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Mak et al.

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(45) **Date of Patent: Dec. 17, 2002**

(54) **PORTABLE ULTRASONIC PALPATION SYSTEM**

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(73) Assignee: **The Hong Kong Polytechnic University**, Kowloon (HK)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 32 days.

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

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

(52) **U.S. Cl.** **600/446**; 600/587; 600/552; 600/480; 600/443; 73/81

(58) **Field of Search** 600/446, 568, 600/436, 588, 300, 566, 448, 567, 159, 463, 587, 480, 552, 443; 73/81, 82

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Primary Examiner—Marvin M. Lateef
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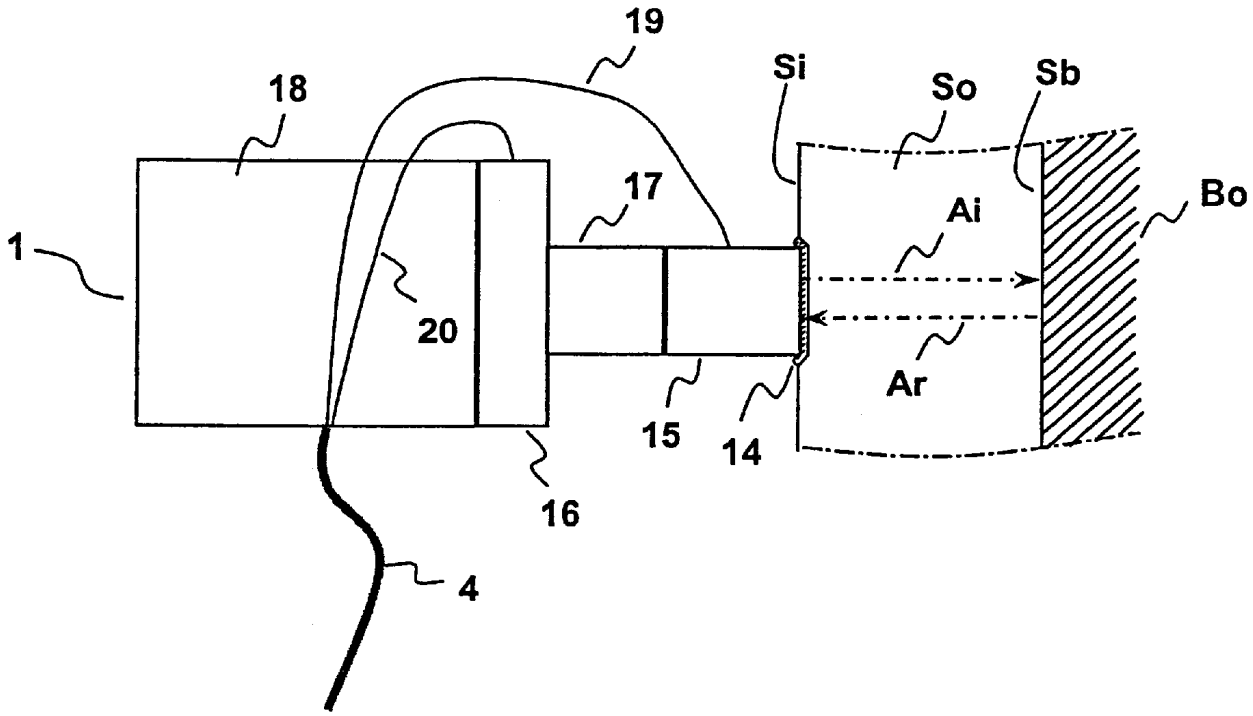
(57) **ABSTRACT**

A portable ultrasound palpation device for measuring the Young's modulus and the thickness of a soft tissue layer includes a hand-holdable palpation probe having an ultrasonic transceiver connected in series with a load cell. During a test, the probe is placed on the tissue surface with a bony substratum. As the operator manually loads and unloads the probe on the tissue surface, a program embedded in a microprocessor module continuously causes the ultrasound emitter to emit ultrasound pulses into the soft tissue. The ultrasound echo signal reflected from the bony interface is received and its flight time is used by the program to calculate the original thickness and the deformation of the soft tissue. The corresponding load applied to the tissue is continuously recorded by the load cell, its driver, and amplifier module, and the data collection module. After collecting the data for a preset number of loading-unloading cycles, the program computes the Young's modulus of the soft tissue from the load-indentation response using an analytical solution of indentation on a layer.

6 Claims, 18 Drawing Sheets



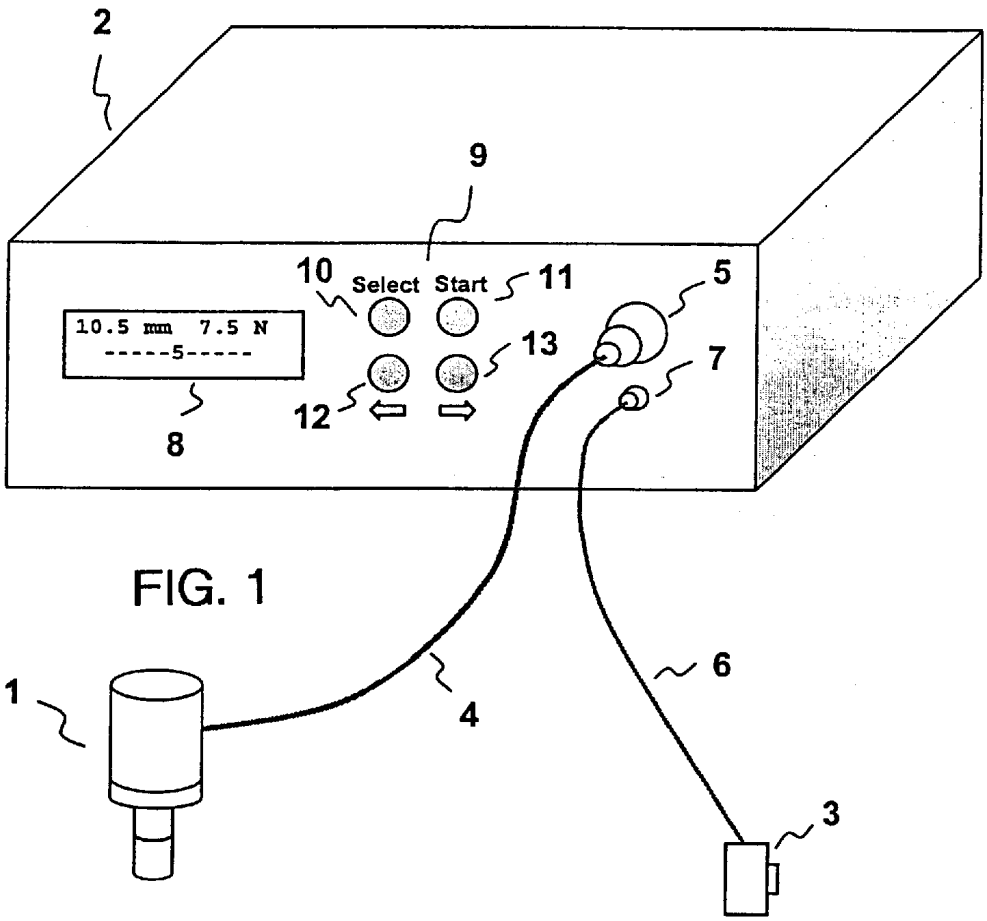

2
9
10
Select
Start
11
5
10.5 mm 7.5 N
-----5-----
13
7
12
8
1
4
6
3

FIG. 1

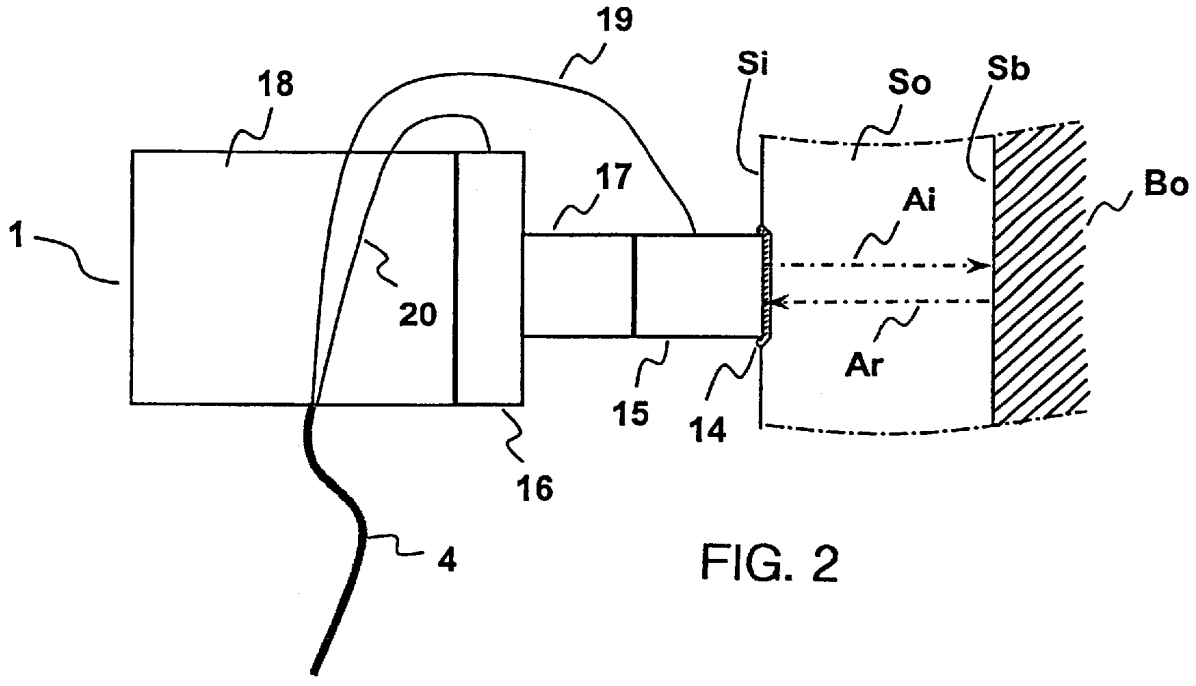

19
18
Si
So
Sb
17
Ai
Bo
1
20
Ar
15
14
16
4

FIG. 2

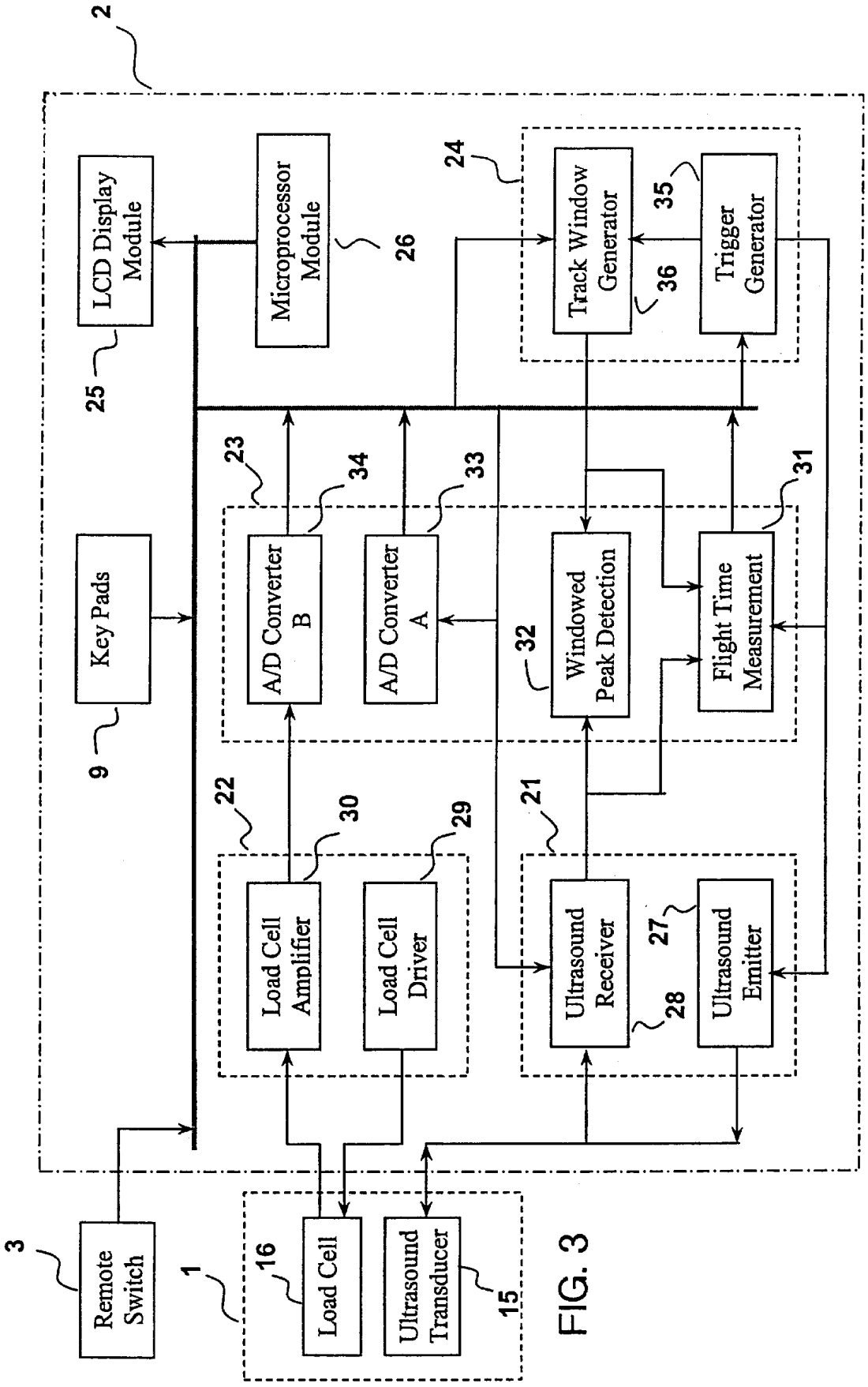

2
LCD Display Module
25
Microprocessor Module
26
24
Track Window Generator
35
36
Trigger Generator
23
34
33
31
Key Pads
9
A/D Converter B
A/D Converter A
32
Windowed Peak Detection
Flight Time Measurement
22
30
29
21
Load Cell Amplifier
Load Cell Driver
Ultrasound Receiver
27
28
Ultrasound Emitter
3
Remote Switch
1
16
Load Cell
Ultrasound Transducer
15

FIG. 3

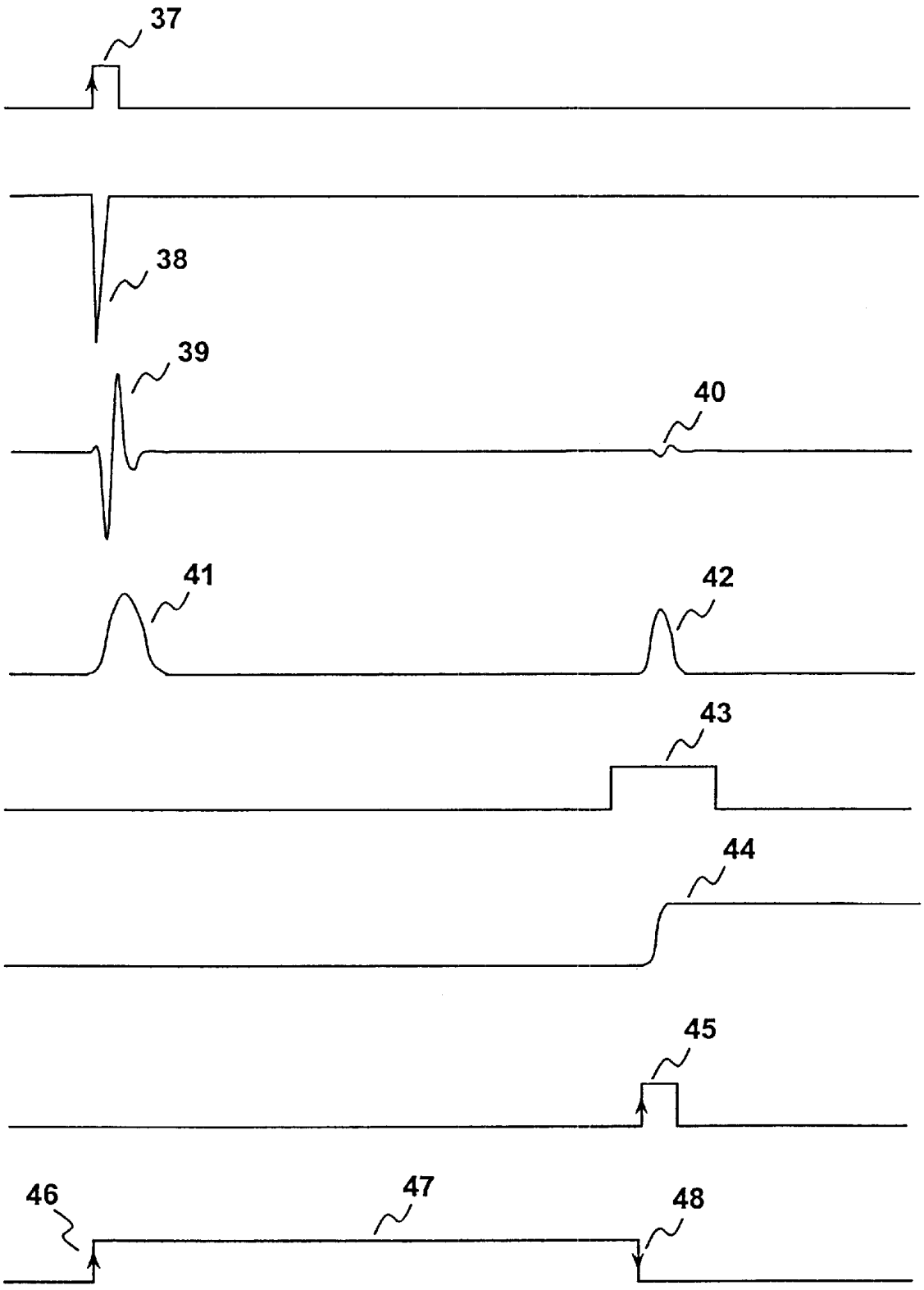


FIG. 4

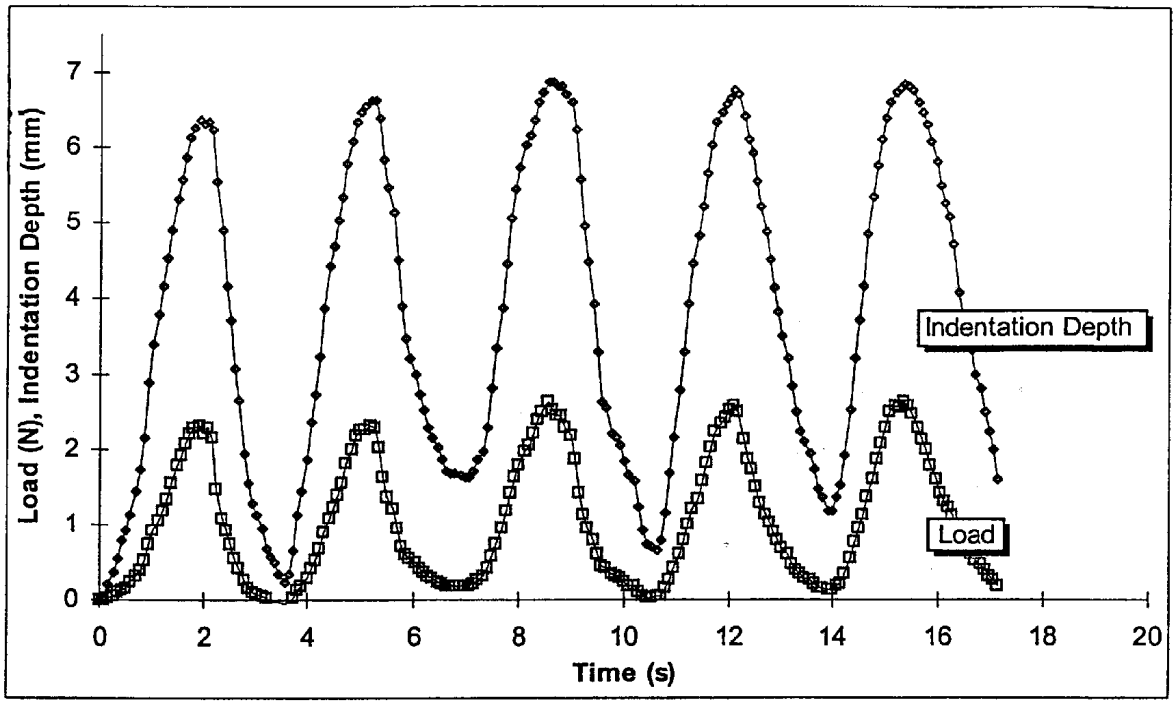

Load (N), Indentation Depth (mm)
Time (s)
Indentation Depth
Load
0
1
2
3
4
5
6
7
0
2
4
6
8
10
12
14
16
18
20

FIG. 5

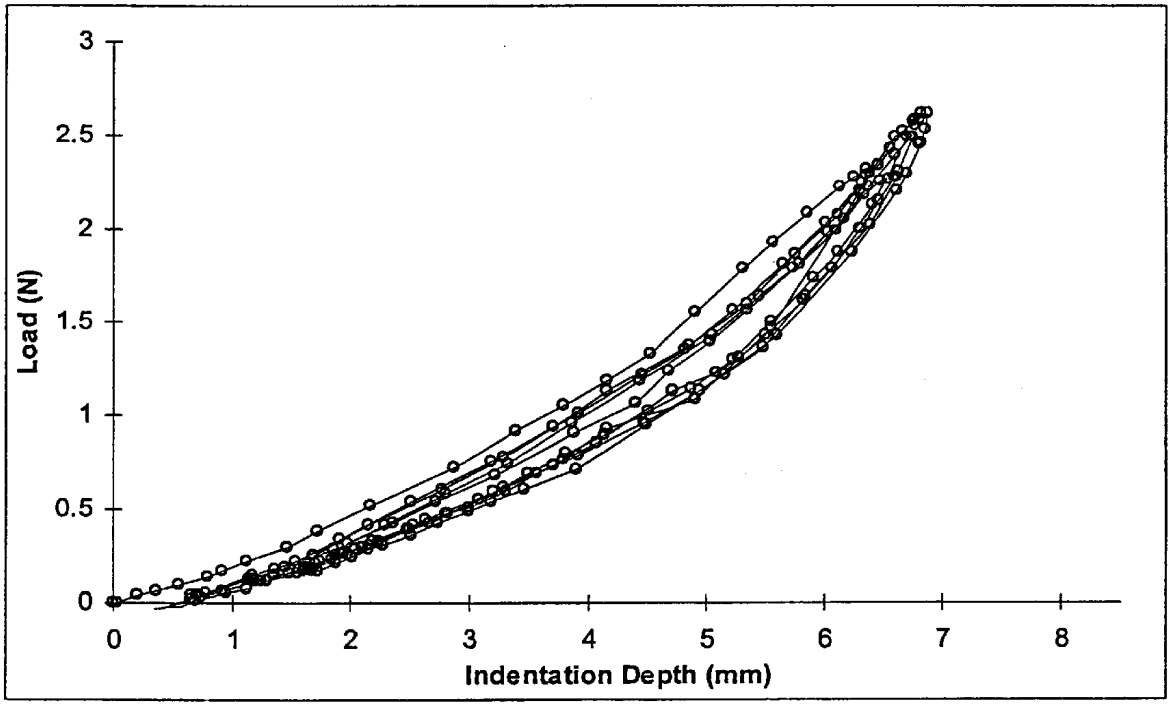

Load (N)
Indentation Depth (mm)
0
0.5
1
1.5
2
2.5
3
0
1
2
3
4
5
6
7
8

FIG. 6

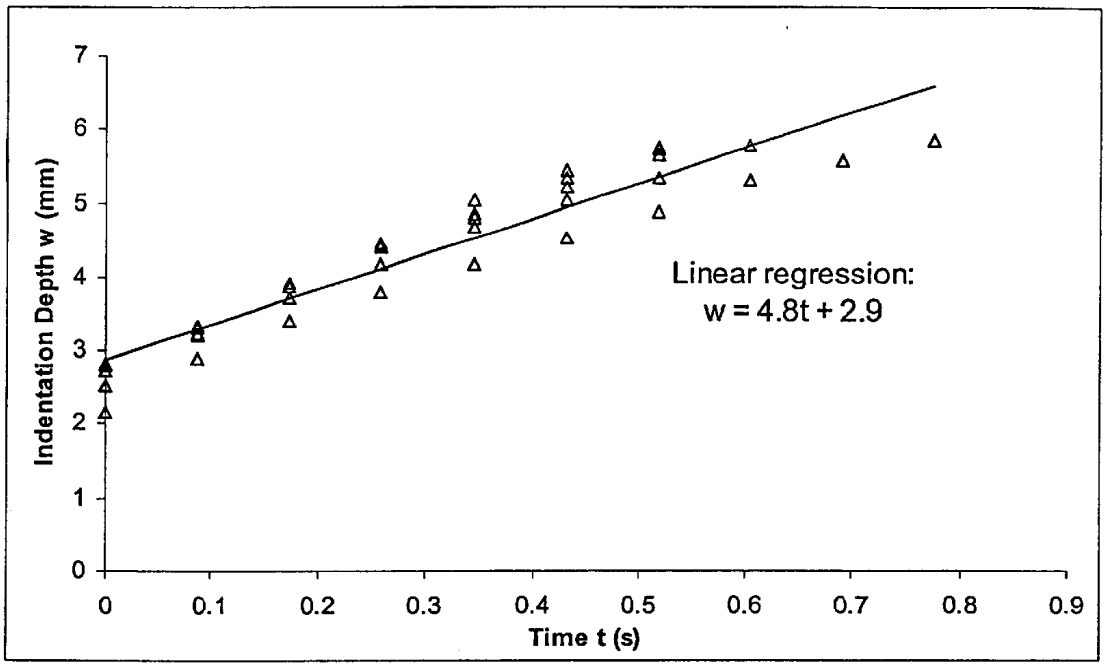


FIG. 7

ν \ a/h	0	0.2	0.4	0.6	0.8	1	1.5	2
0.1	1.000	1.207	1.459	1.717	1.997	2.293	3.107	3.898
0.2	1.000	1.212	1.479	1.755	2.055	2.371	3.222	4.058
0.3	1.000	1.207	1.472	1.784	2.124	2.480	3.400	4.335
0.35	1.000	1.218	1.502	1.839	2.211	2.603	3.629	4.685
0.4	1.000	1.232	1.542	1.917	2.337	2.789	3.996	5.271
0.45	1.000	1.252	1.599	2.031	2.532	3.085	4.638	6.380
0.5	1.000	1.281	1.683	2.211	2.855	3.609	5.970	9.069

FIG. 8

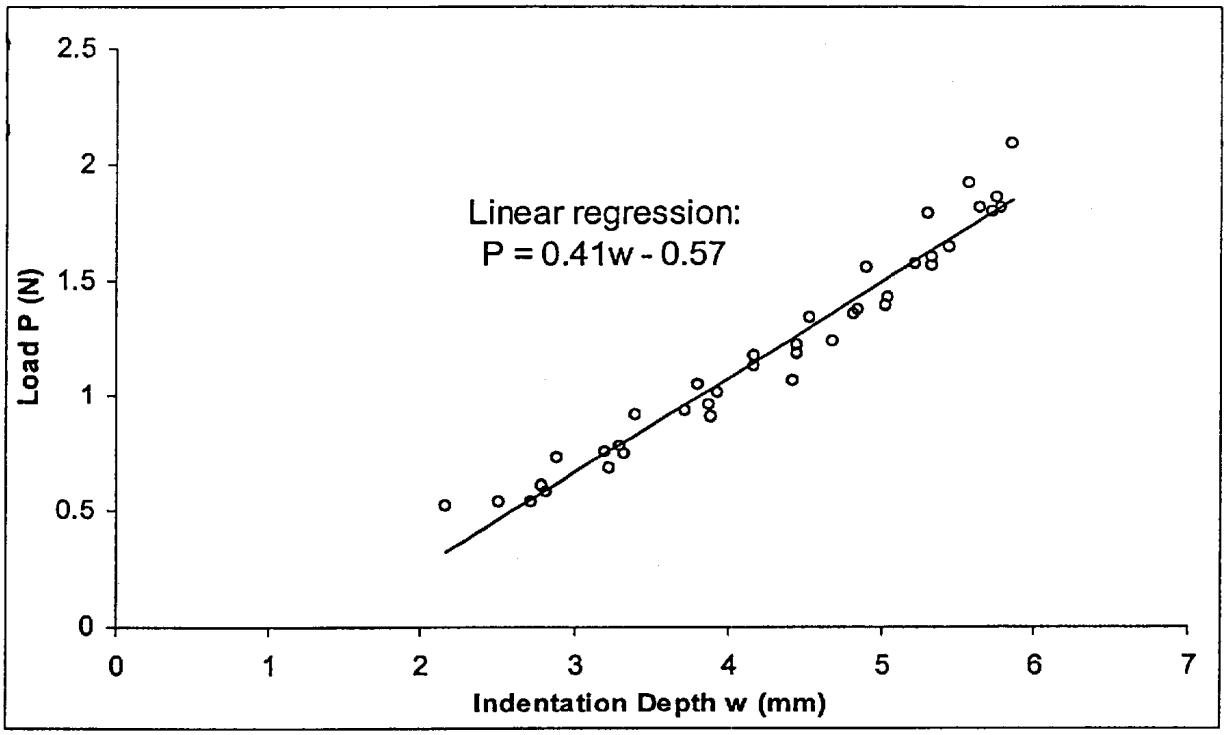

Linear regression:
P = 0.41w - 0.57
Load P (N)
Indentation Depth w (mm)
0
0.5
1
1.5
2
2.5
0
1
2
3
4
5
6
7

FIG. 9

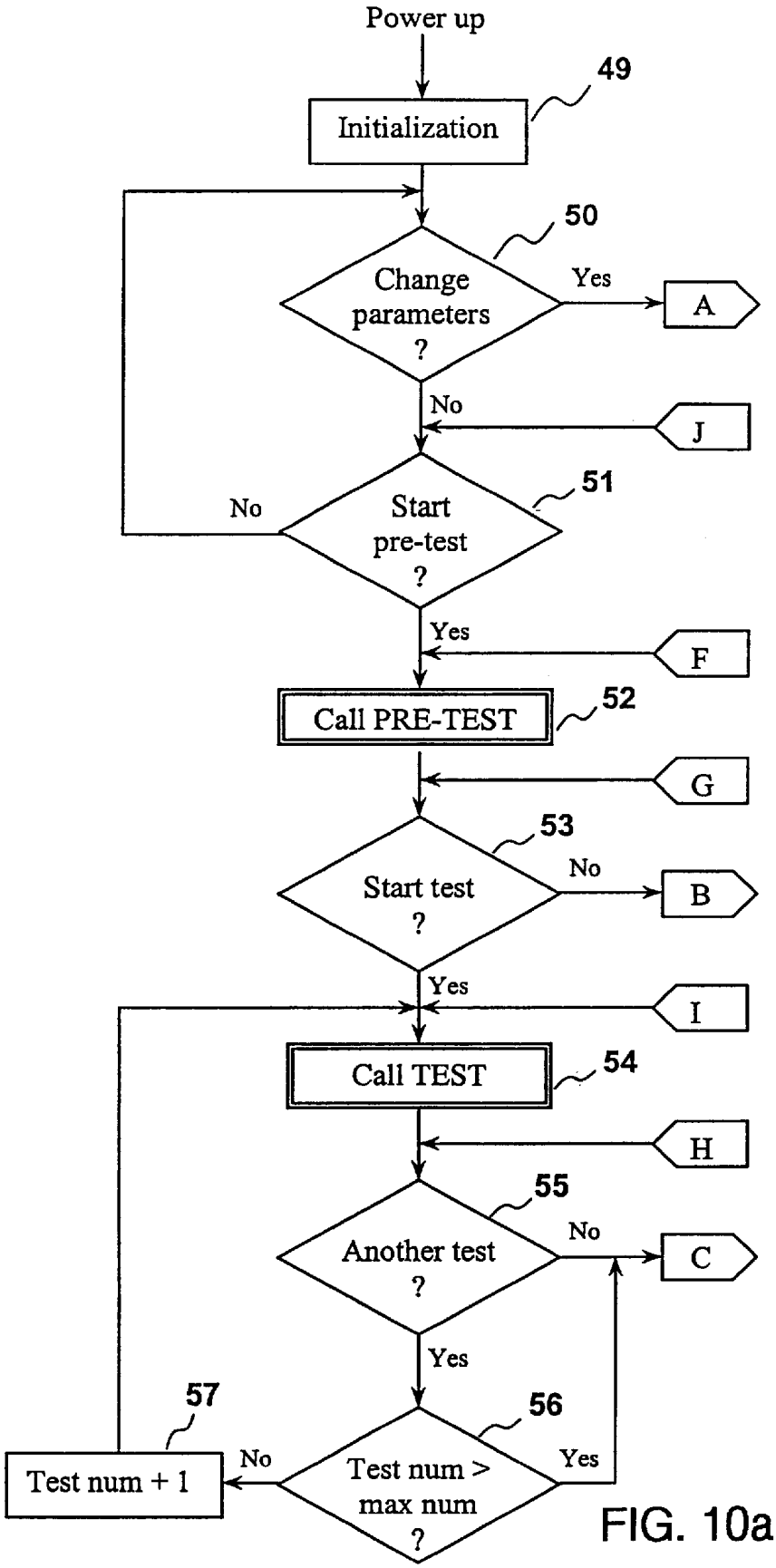

Power up
49
Initialization
50
Change parameters ?
Yes
A
No
J
51
Start pre-test ?
No
Yes
F
Call PRE-TEST
52
G
53
Start test ?
No
B
Yes
I
Call TEST
54
H
55
Another test ?
No
C
Yes
57
56
Test num + 1
No
Test num > max num ?
Yes

FIG. 10a

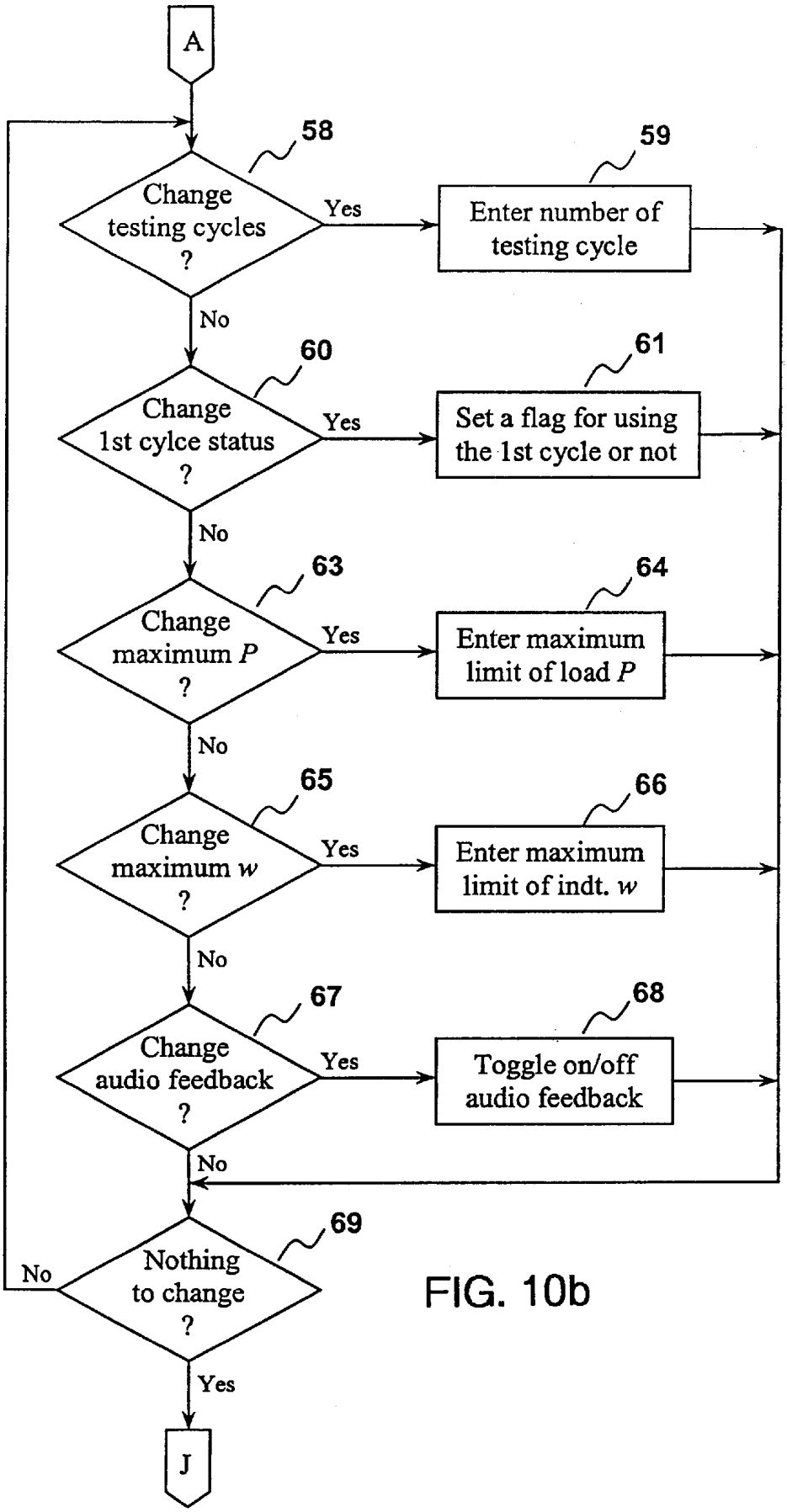

A
58
Change testing cycles ?
Yes
59
Enter number of testing cycle
No
60
Change 1st cylce status ?
Yes
61
Set a flag for using the 1st cycle or not
No
63
Change maximum P ?
Yes
64
Enter maximum limit of load P
No
65
Change maximum w ?
Yes
66
Enter maximum limit of indt. w
No
67
Change audio feedback ?
Yes
68
Toggle on/off audio feedback
No
69
Nothing to change ?
No
Yes
J

FIG. 10b

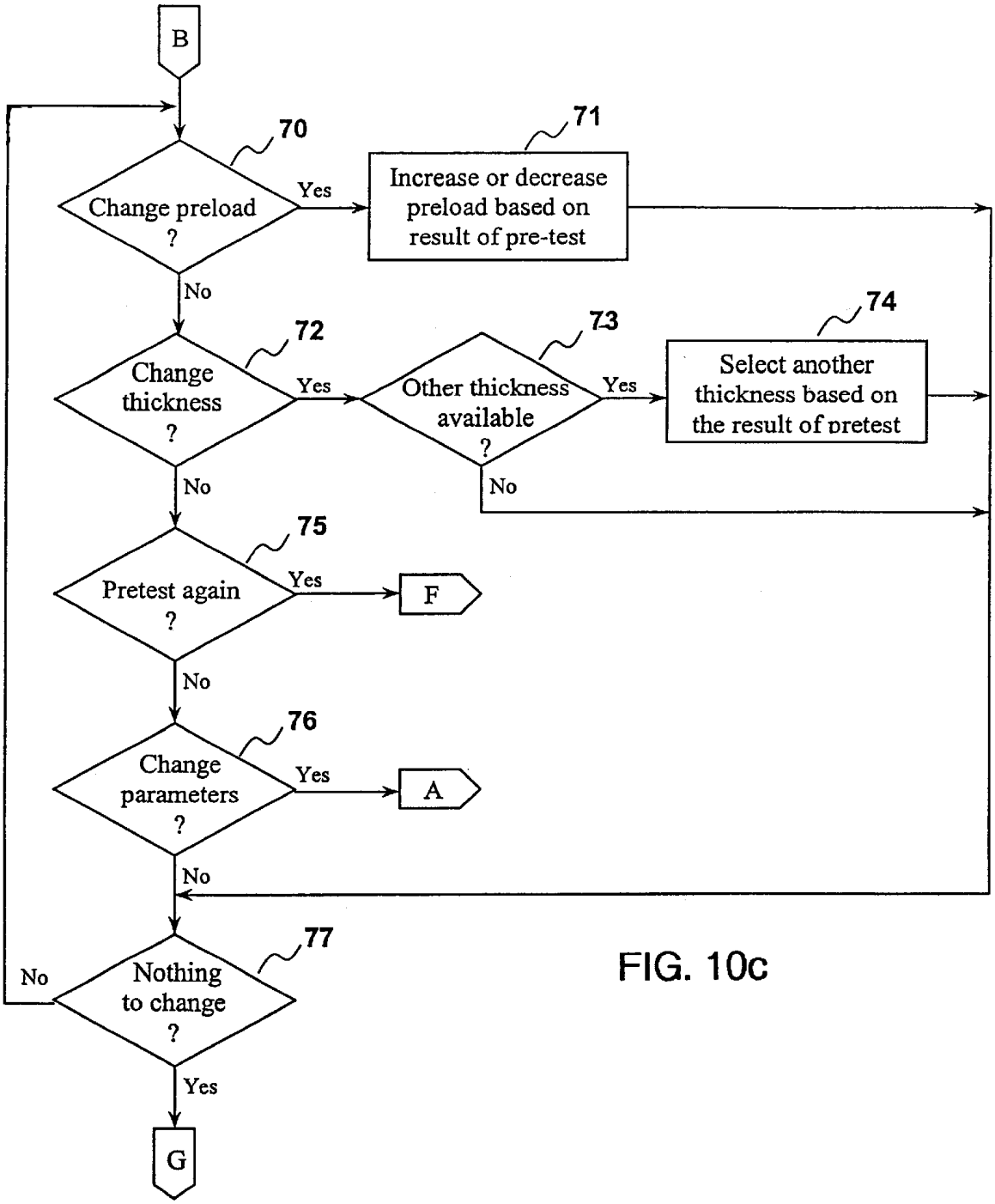

B
70
Change preload ?
Yes
71
Increase or decrease preload based on result of pre-test
No
72
Change thickness ?
Yes
73
Other thickness available ?
Yes
74
Select another thickness based on the result of pretest
No
No
75
Pretest again ?
Yes
F
No
76
Change parameters ?
Yes
A
No
77
Nothing to change ?
No
Yes
G

FIG. 10c

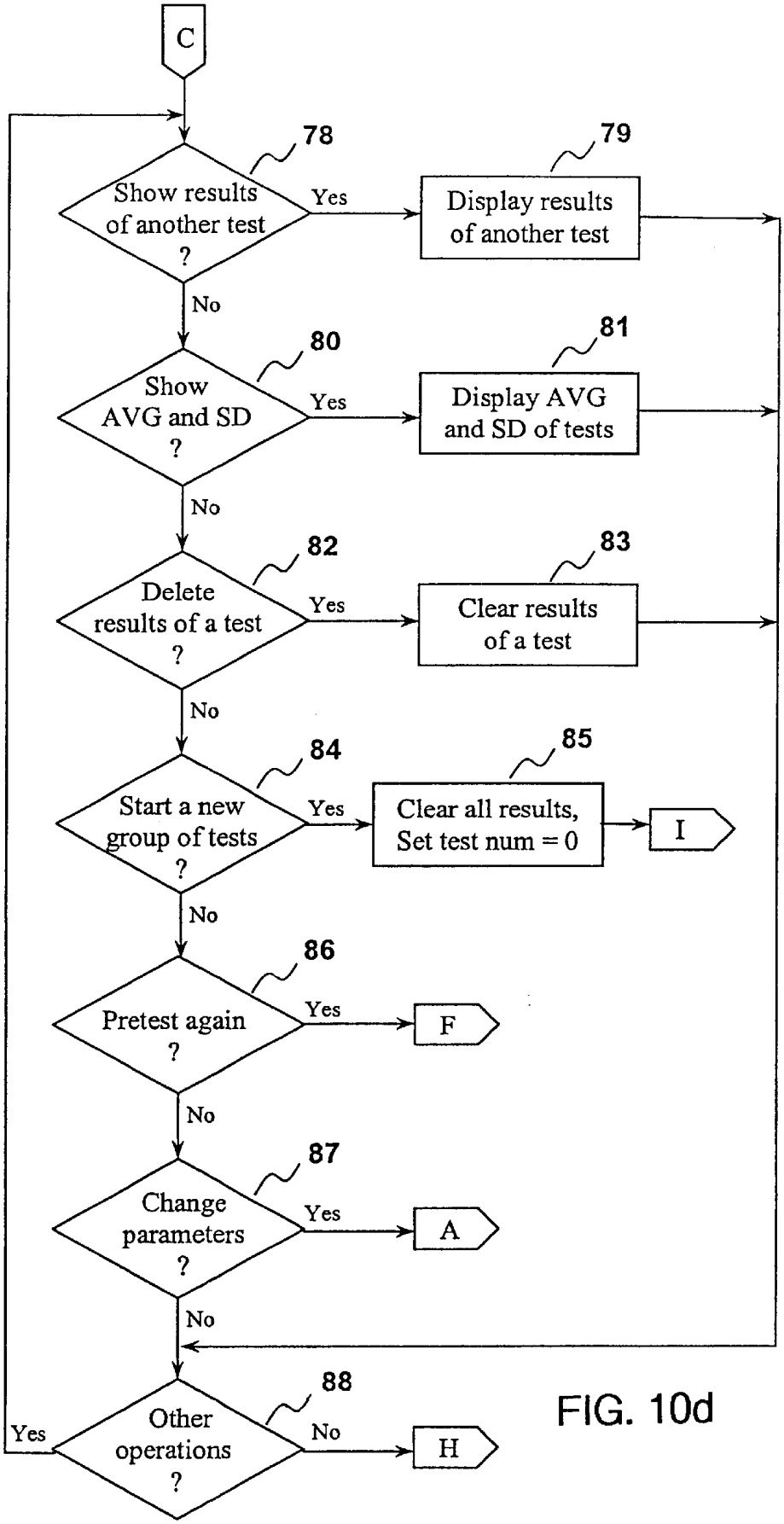

C
78
Show results of another test ?
Yes
79
Display results of another test
No
80
Show AVG and SD ?
Yes
81
Display AVG and SD of tests
No
82
Delete results of a test ?
Yes
83
Clear results of a test
No
84
Start a new group of tests ?
Yes
85
Clear all results, Set test num = 0
I
No
86
Pretest again ?
Yes
F
No
87
Change parameters ?
Yes
A
No
88
Other operations ?
Yes
No
H

FIG. 10d

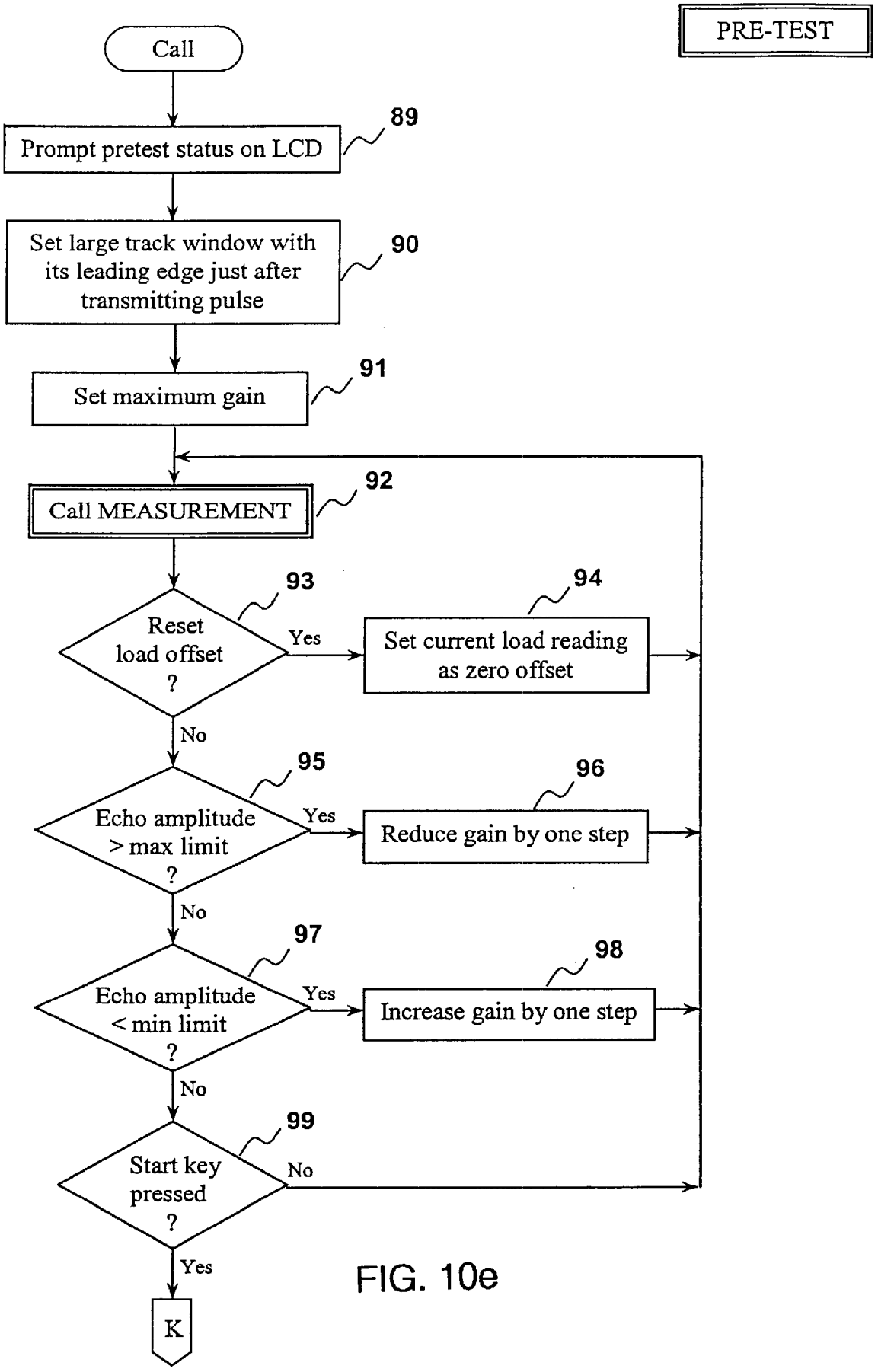

PRE-TEST
Call
Prompt pretest status on LCD
89
Set large track window with its leading edge just after transmitting pulse
90
Set maximum gain
91
Call MEASUREMENT
92
Reset load offset ?
93
Yes
Set current load reading as zero offset
94
No
Echo amplitude > max limit ?
95
Yes
Reduce gain by one step
96
No
Echo amplitude < min limit ?
97
Yes
Increase gain by one step
98
No
Start key pressed ?
99
No
Yes
K

FIG. 10e

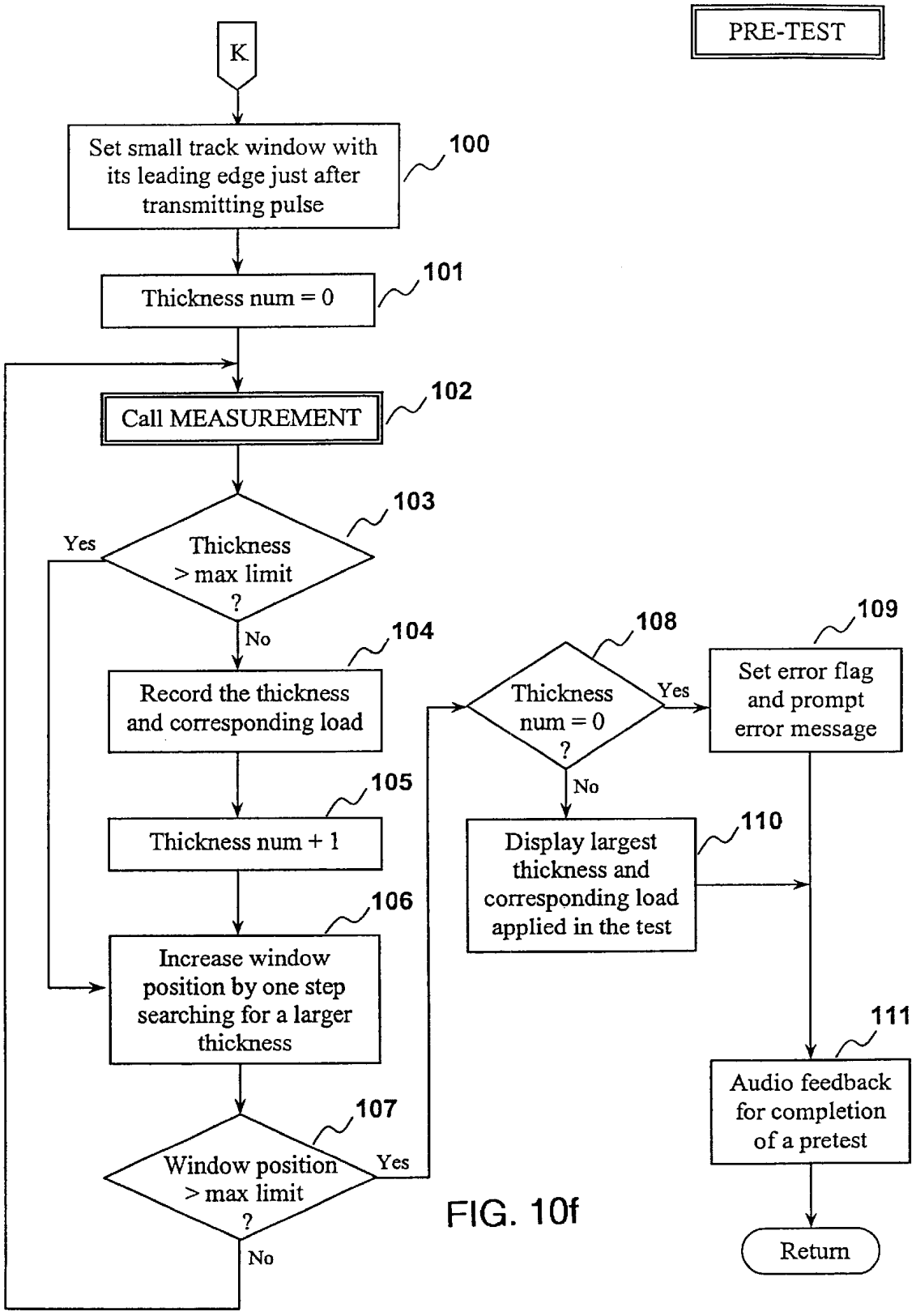

PRE-TEST
K
Set small track window with its leading edge just after transmitting pulse
100
Thickness num = 0
101
Call MEASUREMENT
102
Thickness > max limit ?
103
Yes
No
Record the thickness and corresponding load
104
Thickness num + 1
105
Increase window position by one step searching for a larger thickness
106
Window position > max limit ?
107
Yes
No
Thickness num = 0 ?
108
Yes
No
Set error flag and prompt error message
109
Display largest thickness and corresponding load applied in the test
110
Audio feedback for completion of a pretest
111
Return

FIG. 10f

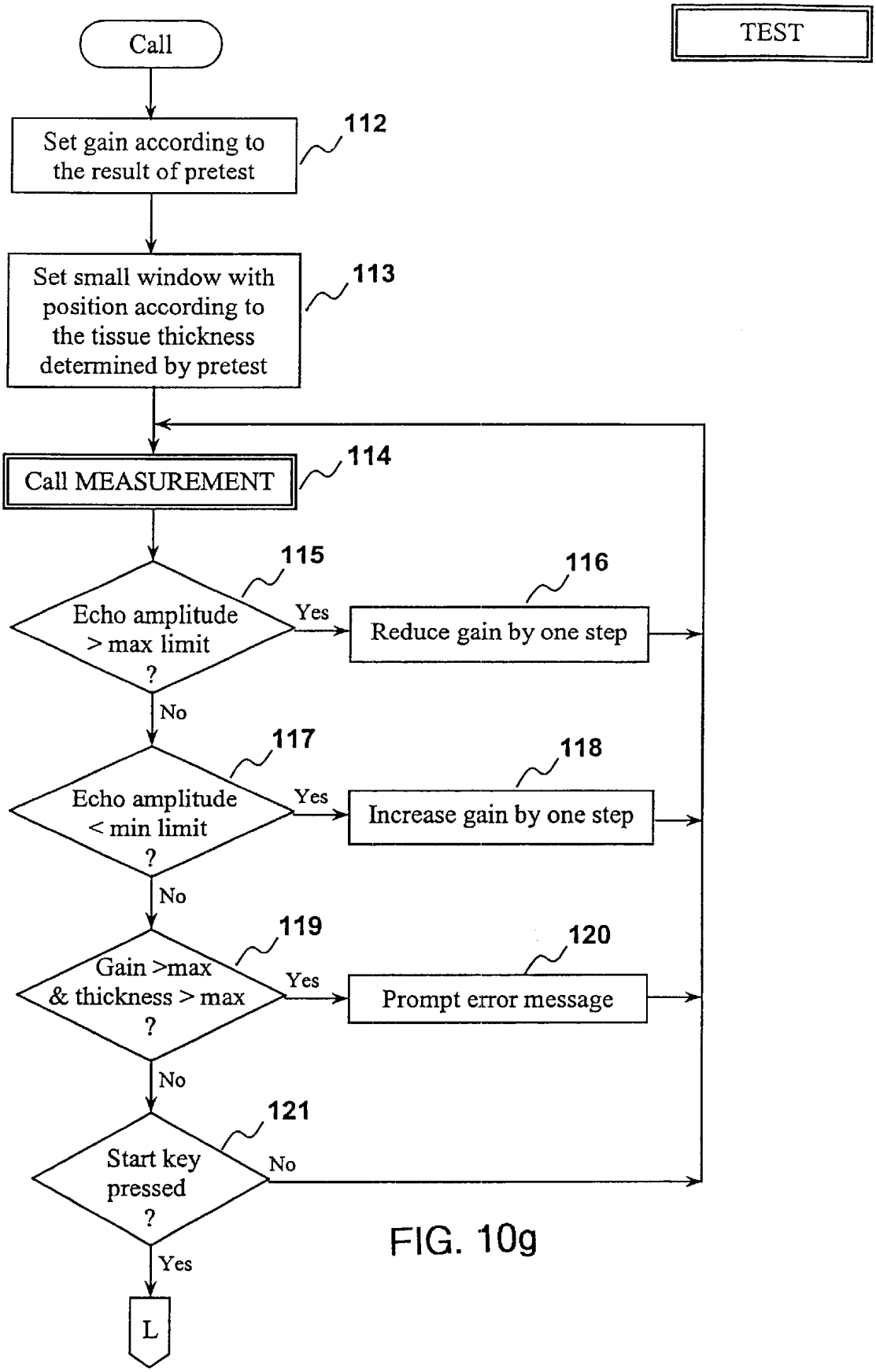

TEST
Call
Set gain according to the result of pretest
112
Set small window with position according to the tissue thickness determined by pretest
113
Call MEASUREMENT
114
Echo amplitude > max limit ?
115
Yes
Reduce gain by one step
116
No
Echo amplitude < min limit ?
117
Yes
Increase gain by one step
118
No
Gain >max & thickness > max ?
119
Yes
Prompt error message
120
No
Start key pressed ?
121
No
Yes
L

FIG. 10g

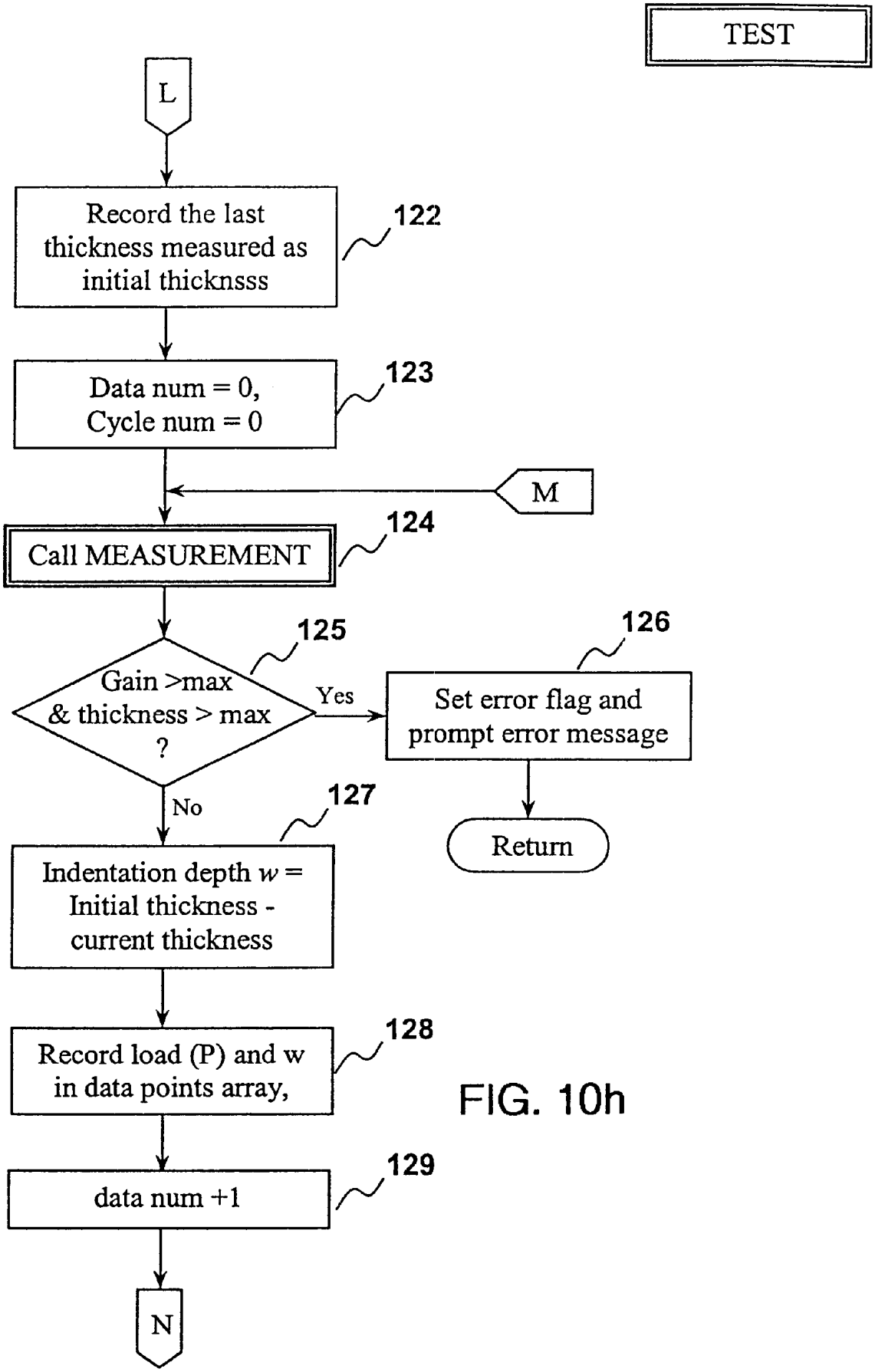

TEST
L
Record the last thickness measured as initial thicknsss
122
Data num = 0, Cycle num = 0
123
M
Call MEASUREMENT
124
125
Gain >max & thickness > max ?
Yes
126
Set error flag and prompt error message
Return
No
127
Indentation depth w = Initial thickness - current thickness
Record load (P) and w in data points array,
128
data num +1
129
N

FIG. 10h

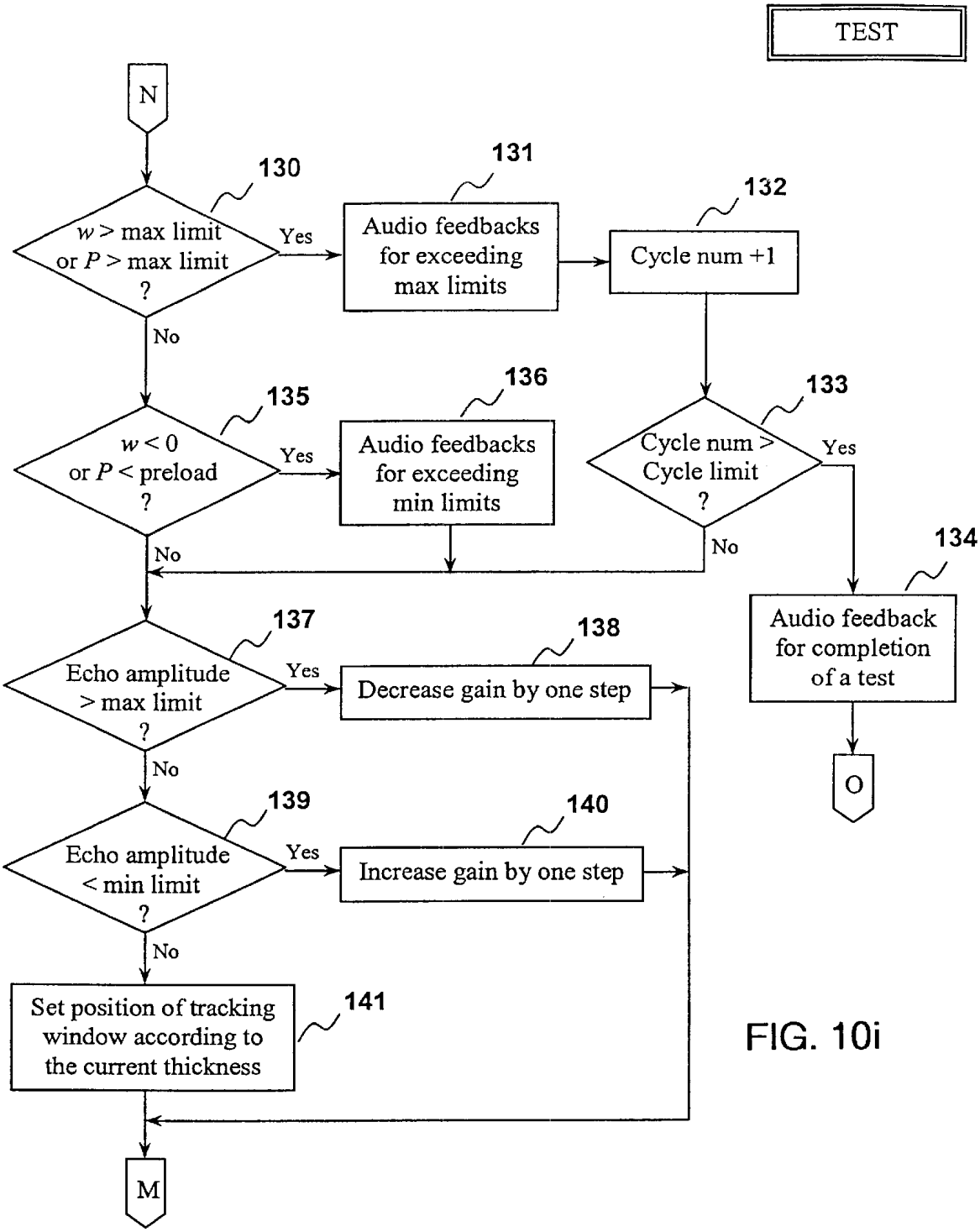

TEST
N
130
w > max limit or P > max limit ?
Yes
131
Audio feedbacks for exceeding max limits
132
Cycle num +1
No
135
w < 0 or P < preload ?
Yes
136
Audio feedbacks for exceeding min limits
133
Cycle num > Cycle limit ?
Yes
No
No
134
Audio feedback for completion of a test
O
137
Echo amplitude > max limit ?
Yes
138
Decrease gain by one step
No
139
Echo amplitude < min limit ?
Yes
140
Increase gain by one step
No
Set position of tracking window according to the current thickness
141
M

FIG. 10i

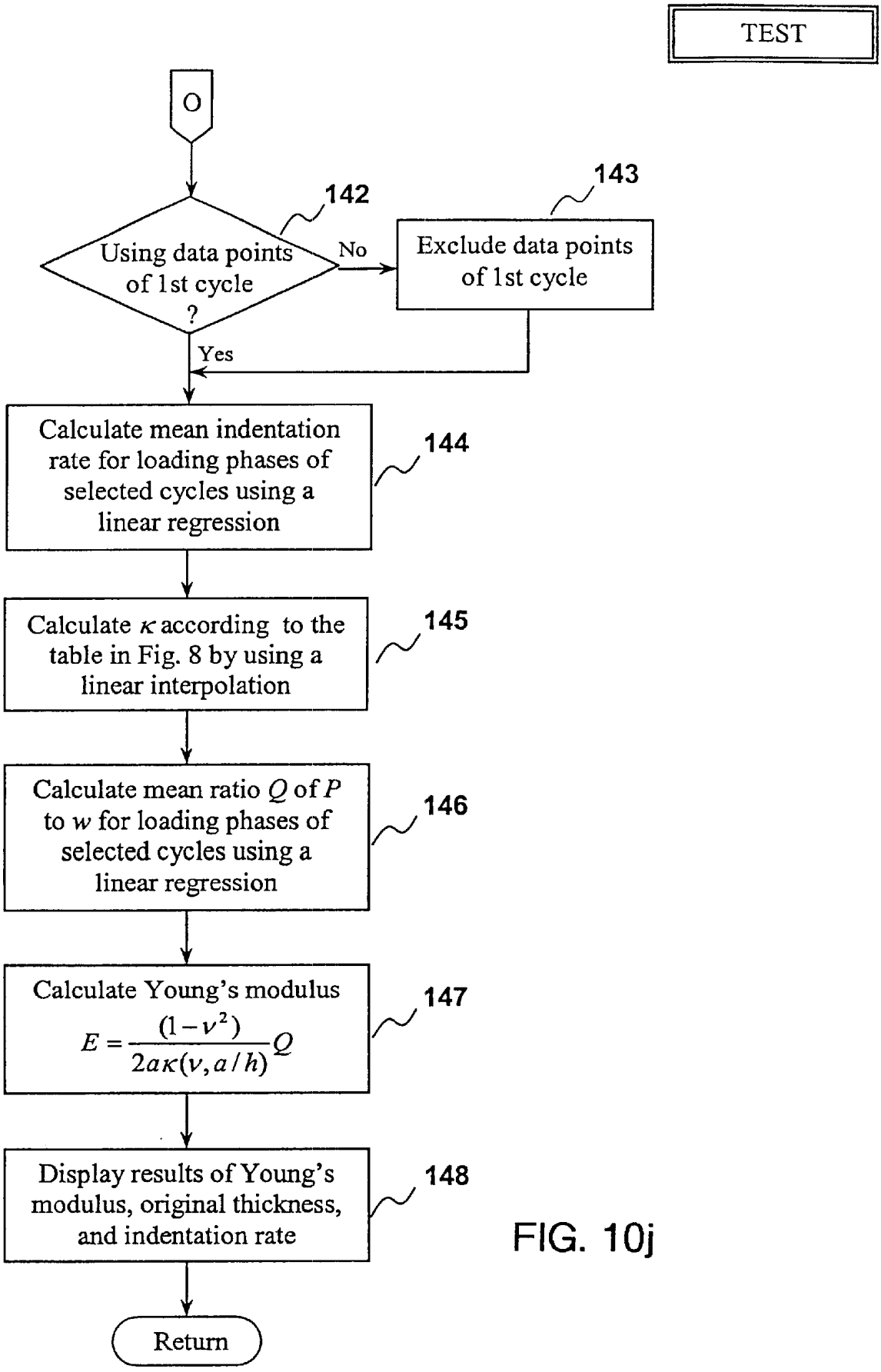

TEST
O
142
Using data points of 1st cycle ?
No
143
Exclude data points of 1st cycle
Yes
Calculate mean indentation rate for loading phases of selected cycles using a linear regression
144
Calculate κ according to the table in Fig. 8 by using a linear interpolation
145
Calculate mean ratio Q of P to w for loading phases of selected cycles using a linear regression
146
Calculate Young's modulus
$E = \frac{(1-\nu^2)}{2a\kappa(\nu, a/h)}Q$
147
Display results of Young's modulus, original thickness, and indentation rate
148
Return

FIG. 10j

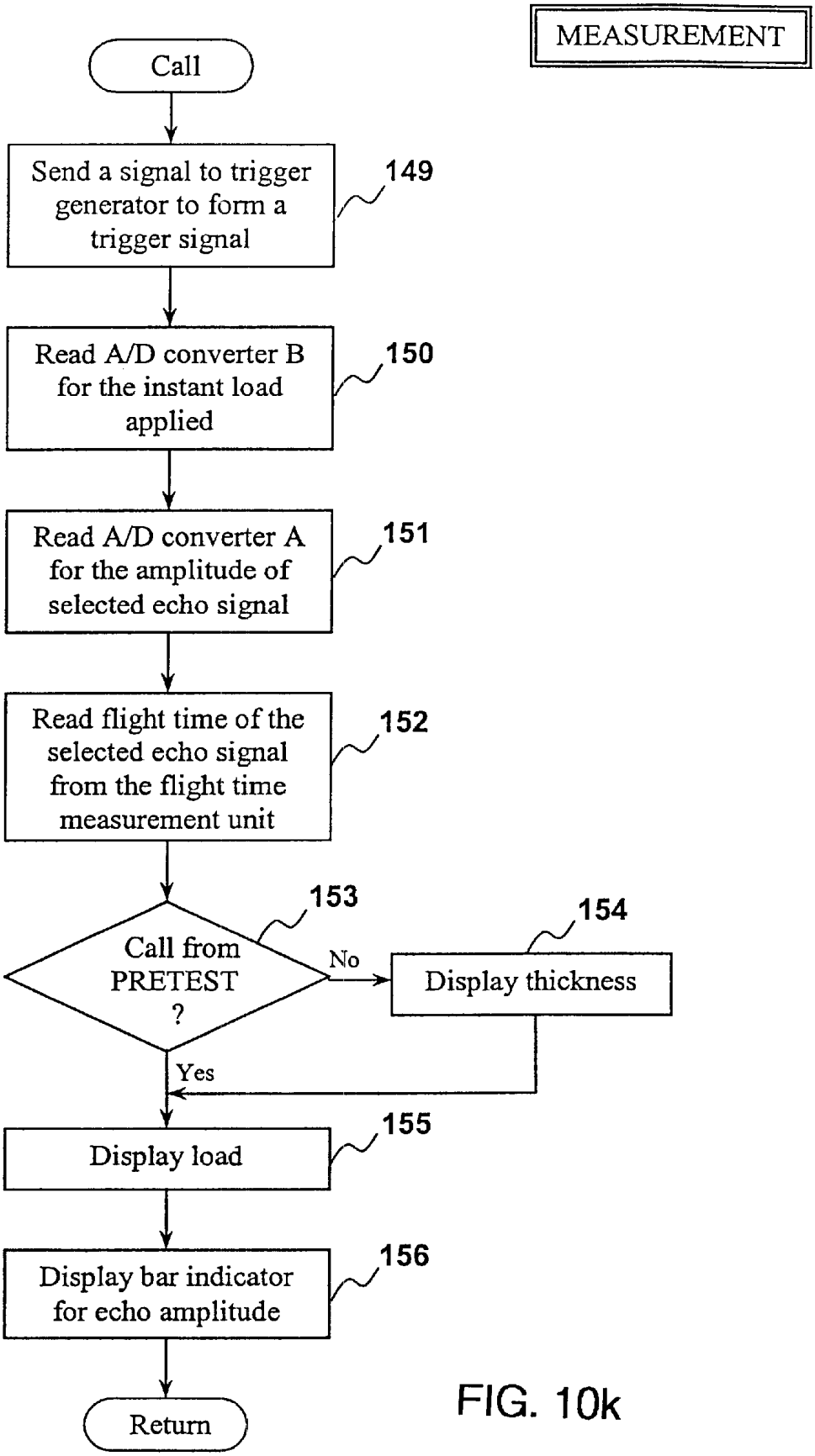

MEASUREMENT
Call
Send a signal to trigger generator to form a trigger signal
149
Read A/D converter B for the instant load applied
150
Read A/D converter A for the amplitude of selected echo signal
151
Read flight time of the selected echo signal from the flight time measurement unit
152
153
Call from PRETEST ?
No
154
Display thickness
Yes
Display load
155
Display bar indicator for echo amplitude
156
Return

FIG. 10k

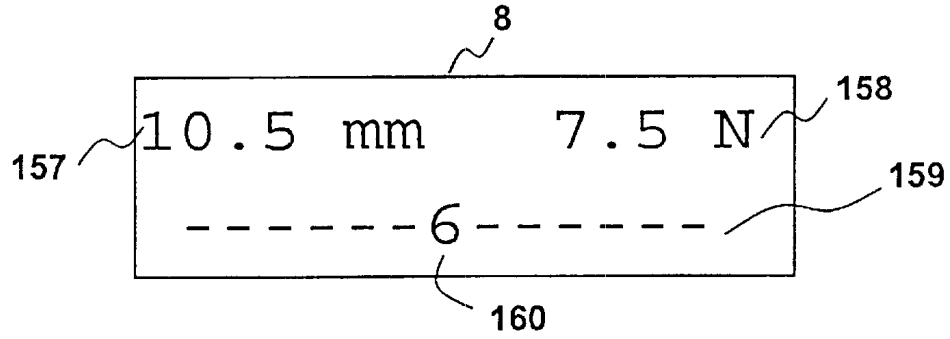


FIG. 11

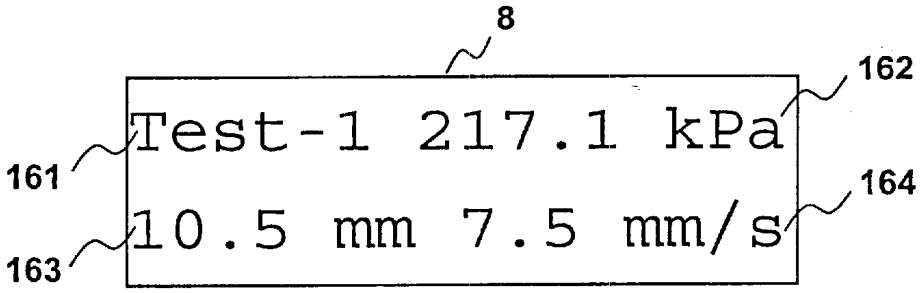


FIG. 12

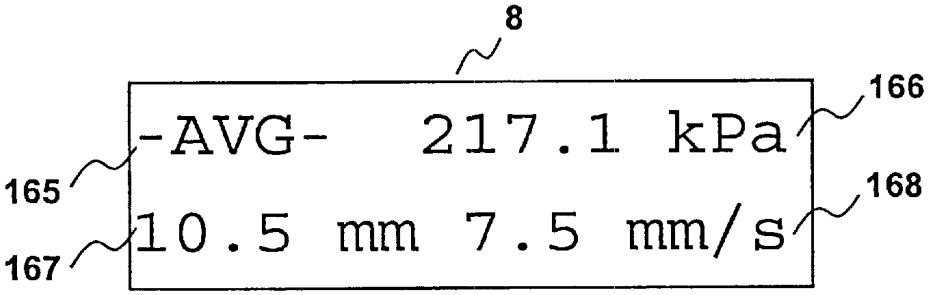


FIG. 13a

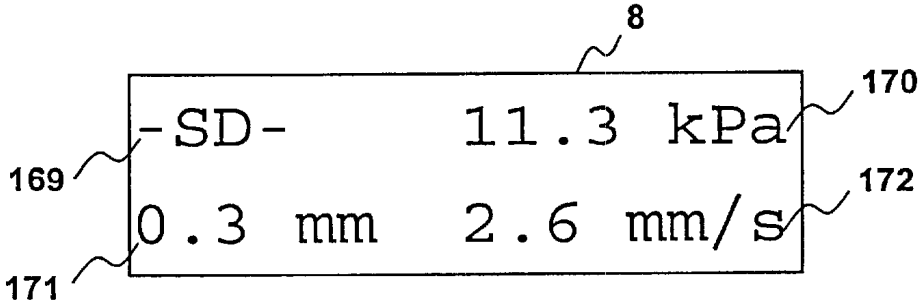


FIG. 13b

PORTABLE ULTRASONIC PALPATION SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to the use of indentation and ultrasound techniques to quantitatively assess the mechanical properties of soft tissues, and in particular of a soft tissues covering a musculoskeletal system of a body.

2. Description of Prior Art

The human musculoskeletal system is entirely covered by layers of soft tissues. At the body support interfaces, such as buttock tissues interfacing with a seat, residual limb tissues interacting with a prosthetic socket, and plantar tissues of a foot interacting with an in-sole/ground, significant loads are transmitted via skin to underlying tissues. Biomechanical assessment of skin and underlying soft tissues is relevant to the designs of respective body support interfaces. These issues are relevant to many clinical rehabilitation problems, such as the design of special cushions for a spinal cord injury, special orthotics for diabetic feet, and custom prosthetic sockets for amputees. Traditionally, biomechanical properties of limb soft tissues are evaluated by palpation. Such a subjective assessment requires substantial experience acquired through trial and error. The qualitative nature makes knowledge accumulation difficult and makes teaching-learning imprecise.

Among the various biomechanical testing protocols, indentation test is an effective and relatively simple way to make biomechanical assessment of the skin and subcutaneous tissues under compression. Tests themselves very much resemble that of palpation. However, existing indentation apparatuses that have been proposed are not feasible for extensive clinical application. In most cases, indentors are driven by electromechanical or pneumatic devices. This makes testing systems difficult to handle, and difficult to operate, with potential hazards to the soft tissues. One of the latest example of electromechanical driving indentation apparatus was introduced in A. P. Pathak, et al., *A rate-controlled indentor for in vivo analysis of residual limb tissues*, IEEE Transactions on Rehabilitation Engineering; Vol. 6, 12–20 (1998). The application of this device in clinical field is still difficult due to the large dimension of the indentation device. A hand-held indentation apparatus with a laser distance sensor to monitor the indentor displacement is disclosed in M. Horikawa, et al., *Non-invasive measurement method for hardness in muscular tissues*, Medical and Biological Engineering and Computing; Vol. 31, 623–627 (1993). The measurement of the displacement by laser has the drawback that the result is significantly influenced by the misalignment, the indented area if the laser beam is too close to the indentor, and the curvature of the limb if the laser beam is too far from the indentor. Furthermore, the existing indentation apparatuses have the drawback that the deformation of the soft tissue is commonly determined by the movement of the indentor, so the soft tissue thickness can not be suitably measured in the test. The stiffness measured in this manner would reflect not only the material properties of the tissues but also some geometric factors. To extract accurate material parameter, the tissue thickness might be obtained using other approaches, such as MRI, X-ray and ultrasound techniques.

Conventional ultrasonic imaging techniques have been used to study the elastic properties of a soft tissue by measuring the strain in the tissue subjected to a given stress.

An approach has been attempted to determine the tissue elasticity, by applying a low frequency vibration to the tissue surface while measuring the amplitude and phase of the internal tissue vibration using ultrasound Doppler technique. See e.g. T. A. Krouskop, et al., *A pulsed doppler ultrasonic system for making non-invasive measurement of mechanical properties of soft tissue*, J. Rehab. Res. Dev. Vol. 24, 1–8 (1987); see also R. M. Lerner, et al., "Sonoelasticity" images derived from ultrasound signals in mechanically vibrated tissues, Ultrasound in Med. & Biol. Vol. 16, No. 3, 231–239 (1990), K. J. Parker, et al., U.S. Pat. No. 5,099,848 (1992), and Y. Yamakoshi, et al., *Ultrasonic imaging of internal vibration of soft tissue under forced vibration*, IEEE Transactions on Ultrasonics, Ferroelectrics and Frequency Control, Vol. 7, No. 2, 45–53 (1990).

Another method for imaging the tissue elasticity is disclosed in J. Ophir, et al., U.S. Pat. No. 5,107,837 (1992), J. Ophir, et al., U.S. Pat. No. 5,293,870 (1994), and M. O'Donnell, et al., *Internal displacement and strain imaging using ultrasonic speckle tracking*, IEEE Transactions on Ultrasonics, Ferroelectrics and Frequency Control, Vol. 41, 314–325 (1994). This method included emitting ultrasonic waves along a path into the soft tissue and recording an echo train resulting from an ultrasonic wave pulse. Another echo train was recorded resulting from a second ultrasonic wave emitting along the path after the tissue was compressed. A selected echo segment of the echo sequence corresponded to a particular echo source within the tissue along the beam axis of the transceiver. Time shifts in the echo segment are examined using cross-correlation technique to measure compressibilities of the tissue regions. The use of MRI for detection of shear waves in soft tissue induced by a mechanical actuator attached to the surface of the tissue is described in R. Muthupillai, et al., *Magnetic resonance elastography by direct visualization of propagating acoustic strain waves*, Science, Vol. 269, 1854–1857 (1995).

The above methods using ultrasound and MRI techniques are needed to generate the elasticity imaging of soft tissues. Their significance was the detection of tissue abnormalities, such as those caused by cancer or other lesions, and their output is the local mechanical property of internal regions of a soft tissue, not the bulk property of an entire tissue layer. For those applications, the deformation of the soft tissue was generally less than 5%, which was much smaller than those of the soft tissues interacting with supporting interfaces, such as residual limb tissue, for which 30% deformation is not uncommon in many cases. Since measurement of relative change of a material property is sufficient for many imaging purposes, these methods are usually not calibrated against any absolute values of the material parameters. This is a drawback when more accurate material parameters are needed.

SUMMARY OF THE INVENTION

It is an object of the invention to overcome these drawbacks.

According to the invention there is provided a portable ultrasonic palpation device for measuring Young's modulus of a soft tissue layer comprising a hand holdable pressure applying probe having an ultrasonic transceiver for transmitting and receiving ultrasound at an outer surface of the tissue layer, an applied pressure sensor for the probe, and a programmed computer arranged to receive signals from the transceiver and from the pressure sensor and to compute the Young's modulus of the tissue layer based on applications of manually applied different pressures to the outer surface.

The probe preferably comprises a cylindrical body having a forward tip containing the ultrasonic transceiver, and a like second cylindrical body attached end-to-end to the first cylindrical and containing the pressure sensor. The cylindrical bodies are preferably approximately 10 mm in diameter.

The computer may be programmed to provide output signals corresponding to an effective depth of the tissue layer.

The computer may be programmed to compute according to the equation:

$$E = \frac{(1-\nu^2)}{2a\kappa(\nu, a/h)} \frac{P}{w} \quad (1)$$

where E is the Young's modulus, P the applied load, w the indentation depth, h the tissue thickness, a the radius of indentor, and K a scaling factor.

BRIEF DESCRIPTION OF THE DRAWINGS

A portable ultrasonic palpation device according to the invention will now be described by way of example in which:-

FIG. **1** illustrates the portable ultrasound palpation system

FIG. **2** illustrates a structure of a palpation probe and a propagation path of ultrasound signals;

FIG. **3** is a block diagram of the portable ultrasound palpation device;

FIG. **4** is a time sequence of the different modules of a control box;

FIG. **5** are load and indentation sequences of a cyclic test determined by the device;

FIG. **6** is a load-indentation curve plotted in accordance with FIG. **5**.

FIG. **7** illustrates a graph for use in calculating a mean indentation rate using a linear regression. (Data points of the loading phases with load≧preload (0.5 N) and ≦maximum load (2.5 N), and indentation ≧0 and ≦maximum indentation (30%) are included from data of FIG. **5** and FIG. **6**.);

FIG. **8** is a table showing the dependence of a scaling factor K to an aspect ratio a/h and Poisson's ratio v. (From W. C. Hayes et al, *A mathematical analysis for indentation tests of articular cartilage*, Journal of Biomechanics; Vol. 5, 541–551 (1972));

FIG. **9** is a graph for use in calculating a mean ratio of load P against indentation depth w. (Data points of loading phases with load≧preload (0.5 N) and ≦maximum load (2.5 N), and indentation≧0 and ≦maximum indentation (30%) are included from data of FIG. **5** and FIG. **6**);

FIGS. **10***a*–**10***k* are flowcharts of programs for the operation of the ultrasound palpation device;

FIG. **11** is a display showing in real time tissue thickness and load data, and a bar indicator for the relative amplitude of the ultrasound reflection signal during a cyclic test;

FIG. **12** is a display showing a determined Young's modulus, the original tissue thickness and the indentation rate after a cyclic test is completed; and

FIGS. **13***a* and **13***b* are displays showing the mean and the standard deviation of the Young's modulus, the original tissue thickness and the indentation rate after a group of cyclic tests are completed.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the invention relate to the use of indentation and ultrasound techniques to quantitatively measure the mechanical parameters of soft tissues. In the described embodiment, the device includes a finger-size probe and a portable control box. The probe comprises an ultrasound transceiver at the tip serving as the indentor and a load cell transceiver connected in series with it. A control box incorporates a microprocessor, connected to an ultrasound emitter and receiver and a load cell driver, an amplifier, data collection and timing modules and a LCD.

During use, the hand-held probe is placed on a tissue surface with a underlying bony substratum. The probe-tissue interface is lubricated with ultrasound couplant, which has ability to couple ultrasound signal from the transceiver into the soft tissue. When a controlling computer program causes the ultrasound emitter to emit an ultrasound pulse wave into the soft tissue, the ultrasound echo signal reflected from the bony interface is received and its flight time is determined by the microprocessor to compute the tissue thickness. The ultrasound speed in most soft tissues is typically around 1540 m/s. The amplitude of the reflected ultrasound echo signal is collected using the data collection module. A corresponding load applied on the tissue is recorded by via load cell. The LCD displays in real time the tissue thickness, the load applied, and a bar indicator to show a relative amplitude of the reflected ultrasound signal. Since the ultrasound reflection signal is maximal when the probe is aligned perpendicularly to the underlying bone interface, any misalignment of the probe will tend to reduce the amplitude of the reflection signal. The amplitude shown in the bar indicator helps the operator to maintain a consistent alignment of the probe.

Before cyclic tests, an original thickness of soft tissue is first measured with a manually controlled pre-load, and the maximum indentation depth and load can be preset by the operator. As the operator manually loads and unloads the probe on the tissue surface, the controlling program continuously causes the ultrasound emitter to emit ultrasound pulses into the soft tissue. The instant tissue thickness and applied load are determined and displayed. The computer provides an audio feedback using different buzzer tones to indicate whether data points exceed the preset maximum indentation depth, maximum load, pre-load, or predetermined original thickness. The operator uses these audio feedbacks to control loading and unloading sequences. After collecting the data for a preset number of loading-unloading cycles, the microprocessor module computes the Young's modulus of the soft tissue (using Equation1, see below) from the load-indentation response using an analytical solution of indentation on a layer. The Young's modulus of the soft tissue as well as the indentation rate and the original tissue thickness are displayed on the LCD after the test. Another cyclic test can follow immediately, and so on. The microprocessor calculates the mean and standard deviation of the Young's modulus, the original thickness and the indentation rate for a group of tests per uses the control of an operator.

The layer indentation model used to calculate Young's modulus is disclosed in W. C. Hayes, et al., *A mathematical analysis for indentation tests of articular cartilage*, Journal of Biomechanics; Vol. 5, 541–551 (1972) where a rigorous mathematical solution is provided. Young's modulus relating to elastic indentation of a thin elastic layer bonded to a rigid half-space with a rigid, frictionless cylindrical plane-ended indentor is given by Equation (1).

$$E = \frac{(1-\nu^2)}{2a\kappa(\nu, a/h)}\frac{P}{w} \quad (1)$$

where E is the Young's modulus, P the applied load, w the indentation depth, h the tissue thickness, a the radius of indentor, and K a scaling factor. This scaling factor provides a theoretical correction for the finite thickness of the elastic layer, and it depends on both an aspect ratio a/h and Poisson's ratio v. The Poisson's ratio v is typically taken here to be 0.45 assuming soft tissue to be nearly an incompressible material. The radius of the indentor is known, according to the dimension of the ultrasound transceiver. The factor P/w is calculated from cyclic load-indentation responses.

The device preferably includes means to prevent influences of noise received during use of the device and changes of the alignment of the probe during a test. An auto-gain-control mean is included to maintain a consistent amplitude of ultrasound reflection signals which may differ for soft tissues of different subjects, with different tissue thickness, different underlying bony geometry, or different pathological conditions, for different probe alignment or different amount of indentation. In addition, the system includes means to select and track ultrasound echo signals reflected from the bony interface. For flexibility of operation, the device also includes means to start a measurement using a switch controllable by a hand or foot of the operator.

Referring to the drawings, in FIG. **1** the portable ultrasound palpation device has a finger-size probe **1**, a control box **2**, and a remote switch **3**. The probe **1** is connected to the controlling box **2** via a cable **4** and a cable connector **5**. The remote switch **3** is connected to the controlling box **2** via another cable **6** and cable connector **7**. A LCD panel **8** (with 16×2 characters) is used to display testing parameters, results, and other information. Panel keypads **9** are used to select functions **(10)**, adjust parameters **(12, 13)**, and start measurements **(11)**. During a test, the probe is held by the fingers of the operator, while the remote switch **3** is controlled by a hand or foot of the operator and used to start a test. Starting a test may also be achieved by a starting keypad **11** on the control box. Hereinafter the starting switch **3** and the starting keypad **11** are both simply referred to as the "starting key".

FIG. **2** illustrates a structure of the probe and a propagation path of the ultrasound signals. In a test, the probe **1** is placed on a tissue surface Si of soft tissue So having an underlying bony substratum Bo. The probe-tissue interface is lubricated with ultrasound couplant **14**. An ultrasound transceiver **15** with a diameter of 9 mm, is at the tip of the probe **1**, and a compression load cell **16** is connected in series with the ultrasound transceiver **15** through a suitable connector **17**. The load cell **16**, comprises a resistive bridge for sensing the compression load. The other end of the load cell **16** is attached to a plastic body **18** that is held by the operator during use. There are two groups of wires, group **19** from ultrasound transceiver **15** and group **20** from load cell **16**, to form the cable **4**, that is enclosed by a heat shrinkable sheath, led from a side of the plastic body **18** to the control box **2** through the connector **5**. Ultrasound pulses Ai are emitted from the ultrasound transceiver **15**, and coupled into the soft tissue so through the ultrasound couplant **14**. When the pulses encounter the bony interface Sb, an echo Ar is reflected and received by the ultrasound transceiver. The reflected signals, or echo signals are amplified and used to determine the thickness of the soft tissue So. Since the echo signals are maximal when the probe **1** is aligned perpendicularly to the bony interface Sb, any misalignment of the probe **1** will tend to reduce the amplitude of the echo signals. This characteristic may be used to help the operator to maintain a consistent alignment of the probe **1** during a test.

In the block diagram FIG. **3**, the control box **2** includes the ultrasound emitter and receiver **21**, a load cell driver and amplifier **22**, a data collection module **23**, a timing module **24**, a LCD module **25**, panel keypads **9**, and a microprocessor **26**. The ultrasound emitter and receiver module **21** (hereinafter simply referred to as ultrasound module) are part of an ultrasound emitting unit **27** and an ultrasound receiving unit **28**. The load cell module **22** comprises a load cell driving unit **29** and a load cell amplifying unit **30**. The data collection module **23** comprises a flight time measurement unit **31**, a windowed peak detection unit **32**, A/D converter A **33**, and A/D converter B **34**. The timing module **24** comprises a trigger generation unit **35** and a track window generation unit **36**. The microprocessor **26** comprises a ROM and a RAM, shown in the Figure. The program is stored in the ROM, and data points collected, results generated, and other information are stored in the RAM during a measurement in a generally conventional fashion. The microprocessor **26** is connected to the other modules via data and address buses and other normal I/O ports.

Time sequences of the different modules are shown in FIG. **4**. The ultrasound emitter **27** is triggered by a trigger signal **37** generated by a trigger generation unit **35**, which is stimulated by the program in the microprocessor **26**. With the stimulation of the trigger signal **37**, the ultrasound emitter **27** generates an electrical pulse **38** with an amplitude of 100 V, and a pulse width of 200 ns. The pulse is supplied to the ultrasound transceiver with a central frequency of 2.5 MHz, 5 MHz, or 10 MHz, via the cable **19**. High frequency transceivers are normally used for thin soft tissue layers, and low frequency transceivers used for thick tissue layers. Ultrasound pulse waves **39** with corresponding frequency are then generated at the tip of the ultrasound transceiver **15**, which is held against the tissue surface Si during a test. Ultrasound reflection, and echo waves **40**, are received and transferred into electrical echo signal by the ultrasound transceiver **15**. The ultrasound echo signals are supplied to the controlling box via cable **4** and **19** and amplified by the ultrasound receiver **28**. The gain of the ultrasound receiving unit **28** is controlled by the program.

The amplified and filtered ultrasound signals **41** and **42** are led to the data collection module in two ways. In one way, the windowed peak detection unit **32** detects the amplitude of the peak of a selected echo **42** using a windowed peak holding circuit. The echo **42** is selected by a track window **43** which is generated by the track window generation unit **36**. The position and the width of the track window **43** are adjustable by the program. When soft tissue is loaded and unloaded by the probe **1** during a test, the program will change the position of the window **43** back and forth to track the movement of the selected echo signal. The peak amplitude signal **44** generated by the windowed peak detection unit **32** is led to the A/D converter A **33** normally with a resolution of 8 bits. After the signal **44** is successfully digitized, the output of the peak holding circuit is reset to zero. The digitized value of the peak amplitude is then read by the program for calculation and display. During a test, if the peak amplitude of the selected echo is smaller than a preset minimum limit or larger than a preset maximum limit, the program will increase or decrease the gain of the ultrasound receiving unit accordingly to maintain a relatively stable ultrasound echo signal.

In the other way, the detected ultrasound signals **41** and **42** are led to the flight time measurement unit **31**. In this unit, the signals are first amplified, then a rising edge of the selected echo is detected, and an echo position signal **45** is generated. The operation of edge detection is limited within the track window **43**; a counter starts to count at the rising edge **46** of a counter enable signal **47**, which is synchronized with the rising edge of the trigger signal **37**, and stops counting at the falling edge **48** of the counter enable signal **47**, which is synchronized with the rising edge of the echo position signal **45**. The value of the counter is then read by the program. According to the value of the counter and the counting frequency, for example, 10 MHz, the flight time of the selected echo can be calculated by the program. This flight time equals double the time that it takes ultrasound signals to propagate from the tissue surface Si to the bony interface Sb if the selected echo is reflected from that interface. Using the mean speed of ultrasound in soft tissue, typically, 1540 m/s, the thickness of the soft tissue can be calculated by the program via I/O ports of the microprocessor module **26**. It should be noted that there are usually more than one set of reflection echoes in practical situations. Additional echoes can arise due to reflections from intermediate interfaces of soft tissue sub-layers, such as, skin-fat interfaces, fat-muscle interfaces, muscle-muscle interfaces, or from multi-reflections of the echo between the tissue surface and the bony interface. The real tissue thickness is determined using a pretest to eliminate spurious reflections which will be described below.

The resistive bridge of the load cell **16** is driven by the load cell driving unit **29**, and the load signal corresponding to the load applied on the load cell **16** is amplified by the load cell amplifying unit **30**. The amplified load signal is digitized by the A/D converter B **34** with resolution of 8 bits. For each trigger signal **37**, the digitized load signal is read by the program via I/O ports of the microprocessor **26**.

FIGS. **10***a*–**10***k* are flowcharts of the program for the operation of the device. Besides a main program, there are three subprograms PRETEST, TEST and MEASUREMENT. The function of main program is to make selection of different functions of the program and input various parameters for a test. The function of PRETEST is to determine the tissue thickness under a certain pre-load before cyclic tests. If there are multi echoes, the real tissue thickness is identified using a pretest. The function of TEST is to make a cyclic test and to extract Young's modulus. The function of MEASUREMENT is to make measurements of load and tissue thickness.

Initially, the main program first initializes the I/O ports of various modules, presets default values for various parameters, shows initializing message on the LCD (block **49**), and then waits for a starting key input. If the option of changing parameters (block **50**) is selected, the operator can change the number of testing cycles, the maximum limit of load and indentation depth, the status of the first cycle to be used or not, and the status of the audio feedbacks to be presented or not (block **58** through **68** in FIG. **10***b*). If there is no parameter to be changed (block **69**), the program waits a starting key to be pressed to start a pretest (block **51**). Before a pretest, the probe **1** is placed at the testing site with the ultrasound couplant **14** lubricating between the tissue surface Si and the tip of the probe **1**, and the probe **1** is then loaded and unloaded for several times to precondition the soft tissue So. If a starting key is pressed (block **51**), the subprogram PRETEST performs a pretest.

The flowchart of the subprogram PRETEST is illustrated in FIGS. **10***e* and **10***f*. The subprogram PRETEST first prompts pretest status on the LCD (block **89**). Then the width of the track window is set large enough to cover the valid tissue depth, for example 15 cm (block **90**). The leading edge of the track window is set just after the falling edge of the transmitting pulse to avoid its influence. The gain of the ultrasound receiver is set to be maximal (block **91**). After these parameters have been set, the subprogram MEASUREMENT is used (block **92**) to make a measurement of load and thickness.

The flowchart of the subprogram MEASUREMENT is illustrated in FIG. **10***k*. The subprogram MEASUREMENT first sends a signal from microprocessor **26** via I/O ports to the trigger generator **35** to form a trigger signal **37** (block **149**). Then the digitized load data is read from the A/D converter B **34** (block **150**), and the digitized peak amplitude of the echo within the track window **43** is read from the A/D converter A **33** (block **151**). The flight time of the selected echo signal is read from the flight time measurement unit (block **152**).

FIG. **11** shows a display in real time of the tissue thickness and the load as the subprogram MEASUREMENT. For the subprogram PRETEST (block **153**), the thickness is not displayed. otherwise, the instant thickness (**157**) is displayed on the LCD **8** (block **154**). The instant load (**158**) is displayed on the LCD **8** in both cases (block **155**) In addition, a bar indicator **159** with levels of, for example, eight, is displayed on the LCD (block **156**) to show the relative amplitude of the echo peak. The figure (O to **7**) in the middle (**160**) equals the number of bars.

Thereafter the program returns from the subprogram MEASUREMENT (block **92**) and first checks if the operator attempts to reset the load offset or not (block **93**). If the keypad for the load offset reset is pressed, the current load reading is set to be the zero offset of load (block **94**). Then, the program checks the amplitude of the echo peak. If the amplitude is larger than a preset maximum limit (block **95**), the gain of the ultrasound receiver is reduced for one step (block **96**), for example, 1 dB. Similarly, if the amplitude is smaller than a preset maximum limit (block **97**), the gain is increased for one step (block **98**), for example, 1 dB. The maximum and minimum limits of echo amplitude are preset in the program, for example, for an 8 levels (0–7) range of relative amplitude, the minimum limit can set to 3, and the maximum limit can be set to 6. Finally, the program checks if the operator attempts to start a pretest (block **99**). If the starting key is pressed, a pretest will be performed. Otherwise, the subprogram MEASUREMENT is called up again, and the above steps are repeated. Repetition can be very fast, for example, 50 times in one second, and the echo amplitude can be adjusted quickly to an accepted level, i.e., larger than the minimum limit and smaller than the maximum limit. The operator is responsible to align the probe **1** as perpendicularly as possible to the underlying bony interface by monitoring the indicator **159** and **160** for echo amplitude on the LCD panel **8** and maintaining the amplitude level as large as possible. When an accepted level of echo amplitude is presented by the amplitude indicator **159** and **160** and an expected pre-load is shown on the LCD panel **8**, the operator can start to search the tissue thickness by pressing the starting key.

When the starting key is pressed, the program first sets a small track window with a width of, for example, 2 μs (block **100**). The leading edge of the track window is set just after the falling edge of the transmitting pulse. By moving this small window, the program searches for valid thicknesses (block **101** through **107**). If a valid thickness is determined, it means that there is a valid echo signal at the depth equal

to that thickness. The number of valid thicknesses is set to zero before the searching procedure (block **101**). By calling up the subprogram MEASUREMENT, the instant load and thickness are measured (block **102**). If the measured thickness is smaller than a preset maximum limit, for example, 15 cm, it is assumed to be a valid thickness and is recorded with the corresponding load, and the number of valid thickness is increased by 1 (blocks **103**, **104**, **105**) Otherwise, the measured thickness is not a valid thickness, and it means that there is no echo within the track window, or the amplitude of echo is too small to detect. The window position is then increased by one step of, for example, 2 μs, to search for a larger thickness (block **106**). If the window position does not exceed the maximum position limit (block **107**), then the subprogram MEASUREMENT is called up again and the above steps (block **102** though **107**) are looped. Otherwise, the program skipped from the loop, and the number of valid thicknesses is checked (block **108**). If the number of valid thicknesses is zero, i.e., there is no valid echo, then an error flag is set and an error message is prompted on the LCD panel **8** (block **109**). Otherwise, there is at least one valid echo detected, and the number of valid thickness is larger than zero. The largest thickness is displayed and assumed to be the real thickness from the tissue surface to the bony interface (block **110**). The corresponding load is also displayed and assumed to be the pre-load (block **110**). Finally, an audio feedback is given to indicate the completion of a pretest (block **111**), and the program returns to where the subprogram PRETEST is called (block **52**).

After the pretest, the operator can select to start a cyclic test, to change the tissue thickness and the pre-load based on the results of pretest, to change other parameters, or to perform pretest again (block **70** through **76**), as shown in FIG. **10***c*. If the load applied during pretest is a little different from the pre-load expected, the operator can select to adjust the pre-load for the cyclic test (block **70**, **71**). If multi echoes are detected, and more than one thickness is determined, the operator can select other thickness rather than the maximum one assumed by the program to be the real tissue thickness (blocks **72**, **73**, **74**), This operation is needed only for the soft tissue with a rather flat tissue-bone interface where multi-reflections of an ultrasound echo will normally occur. If the operator selects to perform a pretest again (block **75**), the program skips to the step of pretest (block **52**). If the operator selects to change other parameters (block **76**), the program skips to the step of changing parameters (block **58**).

If the starting key is pressed after a pretest (block **53**), the test number is set to zero, the subprogram TEST is then called (block **54**), and a cyclic test can be performed. The flowchart of the subprogram TEST is illustrated in FIGS. **10***g–j*. First, the gain of the ultrasound receiver is set to the same value as that used in the pretest (block **112**), and a small track window with a width of, for example, 2 μs, is set with the central position located at the rising edge of the select echo, from which the tissue thickness is determined in the pretest (block **113**).

Then, the subprogram MEASUREMENT is called to make a measurement of the load and the tissue thickness (block **114**). After the measurement, the echo amplitude is checked and the gain is adjusted accordingly (block **115** through **118**). The operation is the same as that described in the subprogram PRETEST (block **95** through **98**). If the gain exceeds the maximum limit and the determined thickness is larger than the maximum thickness limit (block **119**), for example, 15 cm, the program prompts an error message to show that no valid echo is detected within the track window (block **120**). After these steps, the subprogram MEASUREMENT is called again (block **114**). As stated in the description for the subprogram PRETEST, the above steps are looped quickly, and the gain is automatically adjusted to a proper level to make the echo amplitude an acceptable value. The operator can align the probe properly to obtain a valid echo from the tissue-bone interface for measurement by monitoring the amplitude bar indicator **159** and **160**. When the operator is satisfied with the echo amplitude and the pre-load applied, a cyclic measurement can be started by pressing the starting key (block **121**).

The tissue thickness measured just before the starting key pressed is assumed to be the initial thickness of soft tissue (block **122**). The data number and the cycle number are set to be zero (block **123**), and the subprogram MEASUREMENT is called (block **124**). If the gain exceeds the maximum gain limit, and the determined tissue thickness is larger than maximum thickness limit (block **125**), for example, 15 cm, the program sets an error flag, prompts an error message to show that no valid echo is detected within the track window (block **126**), and returns to where the subprogram is called (block **54**). Otherwise, the indentation depth w is calculated by subtracting the initial tissue thickness from the current measured thickness (block **127**). The indentation depth w and applied load P are recorded in the data points array (block **128**), and the data number is increased by one (block **129**). If the indentation depth w or the load P exceeds the maximum limits or minimum limits, audio feedbacks are provided (blocks **130**, **131**, **135**, **136**). The audio feedbacks can be, for example, two different tones from the buzzer, to indicate exceeding maximum and minimum limits, respectively. The operator can load and unload the probe **1** on the tissue surface to perform cyclic tests according to the audio feedbacks. Thus, the pre-load, maximum load and maximum indentation depth are manually controllable. After these steps, the gain is adjusted according to the echo amplitude (block **137** through **140**), and the position of the track window is adjusted according to the current thickness measured to make the middle of the window at the same position of the rising edge of the selected echo (block **141**). Then the subprogram MEASUREMENT is called again (block **124**), and the above steps are looped (block **124** through **141**). On the other hand, after every exceeding of the maximum limit is detected, the cycle number is increased by one (block **132**). If the cycle number exceeds the cycle limit (block **133**), an audio feedback, which differs from those for the load or indentation depth exceeding maximum and minimum limits, is provided to indicate the completion of a cyclic test (block **134**).

After collecting the data points for a cyclic test, the Young's modulus and the indentation rate are calculated and the results are displayed on the LCD **8** (block **142** through **148**). The flowchart of these steps is shown in FIG. **10***j*.

FIG. **5** shows an example of load and indentation sequences of a cyclic test, and FIG. **6** is the load-indentation curve plotted in accordance with FIG. **5**. In the calculation, the data points of the first cycle are excluded (block **142**, **143**) if it is selected to do so (block **60**, **61**) The operator may not control the loading and unloading sequence well during the first cycle of a cyclic test, So exclusion of the first cycle improves the validity of the results. The mean indentation rate for the loading phases of the selected cycles is then calculated using a linear regression as shown in FIG. **7** (block **144**). The first data point of each selected cycle is re-scaled to zero in time, and the time scales of other data points are adjusted accordingly. The Linear regression is operated for these re-scaled data points. The slope of the regression line is defined as the mean indentation rate. In the example shown in FIG. **7**, the mean indentation rate is 4.8 mm/s.

For the calculation of Young's modulus using the indentation model as shown in Equation (1), the scaling factor K is calculated from the table as shown in FIG. **8** using a linear interpolation (block **145**). The Possion's ratio v is assumed to be 0.45 for soft tissues. In this embodiment, the indentor radius a is 4.5 mm, and the calculated original tissue thickness is 19.6 mm. With these parameters, the scaling factor is calculated to be 1.3. The mean ratio Q of the load P to the indentation depth w for the loading phases of the selected cycles calculated using a linear regression is shown in FIG. **9** (block **146**). In this example shown in this figure, the mean ratio Q is 0.28 N/mm. Derived from Equation (1), the Young's modulus of the soft tissue is calculated using equation (2) (block **147**):

$$E = \frac{(1-v^2)}{2a\kappa(v,\, a/h)}Q \qquad (2)$$

For this example, the calculated Young's modulus is 19 kPa. After the calculation, the results of this cyclic test are automatically displayed on the LCD panel **8** (block **148**), and the program returns to where it is called (block **54**).

FIG. **12** is a display showing the number of cyclic test (**161**), the Young's modulus (**162**), the original thickness (**163**), and the mean indentation rate (**164**).

As shown in FIG. **10***d*, after a cyclic test, the operator can select to perform another cyclic test (block **55**), to show results of another test if more than one test have been performed (block **78**, **79**), to show the average (AVG) and the standard deviation (SD) of the results of all tests (block **80**, **81**), to delete results of a test (block **82**, **83**), to erase results of all tests and start a new group of tests (block **84**, **85**), to perform pretest again (block **86**), or to change parameters (block **87**).

FIGS. **13***a* and **13***b* are displays of showing the average (**165**) and the standard deviation (**169**) of the Young's modulus (**166**, **170**), the original tissue thickness (**167**, **171**), and the indentation rate (**168**, **172**) of a group of cyclic tests.

If performing another test is selected (block **55**) and the number of cyclic tests is not larger than the maximum limit (block **56**), the test number is increased by one (block **57**). The subprogram TEST is called again (block **54**), and another cyclic test can be performed. The above steps are looped until enough cyclic tests are conducted, other options are selected, or the program is interrupted by the operator.

We claim:

1. A portable ultrasonic palpation device comprising a hand held probe for palpation measurements including, arranged in series, mechanically, from an application tip of the probe for application to an outer surface of a soft tissue layer of which Young's modulus is to be measured, an ultrasonic transducer for launching and detecting ultrasound at the outer surface of the tissue layer and a pressure sensor for detecting the pressure applied to the tissue layer through the probe.

2. The portable ultrasonic palpation device according to claim **1**, wherein the probe comprises a first cylindrical body having a forward tip, including the application tip, containing the ultrasonic transducer, and a second cylindrical body attached end-to-end to the first cylindrical body and containing the pressure sensor.

3. The portable ultrasonic palpation device according to claim **2**, wherein the first and second cylindrical bodies have respective diameters of approximately 10 mm.

4. A portable ultrasonic palpation device comprising:

a hand held probe for palpation measurements including, arranged in series, mechanically, from an application tip of the probe for application to an outer surface of a soft tissue layer of which Young's modulus is to be measured, an ultrasonic transducer for launching and detecting ultrasound at the outer surface of the tissue layer and a pressure sensor for detecting the pressure applied to the tissue layer through the probe; and

a computer connected to receive signals from the transducer and from the pressure sensor and programmed to compute the Young's modulus of the tissue layer based on the signals received.

5. The portable ultrasonic palpation device according to claim **4**, wherein the computer is programmed to determine depth of the tissue layer from the outer surface to an underlying structure harder than the tissue layer.

6. The portable ultrasonic palpation device according to claim **4**, wherein the computer is programmed to compute

$$\frac{E(1-v^2)P}{2aK(v,\, a/h)w}$$

where

E is the Young's modulus,

v is Poisson's ratio,

P is pressure applied through the probe,

w is indentation depth in the tissue layer,

h is thickness of the tissue layer,

a is radius of an indentor of the probe, and

K is a scaling factor.

* * * * *

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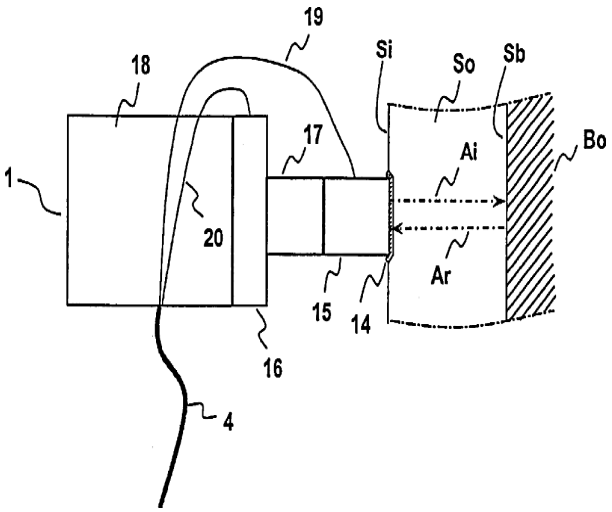
摘要(译)

一种用于测量杨氏模量和软组织层厚度的便携式超声波触诊装置，包括手持式触诊探头，该探头具有与称重传感器串联连接的超声波收发器。在测试期间，将探针放置在具有骨基质的组织表面上。当操作者在组织表面上手动加载和卸载探针时，嵌入微处理器模块中的程序连续地使超声发射器向软组织发射超声脉冲。接收从骨界面反射的超声回波信号，并且程序使用其飞行时间来计算原始厚度和软组织的变形。施加到组织的相应负载由称重传感器，其驱动器和放大器模块以及数据收集模块连续记录。在收集预定数量的加载 - 卸载循环的数据之后，程序使用层上压痕的解析解来计算来自载荷 - 压痕响应的软组织的杨氏模量。