signal; and directing the ultrasonic signal towards a target volume in a region of a body containing adipose and non-adipose tissue, thereby inducing selective cavitation in the adipose tissue while generally not lysing the non-adipose tissue in the target volume.

[0012] In some embodiments, the series of relatively high amplitude portions comprises: one or more initial portions having amplitude above a cavitation initiation threshold; and later portions having an amplitude above a cavitation maintenance threshold.

[0013] In some embodiments, the series of relatively low amplitude portions comprises portions having amplitude below the cavitation initiation and maintenance thresholds.

[0014] In some embodiments, the series of relatively high amplitude portions comprises between 25-500 relatively high amplitude portions.

[0015] In some embodiments, the generating of the time-varying electrical signal comprises generating the series of the relatively high amplitude portions and the series of relatively low amplitude portions at a duty cycle of between 1:5 and 1:20.

[0016] In some embodiments, the ultrasonic signal has a frequency in the range of 150-1000 KHz.

[0017] There is yet further provided, in accordance with an embodiment, an automatically-positionable adipose tissue lysis apparatus, comprising: an ultrasonic transducer secured to a three-dimensional positioning assembly, said ultrasonic transducer being configured to direct ultrasonic energy at a target volume in a region of a body containing adipose and non-adipose tissue, so as to selectively generally lyse the adipose tissue and generally not lyse the non-adipose tissue; a lipolysis control computer having a video camera connected thereto, said video camera being configured to externally image a portion of the body, and said lipolysis control computer being configured to detect indications on the imaged portion of the body; and a positioning control unit configured to control said three-dimensional positioning assembly so as to automatically position said ultrasonic transducer based on the detected indications.

[0018] In some embodiments, the apparatus further comprises a lipolysis control computer connected to said positioning control unit and configured to control the directing of the ultrasonic energy from said ultrasonic transducer based on the detected indications.

[0019] In some embodiments, the apparatus further comprises an ultrasonic imaging sub-system connected to said lipolysis control computer and configured to identify changes in the target volume resulting from the ultrasonic energy, wherein said lipolysis control computer is further configured to control the directing of the ultrasonic energy from said ultrasonic transducer based on the identified changes.

[0020] In some embodiments, the changes identified by said ultrasonic imaging sub-system comprise cavitation in the target volume.

[0021] In some embodiments, the changes identified by said ultrasonic imaging sub-system comprise lysis of adipose tissue in the target volume.

[0022] In some embodiments, the apparatus further comprises an ultrasonic imaging sub-system connected to said lipolysis control computer and configured to detect thicknesses of tissue layers in the region of the body, wherein said lipolysis control computer is further configured to control the directing of the ultrasonic energy from said ultrasonic transducer based on the detected thicknesses.

[0023] In some embodiments, said lipolysis control computer is further configured to control a focus of said ultrasonic transducer, so as to vary a distance of said target volume from said ultrasonic transducer.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] The present invention will be understood and appreciated more fully from the following detailed description, taken in conjunction with the drawings in which:

[0025] FIG. **1** is a simplified pictorial illustration of the general structure and operation of ultrasonic lipolysis apparatus constructed and operative in accordance with a preferred embodiment of the present invention;

[0026] FIG. **2** is a simplified block diagram illustration of a preferred power source and modulator showing a pattern of variation of ultrasonic pressure over time in accordance with a preferred embodiment of the present invention;

[0027] FIGS. **3**A and **3**B are simplified pictorial illustrations of the appearance of an operator interface display during normal operation and faulty operation respectively;

[0028] FIG. **4** is a simplified block diagram illustration of an ultrasonic lipolysis system constructed and operative in accordance with a preferred embodiment of the present invention; and

[0029] FIGS. **5**A, **5**B and **5**C are together a simplified flowchart illustrating operator steps in carrying out lipolysis in accordance with a preferred embodiment of the present invention.

DETAILED DESCRIPTION

[0030] Reference is now made to FIG. **1**, which is a simplified pictorial illustration of the general structure and operation of ultrasonic lipolysis apparatus constructed and operative in accordance with a preferred embodiment of the present invention. As seen in FIG. **1**, an ultrasonic energy generator and director, such as an ultrasonic transducer **10**, disposed outside a body, generates ultrasonic energy which, by suitable placement of the transducer **10** relative to the body, is directed to a target volume **12** inside the body and is operative to selectively generally lyse adipose tissue and generally not lyse non-adipose tissue in the target volume.

[0031] A preferred embodiment of ultrasonic energy generator and director useful in the present invention comprises an ultrasonic therapeutic transducer **13** including a curved phased array **14** of piezoelectric elements **15**, typically defining a portion of a sphere or of a cylinder, and having conductive coatings **16** on opposite surfaces thereof. The piezoelectric elements **15** may be of any suitable configuration, shape and distribution. An intermediate element **18**, formed of a material, such as polyurethane, which has acoustic impedance similar to that of soft mammalian tissue, generally fills the curvature defined by phased array **14** and defines a contact surface **20** for engagement with the body, typically via a suitable coupling gel (not shown). Contact surface **20** may be planar, but need not be.

[0032] Suitably modulated AC electrical power is supplied by conductors **22** to conductive coatings **16** to cause the piezoelectric elements **15** to provide a desired focused acoustic energy output.

[0033] In accordance with a preferred embodiment of the present invention an imaging ultrasonic transducer subassembly **23** is incorporated within transducer **10** and typically comprises a piezoelectric element **24** having conductive surfaces **26** associated with opposite surfaces thereof. Suitably modulated AC electrical power is supplied by conductors **32** to conductive surfaces **26** in order to cause the piezoelectric element **24** to provide an acoustic energy output. Conductors **32**, coupled to surfaces **26**, also provide an imaging output from imaging ultrasonic transducer subassembly **23**.

[0034] It is appreciated that any suitable commercially available ultrasonic transducer may be employed or alternatively, imaging ultrasonic transducer subassembly **23** may be eliminated.

[0035] It is further appreciated that various types of ultrasonic transducers **10** may be employed. For example, such transducers may include multiple piezoelectric elements, multilayered piezoelectric elements and piezoelectric elements of various shapes and sizes arranged in a phase array.

[0036] In a preferred embodiment of the present invention shown in FIG. **1**, the ultrasonic energy generator and director are combined in transducer **10**. Alternatively, the functions of generating ultrasonic energy and focusing such energy may be provided by distinct devices.

[0037] In accordance with a preferred embodiment of the present invention, a skin temperature sensor **34**, such as an infrared sensor, may be mounted alongside imaging ultrasonic transducer subassembly **23**. Further in accordance with a preferred embodiment of the present invention a transducer temperature sensor **36**, such as a thermocouple, may also be mounted alongside imaging ultrasonic transducer subassembly **23**.

[0038] Ultrasonic transducer **10** preferably receives suitably modulated electrical power from a power source and modulator assembly **40**, forming part of a control subsystem **42**. Control subsystem **42** also typically includes a lipolysis control computer **44**, having associated therewith a camera **46**, such as a video camera, and a display **48**. A preferred embodiment of power source and modulator assembly **40** is illustrated in FIG. **2** and described hereinbelow. Ultrasonic transducer **10** is preferably positioned automatically or semi-automatically as by an X-Y-Z positioning assembly **49**. Alternatively, ultrasonic transducer **10** may be positioned at desired positions by an operator.

[0039] In accordance with a preferred embodiment of the present invention, camera **46** is operative for imaging a portion of the body on which lipolysis is to be performed. A picture of the portion of the patient's body viewed by the camera is preferably displayed in real time on display **48**.

[0040] An operator may designate the outline of a region containing adipose tissue. In accordance with one embodiment of the present invention, designation of this region is effected by an operator marking the skin of a patient with an outline **50**, which outline is imaged by camera **46** and displayed by display **48** and is also employed by the lipolysis control computer **44** for controlling the application of ultrasonic energy to locations within the region. A computer calculated representation of the outline may also be displayed on display **48**, as designated by reference numeral **52**. Alternatively, the operator may make a virtual marking on the skin, such as by using a digitizer (not shown), which also may provide computer calculated outline representation **52** on display **48**.

[0041] In addition to the outline representation **52**, the functionality of the system of the present invention preferably also employs a plurality of markers **54** which are typically located outside the region containing adipose tissue, but may be located inside the region designated by outline **50**. Markers

54 are visually sensible markers, which are clearly seen by camera 46, captured by camera 46 and displayed on display 48. Markers 54 may be natural anatomic markers, such as distinct portions of the body or alternatively artificial markers such as colored stickers. These markers are preferably employed to assist the system in dealing with deformation of the region nominally defined by outline 50 due to movement and reorientation of the body. Preferably, the transducer 10 also bears a visible marker 56 which is also captured by camera 46 and displayed on display 48.

[0042] Markers 54 and 56 are typically processed by computer 44 and may be displayed on display 48 as respective computed marker representations 58 and 60 on display 48.

[0043] FIG. 1 illustrates the transducer 10 being positioned on the body over a location within the region containing adipose tissue. Blocks designated by reference numerals 62 and 64 show typical portions of a region containing adipose tissue, respectively before and after lipolysis in accordance with a preferred embodiment of the invention. It is seen from a comparison of blocks 62 and 64 that, in accordance with a preferred embodiment of the present invention, within the region containing adipose tissue, the adipose tissue, designated by reference numeral 66, is lysed, while non-adipose tissue, such as connective tissue, designated by reference numeral 68, is not lysed.

[0044] Reference is now FIG. 2, which is a simplified block diagram illustration of a preferred power source and modulator assembly 40 (FIG. 1), showing a pattern of variation of ultrasonic pressure over time in accordance with a preferred embodiment of the present invention. As seen in FIG. 2, the power source and modulator assembly 40 preferably comprises a signal generator 100 which provides a time varying signal which is modulated so as to have a series of relatively high amplitude portions 102 separated in time by a series of typically relatively low amplitude portions 104. Each relatively high amplitude portion 102 preferably corresponds to a cavitation period and preferably has a decreasing amplitude over time.

[0045] Preferably the relationship between the time durations of portions 102 and portions 104 is such as to provide a duty cycle between 1:2 and 1:250, more preferably between 1:5 and 1:30 and most preferably between 1:10 and 1:20.

[0046] Preferably, the output of signal generator 100 has a frequency in a range of 50 KHz-1000 KHz, more preferably between 100 KHz-500 KHz and most preferably between 150 KHz-300 KHz.

[0047] The output of signal generator 100 is preferably provided to a suitable power amplifier 106, which outputs via impedance matching circuitry 108 to an input of ultrasonic transducer 10

[0048] (FIG. 1), which converts the electrical signal received thereby to a corresponding ultrasonic energy output. As seen in FIG. 2, the ultrasonic energy output comprises a time varying signal which is modulated correspondingly to the output of signal generator 100 so as to having a series of relatively high amplitude portions 112, corresponding to portions 102, separated in time by a series of typically relatively low amplitude portions 114, corresponding to portions 104.

[0049] Each relatively high amplitude portion 102 preferably corresponds to a cavitation period and has an amplitude at a target volume 12 (FIG. 1) in the body which exceeds a cavitation maintaining threshold 120 and preferably has a decreasing amplitude over time. At least an initial pulse of each relatively high amplitude portion 112 has an amplitude at the target volume 12, which also exceeds a cavitation initiation threshold 122.

[0050] Relatively low amplitude portions 114 have an amplitude which lies below both thresholds 120 and 122.

[0051] Preferably the relationship between the time durations of portions 112 and portions 114 is such as to provide a duty cycle between 1:2 and 1:250, more preferably between 1:5 and 1:30 and most preferably between 1:10 and 1:20.

[0052] Preferably, the ultrasonic energy output of ultrasonic transducer 10 has a frequency in a range of 50 KHz-1000 KHz, more preferably between 100 KHz-500 KHz and most preferably between 150 KHz-300 KHz.

[0053] Preferably, each high amplitude portion 112 is comprised of between 2 and 1000 sequential cycles at an amplitude above the cavitation maintaining threshold 120, more preferably between 25 and 500 sequential cycles at an amplitude above the cavitation maintaining threshold 120 and most preferably between 100 and 300 sequential cycles at an amplitude above the cavitation maintaining threshold 120.

[0054] Reference is now made to FIGS. 3A and 3B, which are simplified pictorial illustrations of the appearance of an operator interface display during normal operation and faulty operation respectively. As seen in FIG. 3A, during normal operation, display 48 typically shows a plurality of target volumes 12 (FIG. 1) within a calculated target region 200, typically delimited by outline representation 52 (FIG. 1). Additionally, display 48 preferably provides one or more pre-programmed performance messages 202 and status messages 203.

[0055] It is seen the various target volumes 12 are shown with different shading in order to indicate their treatment status. For example, unshaded target volumes, here designated by reference numerals 204 have already experienced lipolysis. A blackened target volume 12, designated by reference numeral 205 is the target volume next in line for lipolysis. A partially shaded target volume 206 typically represents a target volume which has been insufficiently treated to achieve complete lipolysis, typically due to an insufficient treatment duration.

[0056] Other types of target volumes, such as those not to be treated due to insufficient presence of adipose tissue therein or for other reasons, may be designated by suitable colors or other designations, and are here indicated by reference numerals 208 and 210.

[0057] Typical performance messages 202 may include "CAVITATION IN PROCESS" and "FAT LYSED IN THIS VOLUME". Typical status messages 203 may include an indication of the power level, the operating frequency, the number of target volumes 12 within the calculated target region 200 and the number of target volumes 12 which remain to undergo lipolysis.

[0058] Display 48 also preferably includes an graphical cross sectional indication 212 derived from an ultrasonic image preferably provided by imaging ultrasonic transducer subassembly 23 (FIG. 1). Indication 212 preferably indicates various tissues in the body in cross section and shows the target volumes 12 in relation thereto. In accordance with a preferred embodiment of the present invention, indication 212 may also provide a visually sensible indication of cavitation within the target volume 12.

[0059] Turning to FIG. 3B, it is seen that during abnormal operation, display 48 provides pre-programmed warning messages 214.

[0060] Typical warning messages may include "BAD ACOUSTIC CONTACT", "TEMPERATURE TOO HIGH". The "TEMPERATURE TOO HIGH" message typically relates to the skin tissue, although it may alternatively or additionally relate to other tissue inside or outside of the target volume or in transducer **10** (FIG. **1**).

[0061] Reference is now made to FIG. **4**, which illustrates an ultrasonic lipolysis system constructed and operative in accordance with a preferred embodiment of the present invention. As described hereinabove with reference to FIG. **1** and as seen in FIG. **4**, the ultrasonic lipolysis system comprises a lipolysis control computer **44** which outputs to a display **48**. Lipolysis control computer **44** preferably receives inputs from video camera **46** (FIG. **1**) and from a temperature measurement unit **300**, which receives temperature threshold settings as well as inputs from skin temperature sensor **34** (FIG. **1**) and transducer temperature sensor **36** (FIG. **1**). Temperature measurement unit **300** preferably compares the outputs of both sensors **34** and **36** with appropriate threshold settings and provides an indication to lipolysis control computer **44** of exceedance of either threshold.

[0062] Lipolysis control computer **44** also preferably receives an input from an acoustic contact monitoring unit **302**, which in turn preferably receives an input from a transducer electrical properties measurement unit **304**. Transducer electrical properties measurement unit **304** preferably monitors the output of power source and modulator assembly **40** (FIG. **1**) to ultrasonic therapeutic transducer **13**.

[0063] An output of transducer electrical properties measurement unit **304** is preferably also supplied to a power meter **306**, which provides an output to the lipolysis control computer **44** and a feedback output to power source and modulator assembly **40**.

[0064] Lipolysis control computer **44** also preferably receives inputs from cavitation detection functionality **308**, tissue layer identification functionality **310** and lysed adipose tissue identification functionality **312**, all of which receive inputs from ultrasonic reflection analysis functionality **314**. Ultrasonic reflection analysis functionality **314** receives ultrasonic imaging inputs from an ultrasonic imaging subsystem **316**, which operates ultrasonic imaging transducer **23** (FIG. **1**).

[0065] Lipolysis control computer **44** provides outputs to power source and modulator assembly **40**, for operating ultrasonic therapeutic transducer **13**, and to ultrasonic imaging subsystem **316**, for operating ultrasonic imaging transducer **23**. A positioning control unit **318** also receives an output from lipolysis control computer **44** for driving X-Y-Z positioning assembly **49** (FIG. **1**) in order to correctly position transducer **10**, which includes ultrasonic therapeutic transducer **13** and ultrasonic imaging transducer **23**.

[0066] Reference is now made to FIGS. **5**A, **5**B and **5**C, which are together a simplified flowchart illustrating operator steps in carrying out lipolysis in accordance with a preferred embodiment of the present invention. As seen in FIG. **4**A, initially an operator preferably draws an outline **50** (FIG. **1**) on a patient's body. Preferably, the operator also adheres stereotactic markers **54** (FIG. **1**) to the patient's body and places transducer **10**, bearing marker **56**, at a desired location within outline **50**.

[0067] Camera **46** (FIG. **1**) captures outline **50** and markers **54** and **56**. Preferably, outline **50** and markers **54** and **56** are displayed on display **48** in real time. The output of camera **46** is also preferably supplied to a memory associated with lipolysis control computer **44** (FIG. **1**).

[0068] A computerized tracking functionality preferably embodied in lipolysis control computer **44** preferably employs the output of camera **46** for computing outline representation **52**, which may be displayed for the operator on display **48**. The computerized tracking functionality also preferably computes coordinates of target volumes for lipolysis treatment, as well as adding up the total volume of tissue sought to undergo lipolysis.

[0069] Preferably, the operator confirms the locations of markers **54** and **56** on display **48** and the computerized tracking functionality calculates corresponding marker representations **58** and **60**.

[0070] In accordance with a preferred embodiment of the present invention the computerized tracking functionality employs markers **54** and marker representations **58** for continuously maintaining registration of outline **50** with respect to outline representation **52**, and thus of target volumes **12** with respect to the patient's body, notwithstanding movements of the patients body during treatment, such as due to breathing or any other movements, such as the patient leaving and returning to the treatment location.

[0071] The computerized tracking functionality selects an initial target volume to be treated and positioning control unit **318** (FIG. **4**), computes the required repositioning of transducer **10**. X-Y-Z positioning assembly **49** repositions transducer **10** to overlie the selected target volume.

[0072] Referring additionally to FIG. **5**B, it is seen that following repositioning of transducer **10**, the lipolysis control computer **44** confirms accurate positioning of transducer **10** with respect to the selected target volume. The ultrasonic imaging subsystem **316** (FIG. **4**) operates ultrasonic imaging transducer **23**, causing it to provide an ultrasonic reflection analysis functionality **314** for analysis.

[0073] Based on an output from ultrasonic reflection analysis functionality **314**, the thicknesses of the various tissue layers of the patient are determined. Upon receiving an indication of the tissue layer thicknesses, an operator may approve the selected target volume and activates the power source and modulator assembly **40** (FIG. **1**).

[0074] Turning additionally to FIG. **5**C, it is seen that the following functionalities take place:

[0075] Transducer electrical properties measurement unit **304** provides an output to acoustic contact monitoring unit **302**, which determines whether sufficient acoustic contact with the patient is present, preferably by analyzing the current and voltage at therapeutic transducer **13**.

[0076] Transducer electrical properties measurement unit **304** provides an output to power meter **306**, which computes the average electrical power received by the therapeutic transducer **13**. If the average electrical power received by the therapeutic transducer **13** exceeds a predetermined threshold, operation of the power source and modulator assembly **40** may be automatically terminated.

[0077] Skin temperature sensor **34** measures the current temperature of the skin at transducer **10** and supplies it to temperature measurement unit **300**, which compares the skin temperature to the threshold temperature. Similarly, transducer temperature sensor **36** measures the current temperature at transducer **10** and supplies it to temperature measurement unit **300**, which compares the transducer temperature to the threshold temperature. The outputs of temperature measurement unit **300** are supplied to lipolysis control computer **44**.

[0078] The ultrasonic imaging subsystem **316** operates ultrasonic imaging transducer **23** and receives an imaging output, which is analyzed by ultrasonic reflection analysis functionality **314**. The result of this analysis is employed for cavitation detection and a cavitation detection output is supplied to lipolysis control computer **44**.

[0079] Should any of the following four conditions occur, the power source and modulator assembly **40** automatically terminates operation of therapeutic transducer **13**. Should none of the following conditions occur, the automatic operation of power source and modulator assembly **40** continues:

[0080] 1. Acoustic contact is insufficient.

[0081] 2. Skin temperature exceeds threshold temperature level.

[0082] 3. Transducer **13** temperature exceeds threshold temperature level.

[0083] 4. Cavitation is not detected.

[0084] Returning to FIG. **5**B, it is noted that during automatic operation of power source and modulator assembly **40**, video camera **46** preferably records the target region and notes whether the transducer **10** remained stationary during the entire treatment duration of the selected target volume **12**. If so, and if none of the aforesaid four conditions took place, lipolysis control computer **44** confirms that the selected target volume was treated. The computerized tracking functionality of lipolysis control computer **44** then proposes a further target volume **12** to be treated.

[0085] If, however, the transducer **10** did not remain stationary for a sufficient duration, the selected target volume is designated by lipolysis control computer **44** as having been insufficiently treated.

[0086] It is appreciated that by using multiple transducers multiplicity of target volumes can be treated at various time patterns such as sequential time patterns or partially overlapping time patterns.

[0087] It is also appreciated that the multiplicity of target volumes may also overlap in space or partially overlap in space.

[0088] The computational tracking functionality is set forth in the Computer Program Listing Appendix of U.S. Pat. No. 7,347,855, which is incorporated herein by reference in its entirety.

[0089] It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described hereinabove. Rather the scope of the present invention includes both combinations and subcombinations of the various features described hereinabove as well as variations and modifications which would occur to persons skilled in the art upon reading the specification and which are not in the prior art.

What is claimed is:

1. An apparatus for lysing adipose tissue, the apparatus comprising:

a power source and modulator assembly configured to supply modulated electrical power;

an ultrasonic therapeutic transducer connected to said power source and modulator assembly and configured to convert the modulated electrical power to ultrasonic energy directed at a target volume in a region of a body containing adipose and non-adipose tissue, so as to selectively generally lyse the adipose tissue and generally not lyse the non-adipose tissue;

an ultrasonic imaging sub-system configured to identify changes in the target volume resulting from the ultrasonic energy; and

a lipolysis control computer configured to control said power source and modulator assembly based on the changes identified by said ultrasonic imaging sub-system.

2. The apparatus according to claim **1**, wherein said ultrasonic imaging sub-system comprises an ultrasonic imaging transducer and an ultrasonic reflection analyzer.

3. The apparatus according to claim **2**, wherein the changes identified by said ultrasonic imaging sub-system comprise cavitation in the target volume.

4. The apparatus according to claim **2**, wherein the changes identified by said ultrasonic imaging sub-system comprise lysis of adipose tissue in the target volume.

5. The apparatus according to claim **1**, wherein said ultrasonic therapeutic transducer comprises a director configured to vary a focus of the ultrasonic energy directed towards the target volume.

6. The apparatus according to claim **5**, wherein the varying of the focus comprises changing a volume of said target volume.

7. The apparatus according to claim **5**, wherein the varying of the focus comprises changing a distance of said target volume from said ultrasonic therapeutic transducer.

8. A method for selectively lysing adipose tissue, the method comprising:

generating a time-varying electrical signal having a series of relatively high amplitude portions separated in time by a series of relatively low amplitude portions;

converting the electrical signal to a corresponding ultrasonic signal; and

directing the ultrasonic signal towards a target volume in a region of a body containing adipose and non-adipose tissue, thereby inducing selective cavitation in the adipose tissue while generally not lysing the non-adipose tissue in the target volume.

9. The method according to claim **8**, wherein the series of relatively high amplitude portions comprises:

one or more initial portions having amplitude above a cavitation initiation threshold; and

later portions having an amplitude above a cavitation maintenance threshold.

10. The method according to claim **9**, wherein the series of relatively low amplitude portions comprises portions having amplitude below the cavitation initiation and maintenance thresholds.

11. The method according to claim **9**, wherein the series of relatively high amplitude portions comprises between 25-500 relatively high amplitude portions.

12. The method according to claim **8**, wherein the generating of the time-varying electrical signal comprises generating the series of the relatively high amplitude portions and the series of relatively low amplitude portions at a duty cycle of between 1:5 and 1:20.

13. The method according to claim **8**, wherein the ultrasonic signal has a frequency in the range of 150-1000 KHz.

14. An automatically-positionable adipose tissue lysis apparatus, comprising:

an ultrasonic transducer secured to a three-dimensional positioning assembly, said ultrasonic transducer being configured to direct ultrasonic energy at a target volume in a region of a body containing adipose and non-adipose tissue, so as to selectively generally lyse the adipose tissue and generally not lyse the non-adipose tissue;

a lipolysis control computer having a video camera connected thereto, said video camera being configured to externally image a portion of the body, and said lipolysis control computer being configured to detect indications on the imaged portion of the body; and

a positioning control unit configured to control said three-dimensional positioning assembly so as to automatically position said ultrasonic transducer based on the detected indications.

15. The apparatus according to claim **14**, further comprising a lipolysis control computer connected to said positioning control unit and configured to control the directing of the ultrasonic energy from said ultrasonic transducer based on the detected indications.

16. The apparatus according to claim **15**, further comprising an ultrasonic imaging sub-system connected to said lipolysis control computer and configured to identify changes in the target volume resulting from the ultrasonic energy, wherein said lipolysis control computer is further configured to control the directing of the ultrasonic energy from said ultrasonic transducer based on the identified changes.

17. The apparatus according to claim **16**, wherein the changes identified by said ultrasonic imaging sub-system comprise cavitation in the target volume.

18. The apparatus according to claim **16**, wherein the changes identified by said ultrasonic imaging sub-system comprise lysis of adipose tissue in the target volume.

19. The apparatus according to claim **15**, further comprising an ultrasonic imaging sub-system connected to said lipolysis control computer and configured to detect thicknesses of tissue layers in the region of the body, wherein said lipolysis control computer is further configured to control the directing of the ultrasonic energy from said ultrasonic transducer based on the detected thicknesses.

20. The apparatus according to claim **19**, wherein said lipolysis control computer is further configured to control a focus of said ultrasonic transducer, so as to vary a distance of said target volume from said ultrasonic transducer.

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[标]申请(专利权)人(译)	超形态公司		
申请(专利权)人(译)	ULTRASHAPE LTD.		
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摘要(译)

一种用于裂解脂肪组织的装置，该装置包括电源和调制器组件，其配置成提供调制的电能;超声治疗换能器，连接到所述电源和调制器组件，并配置成将调制的电功率转换成指向包含脂肪和非脂肪组织的身体区域中的目标体积的超声能量，以便选择性地通常裂解脂肪组织并且通常不溶解非脂肪组织;超声成像子系统，被配置为识别由超声能量产生的目标体积的变化;和脂解控制计算机，配置成基于由所述超声成像子系统识别的变化来控制所述电源和调制器组件。