(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 September 2007 (27.09.2007)

PCT

(10) International Publication Number
WO 2007/107908 A2

(51) International Patent Classification:
A61B 7/00 (2006.01)

(21) International Application Number: PCT/IB2007/050800

(22) International Filing Date: 10 March 2007 (10.03.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/785,357 23 March 2006 (23.03.2006) US

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(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

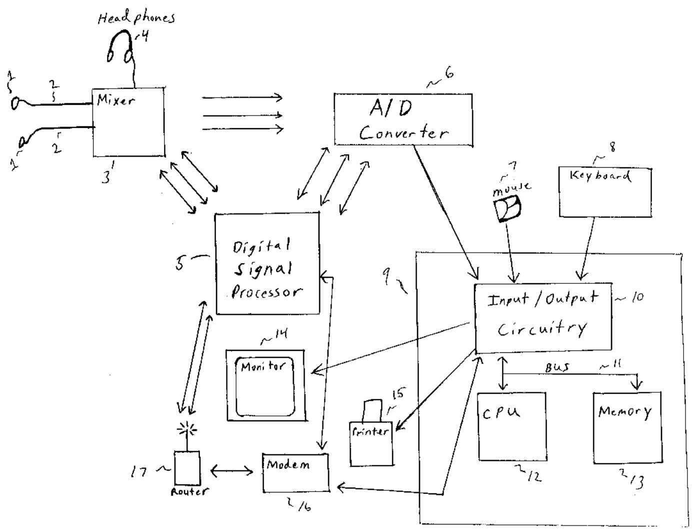
(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:
— *as to the identity of the inventor (Rule 4.17(i))*
— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SYSTEM AND METHOD FOR ACQUISITION AND ANALYSIS OF PHYSIOLOGICAL AUDITORY SIGNALS



(57) Abstract: A diagnostic system for collecting, processing, recording and analyzing sounds associated with the physiologic activities of various human organs. The system includes a plurality of transducers placed on the body surface at the operator's discretion. The microphones are coupled to analogue/digital signal processing circuitry for enhancement of the desired signal and exclusion of ambient noise. An A/D converter digitizes the incoming data and transmits data, which is divided into a multitude of discrete blocks, received over very finite intervals of time, to a computer workstation and moved through an analysis program sequentially. The program is displayed as a series of icons which depict operations that the program performs and which allow the operator to reprogram the system at any time. The data is displayed in graphical format and stored in memory as the program processes each block sequentially.

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Description

[1] **SYSTEM AND METHOD FOR ACQUISITION ANDANALYSIS OF PHYSIOLOGICAL AUDITORY SIGNALS**

Technical Field

[2] The present invention relates generally to the field of diagnostic methods and systems, and particularly to the acquisition and analysis of physiological auditory signals.

Background Art

[3] Throughout this application, various publications are referenced. The disclosures of these publications in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art as known to those skilled therein as of the date of the invention described and claimed herein.

[4] Auscultation of the lung and heart is probably the most widely used physical diagnostic method in respiratory and cardiac disease. However, due to the limitations of the human auditory system, auscultation has such low sensitivity and specificity that many physicians no longer rely solely on it as a diagnostic tool. Although digital acquisition and analysis of physiologic sounds has the potential to be of tremendous diagnostic/therapeutic benefit to patients, the medical community has been slow to embrace this technology. In order to overcome this obstacle, any system for digital acquisition and analysis of physiologic sounds must he lightweight and easy for individuals without technical expertise to operate and modify. In addition, all generated results must be presented in a format that allows for rapid interpretation and correlation with important physiologic values obtained from other tests. A description of the prior art and their perceived shortcoming relevant to the objectives of the present invention follows herein.

[5] Physiologic sounds may be captured electronically, processed, and transmitted back to the clinician thus enabling the human auditory system to obtain greater information conveyed by the signal. For example, U.S. Patent No. 5,774,563 discloses a device for acquiring physiologic sounds. Electronic circuitry embedded in the device enables the operator to filter and amplify the incoming signal. Furthermore, this device also allows the user to listen to the post-processed signal through implementation of earpieces. However, no plan is described for enabling clinicians of ordinary ability to modify the system. Thus, the effective frequency range measured by this device is 70 - 480 Hz, which is essentially unalterable, has minimal clinical applications. In addition, this system does not provide a means for digital acquisition/display/analysis of the recorded signal, which serves to severely limit the use of this device in a clinical setting. Other forms of analogous art, which are based on these same principals, share

similar disadvantages.

[6] Analogous inventions in the art have depicted devices capable of acquiring, processing and digitally recording/analyzing physiologic signals. U.S. Patent 6,139,505 discloses an electronic stethoscope for the digital acquisition and analysis of physiologic sounds. The device consists of a microphone, which can be embedded inside conventional chest pieces. After amplification and filtering, the signal is transferred to an analogue to digital converter (A/D converter) for computer analysis. The system disclosed contains a modifiable number of independent transducers to record physiologic sounds at any particular location, which the operator desires. The device allows for amplification/filtering of the recorded signal, store these recordings in memory, perform root mean square (RMS) and time expanded waveform analysis, and display data on a monitor for visual analysis/printing. This device is also fairly easy to modify/upgrade/repair and includes a built in program for analyzing respiratory sounds and generating a probable diagnosis based on this information.

[7] However, this device does not disclose a method to enable the physicians to listen to the sound as it is being recorded, but instead, requires them to discern phases of the respiratory cycle simply by inspection of the time expanded waveform. The patent describes a method by which physiologic sound may be processed and transmitted to a computer workstation using analogue circuitry which is bulky and not easily customized thus limiting the device's practical application. Further, no information is given about how this device can be used for higher level analysis (such as performance of Fourier Transformation or wavelet) of the desired signal, only time expanded waveform analysis and RMS of the complete spectrum arc illustrated. These quantities give incomplete information regarding the sound and the program is not easily operated/modified by a clinician of ordinary skill. Lastly, no method is outlined by the inventors for reducing the corruption of the data from inadvertent pickup of ambient noise or superimposed signals emitted from other organs in close proximity to the transducer. The probable diagnosis product available with this device is also extremely limited since it provides no quantitative information regarding the degree of functionality of the desired organ system. Although Murphey's electronic stethoscope represents significant improvement from analogous art as a system for the display and analysis of physiologic sounds, the limitations of this device as described above decrease its usefulness in a clinical setting.

[8] Additional devices have been patented which attempt to provide more sophisticated means for mathematically analyzing physiologic sounds and transmitting results to remote locations. One such example can be found in U.S. Patent No. 6.699,204, which illustrates a device for recording physiologic sound using multiple sensors that are secured to a patient via a harness. Physiologic sound can be recorded by the sensors

and relayed to a processing station for filtering/amplification using analogue circuits. The signal is then transferred to a sampler Ech (sound card) for digital recording via analogue circuitry or modem (not shown). With the aid of a specialized calculation manager (Matlab(®) for example), the device can evaluate a set of transformed intensity levels, each associated with a predetermined sound frequency and means for storing each transformed intensity level in correspondence with an associated frequency for the purpose of displaying these intensity levels, transformed on the basis of frequencies as a spectral representation of the auscultation sound.

[9] The device depicted by Kehyayan ci al. is a further improvement over analogous art since it provides an accurate spectral representation of the auscultation sound as the intensity varies with time. However, a physician of ordinary ability cannot be expected to have the technical expertise necessary to easily operate and/or modify this analysis program in order to examine a wide array of physiologic sounds. Also, no plan is outlined by the inventor for preventing extraneous sounds (from ambient noise or sound emitted from other organs) from influencing the results displayed on the spectral plots. Lastly, the spectral plots contain too much information for a clinician to interpret in a timely manner. Thus, it is unlikely that the invention proposed by Kehyayan will be useful in a practical setting, and thereby widely embraced by the medical community.

Disclosure of Invention

Technical Problem

[10]

Technical Solution

[11]

Advantageous Effects

[12] It has been proven that organs in the human body emit characteristic physiologic signals when they are functioning in the absence of pathology. It is an object of the present invention to provide an improved system for accurately assessing organ (particularly lung) function and thereby facilitating the diagnosis of certain diseases based upon digital recording, processing and analysis of these physiologic sounds.

[13] One of the main obstacles to widespread acceptance of electronic stethoscopes is that these devices are too cumbersome, and also, too complicated for health care professionals to operate in a professional setting. Thus, it is a further object of this invention to provide a compact, customizable device. But most important, the device will be an improvement over analogous art by providing a simple interface which allows medical professionals with limited technical background to easily manipulate vital parameters such as block length, overlap, sampling rate, low/high pass filtering,

adjusting the Fast Frouier Transformation (FFT) and RMS analysis to cover any component of the frequency spectrum, and applying data windows without the need for computer programming knowledge.

[14] Another object of this invention is to boost the accuracy of recording physiological sounds by providing the physician with an efficient method of eliminating background noise (which is either present in the ambient environment and/or emitted by other body organs in the vicinity of the transducer) from the desired signal in real time. Accomplishing this task will not only lead to greater accuracy in the measurement of physiologic sounds, but it will also allow the device to operate with a greater degree of autonomy when compared to analogous art.

[15] Lastly, acoustic signals from human organs occur over many different frequency ranges (depending on the specific organ and any pathology present) and are often of minimal intensity. Therefore, detecting differences in these signals between normal physiologic and pathologic states over a finite time interval for any given organ requires a system of mathematical analysis with greater sensitivity then that described in many versions of analogous art. Thus it is an additional objective of this device to provide a means for adjusting the frequency band in the Power Spectrum Density (PSD), which the RMS values are calculated from. The PSD results from performing the FFT on the digital data corresponding to the audio signal.

[16] As noted above, this invention relates to a system for recording and analyzing physiologic sounds to provide the clinician with information relating to functional status of the organ being examined. This information may provide clues, that when combined with other elements of a diagnostic workup (history. physical exam, lab tests, medical imaging. etc.) may facilitate the diagnosis of various disease states (pulmonary disease for example). Consistent with other forms of analogous art, the system includes a plurality of transducers, such as microphones embedded in small rubber tubes coupled to a thin plastic diaphragm(s) which may be placed at pre-selected sites on the patient using either light pressure or a harness of some type. Physiologic signals of interest vibrate the plastic diaphragm, which transmits the sound by moving air molecules in the tube. The transducers detect these sounds and convert them into electrical signals. The system contains a preamplifier that not only increases the intensity of the incoming electrical signal, but also polarizes the transducers with an electromotive force (preferably 48 Volts) applied equally to both inputs to the sensor with respect to ground (phantom power). In order to provide this polarizing potential high voltage commercial alternating current is converted to high voltage direct current. This voltage is applied to same wires that carry the audio signal. Since the preamplifier can supply such high voltage (unlike many computer sound cards available commercially) this invention can make use of transducers with higher signal

to noise ratios then those used in analogous art. Furthermore, portability may be maximized by supplying the phantom power though a rechargable battery.

[17] The system also includes a digital signal processor for conditioning the signal (filtering, gating, limiting, or excluding background noise). In the preferred embodiment of the invention, analogue circuitry or a digital signal processor employing Super Harvard Architecture (SHARC) can be added for additional filtering, expansion, compression or conversion of the processed signal back to sound energy thereby enabling the operator to hear the altered sound in real time. After processing, the analogue signals generated by the transducers arc converted into digital data and transferred to a computer workstation. In order to increase the portability of this device, digital data may be transmitted to the workstation over wireless internet. A further advantage of utilizing a SHARC processor is that optimal settings for detecting sound from a variety of sources may be stored in memory for instantaneous recall by the operator. These aforementioned settings which are programed into the SHARC processor may enable the claimed invention to acquire properties of sound transmission which are identical to a conventional acoustic stethoscope. This is important because acoustic stethoscopes remain popular in clinical settings due to the fact that a tremendous amount of research has already been done with them and the steadfast hesitancy among health-care professionals to abandon their use of these devices.

[18] The computer station includes a microprocessor, input/output circuitry, and random access memory for data storage, one or more input devices (such as a keyboard or mouse), a modular interface with many different graphical displays of incoming data, and one or more output devices (such as a printer, monitor or modem for transmission over the Internet).

[19] Executing on the computer is an application program constructed from a set of modular elements synthesized using a graphical programming language. The application program collects the data and organizes it into discrete sections (blocks) before moving it though a series of modules. By clicking on any specific module with the mouse, the operator can set the sampling rate, block size and overlap. Furthermore, the operator may elect to further high/low pass filter the data digitally or apply a mathematical window analogous to FFT processing in order to minimize distortion of calculated results.

[20] After breaking the signal into multiple blocks (which correspond to discrete time intervals) and then pre-processing these blocks, the program calculates the power spectrum density of the portion of the signal contained in each block using the FFT. After calculation the computer displays the results graphically as a plot of Intensity vs. Frequency. These results are updated continuously as the PSD is calculated anew for

each incoming block and the results of the previous block are saved in memory.

[21] As the PSD is calculated for each incoming block, the computer may exclude portions of the PSD that are outside the selected thresholds specified by the operator. This is possible because the program may contain a trigger, which enables the operator to exclude portions of the spectrum, which are not of interest with a simple mouse click. Once the PSD is determined, the program calculates the root mean square (RMS) value of the signal in the frequency band(s) chosen by the operator. The computer performs this calculation on each incoming block and displays the data as a list during the time of operation. This method is method is highly advantageous to the clinician since it takes a very complicated quantity (the PSD of each block that gives information about the power of all frequency components in the block) and converts it into a simple quantity (RMS), while still relaying the necessary information about the signal to the clinician. Secondly, by performing these calculations on each incoming block of the data, the properties of the signal outlined above can be analyzed as they vary over time. The clinician can then use this information about an organ's spectral characteristics to assess its' degree of functionality in a quick, inexpensive, accurate and non-invasive manner. The analysis program illustrated in the present invention can be used either as a stand alone application or in combination with a number of additional program elements which may include patient's electronic medical records. As a result, this system has the potential to dramatically improve efficiency in the healthcare system and clinical outcomes for patients.

[22] It has been proven that organs in the human body emit characteristic physiologic signals when they are functioning in the absence of pathology. It is an object of the present invention to provide an improved system for accurately assessing organ (particularly lung) function and thereby facilitating the diagnosis of certain diseases based upon digital recording, processing and analysis of these physiologic sounds.

[23] One of the main obstacles to widespread acceptance of electronic stethoscopes is that these devices are too cumbersome, and also, too complicated for health care professionals to operate in a professional setting. Thus, it is a further object of this invention to provide a compact, customizable device. But most important, the device will be an improvement over analogous art by providing a simple interface which allows medical professionals with limited technical background to easily manipulate vital parameters such as block length, overlap, sampling rate, low/high pass filtering, adjusting the Fast Frouier Transformation (FFT) and RMS analysis to cover any component of the frequency spectrum, and applying data windows without the need for computer programming knowledge.

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noise (which is either present in the ambient environment and/or emitted by other body organs in the vicinity of the transducer) from the desired signal in real time. Accomplishing this task will not only lead to greater accuracy in the measurement of physiologic sounds, but it will also allow the device to operate with a greater degree of autonomy when compared to analogous art.

[25] Lastly, acoustic signals from human organs occur over many different frequency ranges (depending on the specific organ and any pathology present) and are often of minimal intensity. Therefore, detecting differences in these signals between normal physiologic and pathologic states over a finite time interval for any given organ requires a system of mathematical analysis with greater sensitivity then that described in many versions of analogous art. Thus it is an additional objective of this device to provide a means for adjusting the frequency band in the Power Spectrum Density (PSD), which the RMS values are calculated from. The PSD results from performing the FFT on the digital data corresponding to the audio signal.

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[30] After breaking the signal into multiple blocks (which correspond to discrete time intervals) and then pre-processing these blocks, the program calculates the power spectrum density of the portion of the signal contained in each block using the FFT. After calculation the computer displays the results graphically as a plot of Intensity vs. Frequency. These results are updated continuously as the PSD is calculated anew for each incoming block and the results of the previous block are saved in memory.

[31] As the PSD is calculated for each incoming block, the computer may exclude portions of the PSD that are outside the selected thresholds specified by the operator. This is possible because the program may contain a trigger, which enables the operator to exclude portions of the spectrum, which are not of interest with a simple mouse

click. Once the PSD is determined, the program calculates the root mean square (RMS) value of the signal in the frequency band(s) chosen by the operator. The computer performs this calculation on each incoming block and displays the data as a list during the time of operation. This method is method is highly advantageous to the clinician since it takes a very complicated quantity (the PSD of each block that gives information about the power of all frequency components in the block) and converts it into a simple quantity (RMS), while still relaying the necessary information about the signal to the clinician. Secondly, by performing these calculations on each incoming block of the data, the properties of the signal outlined above can be analyzed as they vary over time. The clinician can then use this information about an organ's spectral characteristics to assess its' degree of functionality in a quick, inexpensive, accurate and non-invasive manner. The analysis program illustrated in the present invention can be used either as a stand alone application or in combination with a number of additional program elements which may include patient's electronic medical records. As a result, this system has the potential to dramatically improve efficiency in the healthcare system and clinical outcomes for patients.

[32]

Description of Drawings

[33] The advantages of the present invention may be further illustrated by referencing the following description and corresponding drawings, in which:

[34] Figure 1 provides a general overview of the preferred embodiment of the present invention.

[35] Figure 2 is an illustration of the computer station component of Figure 1.

[36] Figure 3A - C is a block diagram of the preferred embodiment of the present invention, absent the computer processing station.

[37] Figure 4 is a diagram displaying the different ways in which an operator may process the incoming signal (as depicted in the product operations manual) using a digital equalizer containing SHARC processors such as the DEQ2496 manufactured and sold by Behringer.

[38] Figure 5 illustrates a display of the RMS values for the incoming signal (ambient noise) received from the test microphone. These values can be helpful in quantifying the effect of ambient noise on the calculation of the RMS values of the desired signal.

[39] Figure 6 is a flow chart of the data collection and analysis program. Each icon represents an operation which is performed on incoming data and selecting a corresponding icon can modify these operations.

[40] Figures 7A and 7B represent time expanded waveforms of physiologic sounds.

[41] Figure 8 is a graphical representation of the power spectrum density calculated using the Fast Fourier transformation from an incoming data stream representative of

physiologic sounds received by the transducer positioned over the heart.

[42] Figure 9 depicts the sequential display of RMS values calculated from the PSD after processing for heart sounds. This data may then be used to assess the degree of functionality of the target organ.

[43] Figure 10 depicts the PSD calculated from tracheal breath sounds using the FFT.

[44] Figures 11A and 11B depict the sequential display of RMS values calculated from the PSD after processing of the tracheal breath sound.

[45] Figure 12A - 12C depict the sequential display of values corresponding to the maximum frequency 12A and corresponding intensity 12B/12C from the desired portions of the PSD after processing of the incoming signal from the heart. Data is displayed as it is obtained from each incoming block.

[46]

Best Mode

[47] Figure 1 provides an overview of the sound recording and analysis system of the present invention. This system includes a transducer **1** , such as an analogue condenser microphone, which can be placed at various sites around the patient to listen to sounds emitted by different organs. It should be understood that the system could be expanded to include additional transducers **1** if desired so that data from multiple sites can be collected concurrently. To isolate the sensors from external sounds (and thereby improve signal to noise), they may be embedded in the tubing/chest pieces of conventional stethoscopes. The transducer(s) **1** may be held against the surface of the patient with mechanical pressure applied by the operator, adhesive tape or suitable strapping to prevent movement during the data acquisition process.

[48] Leads **2** extending from the sensors are balanced cables with XLR inputs **97** that connect to a signal conditioning station. A suitable signal conditioning circuit for use in the present invention could be the Eurorack 1202, a sound mixer **3** made by Behringer. This station performs many important functions. First, it supplies the electromotive force needed to polarize the transducer **1**. In the preferred embodiment, the mixer **3** converts standard alternating current (120 volts) into direct current (48 volts). It has been proven that to accurately record physiologic sounds, it is important to have a transducer **1** with a high signal to noise ratio and a flat frequency response. These types of sensors may demand high voltages, which are not readily supplied by analogous art that utilizes sound cards built into most commercially available personal computers **9** or batteries.

[49] The voltage is then supplied to the sensor through both XLR inputs **97** equally with respect to ground (phantom power) **93**. The audio signal is transmitted through these same inputs approximately 180 degrees out of phase of each other thereby ensuring a balanced signal . Balanced signals are less corrupted by ambient noise relative to un-

balanced ones. Inside the stethoscope tube, sound energy generated from organs inside the body is converted into an electrical signal by the microphone. This electrical signal (which is a representation of the sound) is then transmitted to the mixer **3** though the same leads **2** that supply the voltage in the manner described previously. To further prevent this desired signal from being corrupted by external electric/magnetic fields, the cables maybe shielded. The mixer **3** may have additional ports to receive electrical signal from additional sensors. In addition, phantom power **93** may be supplied via alkaline (such as the ART Phantom Power Adapter), or other rechargeable 9 volt batteries.

[50] Once the electrical signal is received by the mixer **3** , it may be amplified **255** and/or filtered **256** . In the preferred embodiment the mixer contains circuitry **383** , which can act as a high pass filter (80 Hz) **256** and/or low pass filter (12 kHz) **256** , although other frequencies are possible. It should be noted that the invention gives the operator the ability to bypass this processing if they choose. After amplification/filtering, the signal may be sent to a headset where it is converted back to sound energy, thereby enabling the operator to listen to the sound **4** as it is recorded. The signal may also be sent for recording on cassette tapes or it can be sent to a digital signal processor (DSP) **5** . One such example is the DEQ 2496, a digital equalizer with Super Harvard Architecture(SHARC) signal processors **76,77,78,79,80,81,82,83,84,85,86,87,88,89,90** and specialized software, made by Behringer which is depicted in Figures 4 and 5.

[51] The digital processor **5** performs the fast fourier transformation on the signal and displays both the discrete frequency bands and the power of the signal in each band (power spectrum density) **622** . From here, the operator can selectively amplify/attenuate components of the signal in any frequency band from 20 - 20000 Hz (similar to an equalizer) **612-615** . Unwanted signal can be excluded by compressing **615** (the processor reduces the intensity of all signal components with a volume that is greater then desired) or expanding **615** (reducing the intensity of all frequency components with an intensity less then that desired by the operator) frequencies detected by the transducer **1** . Of note, the device can function as a noise gate and/or limiter if compression/expansion is performed to a maximum degree. All operations undertaken by the digital signal processor **5** to alter the incoming audio signal can be displayed via LCD **619** , and device setting **612 - 623** may be saved in memory **620** for instant recall by the operator at some future time. The adjustment of stereo width function **623** may or may not be necessary. It is understood that specific settings **612 - 619** of the digital signal processor **5** may cause the invention to acquire properties of sound transmission similar to conventional acoustic stethoscopes. This characteristic of the claimed invention is a valuable attribute, since a tremendous body of research has already been conducted in the analysis of physiologic auditory signals using said acoustic

stethoscopes. Secondly, it is well known that such conventional stethoscopes are still widely popular in the market place. Specifically, settings contained in the digital signal processor **5** may allow clinicians to measure blood pressure values, grade cardiac murmurs (I - VI) and listen to other physiological sounds in a manner which correlates well with findings obtained from a conventional acoustic stethoscope. The ability to perform compression/expansion is an improvement over other forms of analogous art since it allows the device to record physiologic sounds from the human body without having to constantly be directed to by the operator **IC5** . However, it should be noted that the device might set up so that it is required to be directed by the operator before making recordings.

[52] Furthermore, the digital signal processor **5** contains a test transducer **1** , which can be deployed by the operator if desired. This test transducer **1** may be affixed to body surface or exposed to the ambient environment. The test transducer **1** records sounds from sources that might corrupt the signal being recorded from the organ of interest. This may include noise present in the ambient environment or sound emitted from other organs in the vicinity of the target organ. The power spectrum density **621** of these ambient signals can be used to calculate and display the corresponding RMS values **622A** for the signal as demonstrated in Figure 5. The components of the undesired signal, which interfere with the signal of interest, are effectively quantified in real time. The DSP **5** may transmit data directly to a computer workstation **9** for further analysis via cable or wireless internet connection ***16,17*** . This is a significant improvement over analogous art because it can be used to remove ambient noise that contains identical frequency components to those of the target organ, thus producing a much clearer signal from the target organ in addition to enabling the clinician to obtain standardized measurements regardless of the noise level present in the ambient environment at the time of measurement. The processing methods may include (but is not limited to) graphic **612** , parametric **613** , digital **614** and/or dynamic equalizers **615** , as well as signal compression/expansion/boosting/cutting and feedback destruction **622** or bypassed altogether **616** .

[53] After this additional processing, the signal from each analogue output is transmitted to an analog-to-digital converter (A/D converter) **6** , which may or may not be part of the computer station **9** . The A/D converter **6** converts the processed audio information into a digital data stream for transmission to the workstation **9** . One advantage of employing a SHARC processor **5** is that digital data may transmitted the computer workstation **9** over wireless internet **16,17**. This process can be achieved by coupling the SHARC processor **5** to a modem **16** with a WiFi PC card (not shown). Digital data acquired during stethoscope operation may be transferred to a WiFi Access Point/ Router **17**, and afterward, sent to a modem **16** via CAT5 cable or WiFi

USB adapter .

[54] The sampling rate used in the digitizing the data may be adjusted by the operator and should be greater then 44.1 KHz with a bit rate preferably greater then 24 bits per sample. The A/D converter **6** is preferably multi-channel which may contain an additional preamp such as the Edirol UA-25 sold by the Roland Corporation. Figure 3 is a schematic of all of the hardware components which comprise the preferred embodiment of the invention (components for transmission of data over a wireless network are not shown). A suitable workstation **9** may be a personal computer of the E-machines series as sold by Lenovo, comprising a microprocessor **12** , input/output circuitry **10** , and memory for data storage **13** , one or more input devices (such as a keyboard **8** or mouse **7**), a modular interface with many different graphical displays of incoming data as depicted in Figure 6, and one or more output devices such as a printer **15** , monitor **14** or modem **16** for transmission over the Internet. However, it should be understood that other models may be substituted. These computers are controlled and coordinated by operating system **16A** , such as Microsoft Windows XP or other system. The operating system **16A** may also comprise a window manager **17A** , printer manager **18** and additional device managers **21** in addition to one or more device drivers **19,20,22** in order to allow the computer workstation **9** to interface with hardware components.

[55] In the present invention digital data from the A/D converter **6** is transmitted to input/Output (I/O) circuitry **10** of the computer via USB cable **JK1** . Figure 2 illustrates the interaction of software elements on the computer workstation **9** with the application programs **210,220,230** and operating system **16A** relationships shown by arrows **306,307,308** via system calls. The program (Fig 6) is organized by a series of graphical icons that are provided via specialized data acquisition software such as DASY LAB 9.0, a product manufactured and sold by Capital Equipment. Each icon, constructed using a graphical programming language, represents a command(s) for the workstation **9** to perform. This program **210** is fully customizable since simply inserting/deleting icons in the flow diagram can make new programs. All commands given to the analysis program by the clinician are accomplished via simple keyboard **8** entries or mouse **7** 'clicks.' Thus, knowledge of computer programming languages (which many health care personal do not possess) is not a required prerequisite for proper operation of the instant device.

[56] Prior to first listening to the sound the clinician chooses the sampling rate by clicking on a tab marked 'experimental setup.' The A/D input icon **404** receives data via I/O circuitry **10**. The Recorder Icon **407** displays the time-expanded function of the incoming signal illustrated in Figures 7A and 7B in accordance with the description set forth in U.S. Pat. No 3.990,435. The clinician then clicks the Filter icons **405,406** in

order to select frequencies where the signal can be high/low pass filtered digitally. Some examples include digital high/low pass filtering, application of a windowing function to incoming data analogous to PSD calculation, adjustment of sample rate, block size, degree of overlap and recording time. Through the use of these icons, the clinician may also determine the characteristic (Butterworth, Bessel, etc.) and order of the digital filter. The clinician will click the Data Window Icon **408**, to select the desired block length, appropriate mathematical window to fit the data with, and determine the degree of overlap (if any) between successive blocks. The FFT icon **409** in the program **210** instructs the computer to calculate the FFT on the portion of the signal represented by each block. The Y/T Icon **413** enables the clinician to view a display of the PSD on a monitor **14** for each block after it is calculated as illustrated in Figures 8 and 10. By clicking the FFT max icon **410**, the clinician can specify the frequency range within the PSD where both the frequency of maximum intensity and its' magnitude may be calculated as illustrated in Figures 12A, 12B and 12C. These quantities may be displayed by the icon marked 'Digital Meter' **411** or List icon **412**. By clicking the Trigger Icon, the clinician can determine which frequency components of the PSD will be excluded from the RMS calculation (not shown).

[57] Since different body organs emit sound in different frequency ranges. The ability to adjust the frequency range is vital if one hopes to construct a single device that can be used to analyze sounds from all of the different organs (not just lung). The Statistics Icon **414** instructs the computer to calculate the RMS value of the signal in the desired frequency range set by the digital high/low pass filters **405,406** or Trigger Icon in the specified range. The List Icon **415** displays the RMS value sequentially as it is calculated from each incoming block as shown in figures 10 and 12. Additional modules may be added to the program **210** for the purpose of determining the magnitude of the change in RMS values with respect to time at a given anatomic position. These RMS values, either as displayed by the List Icon **415** or when combined with additional analysis programs **220,230** on the workstation **9**, give the attending physician a mechanism for comparing the intensity of physiologic sound recorded by the sensor in any desired frequency range and over any duration of time.

[58] In operation, the sensors **1** are affixed to any part of the body surface according to the discretion of the clinician. The system is then initialized and data is transmitted to application program **210** , as the patient inhales/exhales, sound is converted to audio signals which maybe amplified/filtered/processed before being relayed to both the clinician and the application program **210** in the computer workstation **9** . At any instant in time (if the physician hears an interesting sound) the physician can start the digital recording by clicking the Record Icon, a green arrow in the upper left hand corner of the screen. After the signal of interest is no longer audible, the physician may

stop recording by clicking the red square icon or specifying the duration of recording via the 'Stop' icon **416** . The computer recording may be influenced by the DSP **5** via compression/limiting **615** or equalization **612,613,614** as described above. After recording is complete, the clinician may click the list icon **415** to obtain a columnar display of the desired RMS values. Review of this list may give the clinician valuable information regarding the degree of functionality/pathology present in certain organs (lung, heart, bowel. etc.). The settings and/or outputs of the PSD (calculated from the Y/T icon **413**), Time Expanded Waveform **407** , FFT Maximum **410** , Filters **405,406** and List **412,415** can all be saved in memory **13** , printed on paper via printer **15** or transmitted via modem **16** to another computer **9** though the internet. It should be understood that additional icons may be added to the program in Figure 6 if additional data manipulation is desired. In addition, program settings for analysis of auditory signals from two or more different sources(organs, ambient noise, ect.) such as the heart and trachea (Figures 9 and 11) may be combined, thereby enabling the operator to analyze discrete frequency bands within a signal. For instance, if an observed physiologic sound is composed of sounds from the trachea and heart superimposed on each other, the operator may combine modules from Figure 9 and 11 into a single program that will separately analyze the signals from each source simultaneously. If there exists overlap, additional methods may be deployed to separate out the overlapping frequency components of the two or more sources.

[59] Lastly, data generated from this analysis program **210** maybe integrated with numerical/text data contained in a patients electronic medical records **220**. The integration of data among these programs **210, 220,230** can be directed by an operator using a mouse **7**, keyboard **8** or other input. U.S. Patent No. 6,944,821 and 6,154,756 demonstrate two such methods for performing said integration of data contained on multiple program elements. Additional software programs **230** may combine data from the analysis program **210** and electronic medical records **220** for the purposes of assessing target organ functionality, characterization of pathology if present, and generating accurate predictions regarding the degree of functionality of the target organ system in the near future.

[60] A description on the preferred embodiment of the invention outlines a very specific method for analysis of physiologic sounds. The device as claimed is capable of variants and it should be appreciated by one skilled in the art that substitution of materials and modification of details can be made without departing from the spirit of the invention.

Mode for Invention

[61]

Industrial Applicability

[62]

Sequence List Text

[63]

Claims

[1] 1. A diagnostic system for use in acquiring, storing and analyzing physiologic sounds during a time interval desired by an operator comprising:
at least one transducer which detects a set of physiological sound outputs produced by a subject, wherein said at least one transducer is placed around one or more desired anatomic sites on said subject;
means for converting said set of physiologic sound outputs into electrical signals;
means for amplification of said electrical signals;
means for grouping said electrical signals into desired electrical signals and undesired electrical signals by using analogue circuits for high pass and low pass filtering;
means for converting said desired electrical signals back into audio signals so that the operator may listen to a representation of the sound detected by the transducers in real time after amplification and filtering; and
means for converting said desired electrical signals into a stream of digital data that can be received and output by a computer workstation.
2. The diagnostic system of claim 1 wherein said at least one transducer comprises a plurality of transducers.
3. The diagnostic system of claim 1 wherein high voltage AC is converted into high voltage DC and supplied to said plurality of transducers equally via a set of two separate inputs with respect to ground and wherein an output signal of said plurality of transducers is transmitted through a same set of electrical lines that supply an input voltage and wherein a phantom power supply may be provided to said plurality of transducers via a microphone pre-amplifier, alkaline, lithium-ion or other rechargeable battery.
4. The diagnostic system of claim 1 wherein said electrical signals are transmitted to a digital signal processor containing a test microphone and memory system disposed for storing and displaying a set of digital sound signals received from an ambient environment and a set of other organs not under analysis, wherein the output data of said digital signal processor may be transmitted to a computer workstation by way of cable or wireless network for further analysis and wherein said computer workstation comprises a means for elimination of undesired noise from the desired signal.
5. The diagnostic system of claim 4 wherein information regarding the operations performed in processing the incoming audio signal are displayed via LCD and comprising means for saving said operations in memory for instantaneous recall by the operator at a later time.

6. The diagnostic system of claim 4 wherein said digital signal processor attenuates a set of frequencies within said transmitted set of digital sound signals which possess intensities that are either below or above a pre-determined intensity threshold, defined as compression or expansion.
7. The diagnostic system of claim 6 wherein individual frequency bands of said digital signal processor, may be selected for amplification or attenuation, wherein said digital signal processor contains narrow band filters for destruction of acoustic feedback function and wherein said digital signal processor functions as a device selected from the group consisting of graphic, parametric, digital and dynamic equalizer.
8. The diagnostic system of claim 7 wherein said root-mean-square of undesired ambient noise received by a test microphone is displayed by said digital signal processor in real time.
9. The diagnostic system of claim 8 wherein upon entering said system, a set of digital signals is divided into a plurality of blocks, of which an individual block represents a small portion of said incoming digital signal over a finite time interval determined by the operator.
10. The diagnostic system of claim 9 wherein said individual blocks are acted upon sequentially by an analysis program.
11. The diagnostic system of claim 10 wherein a set of results of said analysis program is illustrated on a monitor by a series of interconnected icons, selectable by use of a mouse or a keyboard and wherein different frequency bands within an incoming digital signal may be processed simultaneously.
12. The diagnostic system of claim 9 wherein a system sampling rate can be chosen.
13. The diagnostic system of claim 9 wherein a desired block length can be chosen.
14. The diagnostic system of claim 9 wherein a degree of overlap between succeeding of said plurality of blocks of data can be determined.
15. The diagnostic system of claim 9 wherein a type of mathematical window to apply to incoming data can be chosen, prior to calculation of a power spectrum density.
16. The diagnostic system of claim 15 wherein said power spectrum density of a portion of a signal contained in said individual blocks can be calculated sequentially using a fast fourier transformation or other form of mathematical analysis and presented in a set of graphical displays such as a Power vs. Frequency plot.
17. The diagnostic system of claim 16 wherein frequency ranges of said

calculated power spectrum densities are excluded prior to further analysis using a digital filter mechanism or trigger function.

18. The diagnostic system of claim 17 wherein for portions of the incoming data that were not excluded prior to further analysis said analysis program determines the root-mean-square value sequentially from the portion of the signal represented in said blocks or over a series composed of an arbitrary number of said individual blocks as selected by the operator.

19. The diagnostic system of claim 18 wherein said root-mean-square values are displayed sequentially in a columnar format and is transferred to at least one separate analysis programs which may incorporate additional data selected from the group consisting of patient demographics, background noise, results from additional laboratory, imaging and physical exam tests in order to provide quantitative measurements relating to the degree of functionality and presence of pathology in the target organ system.

20. The diagnostic system of claim 19 wherein said at least one separate analysis programs may also possess means to characterize changes in RMS values with respect to time and wherein said at least one separate analysis program is combined with a set of additional clinical information in order to prediction a degree of functionality of an investigated organ system for a time period.

21. The diagnostic system of claim 20 wherein the frequency of maximum intensity can be determined by said analysis program for each said blocks on all portions not excluded prior to further analysis.

22. The diagnostic system of claim 16 wherein a set of application programs and said set of graphical displays is permanently stored in the random access memory of computer workstation.

23. The diagnostic system of claim 10 wherein digital high pass/low pass filtering is performed by selecting a Filter icon prior to Fast Fourier Transfer calculation.

24. The diagnostic system of claim 16 further comprising a printer coupled to said computer wherein said analysis program is configured to print said graphical display on paper.

25. The diagnostic system of claim 16 further comprising a modem coupled to said computer wherein said analysis program may transmit information contained in said graphical displays to a set of computer workstations via a world wide web network connection.

26. The diagnostic system of claim 16 wherein data stored in a RAM may be copied to magnetic disk or compact disc.

27. The diagnostic system of claim 16 further comprising means for displaying

an intensity of said signal contained in each block as an arbitrarily expandable or contractible time domain plot.

28. The diagnostic system of claim 16 wherein said axis scale of said graphical displays are chosen arbitrarily such as through a zoom function.

29. The diagnostic system of claim 9 further comprising a means for initiating or terminating a digital recording of said set of digital signals by selecting a user interactive screen button.

30. The diagnostic system of claim 20 further comprising means for combining numerical/textual elements of an electronic medical record with data obtained form the analysis program under the direction of an operator using a peripheral input device connected to said computer workstation for import of data into additional programs for further analysis which may be selected from a group comprising degree of target organ functionality at present time, characterization of pathological process(s) (if present), and near-future prognostic predictions regarding the target organ system.

31. A diagnostic system for use in acquiring, storing and analyzing physiologic sounds during a time interval desired by an operator comprising:

at least one transducer which detects a set of physiological sound outputs produced by a subject, wherein said at least one transducer is placed around one or more desired anatomic sites on said subject;

means for converting said set of physiologic sound outputs into electrical signals;

means for amplification of said electrical signals;

means for grouping said electrical signals into desired electrical signals and undesired electrical signals by using analogue circuits for high pass and low pass filtering;

means for converting said desired electrical signals back into audio signals so that the operator may listen to a representation of the sound detected by the transducers in real time after amplification and filtering; and,

means for converting said desired electrical signals into a stream of digital data that can be received and output by a computer workstation; and, wherein an amount of time elapsed prior to termination of recording can be determined by selecting a user interactive screen button Stop icon and inputting a desired duration of recording via keyboard.

32. A diagnostic system for use in acquiring, storing and analyzing physiologic sounds during a time interval desired by an operator comprising:

at least one transducer which detects a set of physiological sound outputs produced by a subject, wherein said at least one transducer, which may be a condenser microphone with balanced XLR input/output, is placed around one or

more desired anatomic sites on said subject;
means for converting said set of physiologic sound outputs into electrical signals;
means for amplification of said electrical signals;
means for grouping said electrical signals into desired electrical signals and undesired electrical signals by using a set of analogue circuitry and digital signal processor settings for high pass and low pass filtering;
means for converting said desired electrical signals back into audio signals so that the operator may listen to a representation of the sound detected by the transducers in real time after amplification and filtering;
means for converting said desired electrical signals into a stream of digital data that can be received and output by a digital signal processor wherein at least one set of operations allow transmittal of physiologic sounds to an operator in a manner which is indistinct in comparison to a conventional acoustic stethoscope from the prospective of said operator;
means for storing said at least one set of operations in digital memory for instantaneous recall by the operator;
means for configuring a set of analogue amplifier, analogue filter and digital signal processor settings to optimize transmission of physiologic sounds from the group consisting of lungs, trachea, heart, heart murmurs, bowels, blood pressure measurements, bruits, and peripheral pulses;
means for correlating the transmitted electronic representations of said physiologic sounds with a set of corresponding representations obtained from an acoustic non-electronic stethoscope; and,
means for configuring said set of analogue circuitry and digital signal processor settings to optimize measurement of functions from the group consisting of blood pressure, trachea/lung sounds, cardiac function and cardiac murmurs;
means for configuring said set of analogue circuitry and digital signal processor settings to optimize assessment peripheral pulses and bowel sounds such as obstruction or ileus;
means for configuring said analogue circuitry and digital signal processor settings to optimize grading the severity of bruits;
means for configuring said analogue circuitry and digital signal processor settings to optimize assessment the functionality/location of foreign bodies within the patient which includes the group consisting of endotracheal tube, feeding tubes, catheters, pacemakers, and central/peripheral lines, shunts and stents.

Figure #1

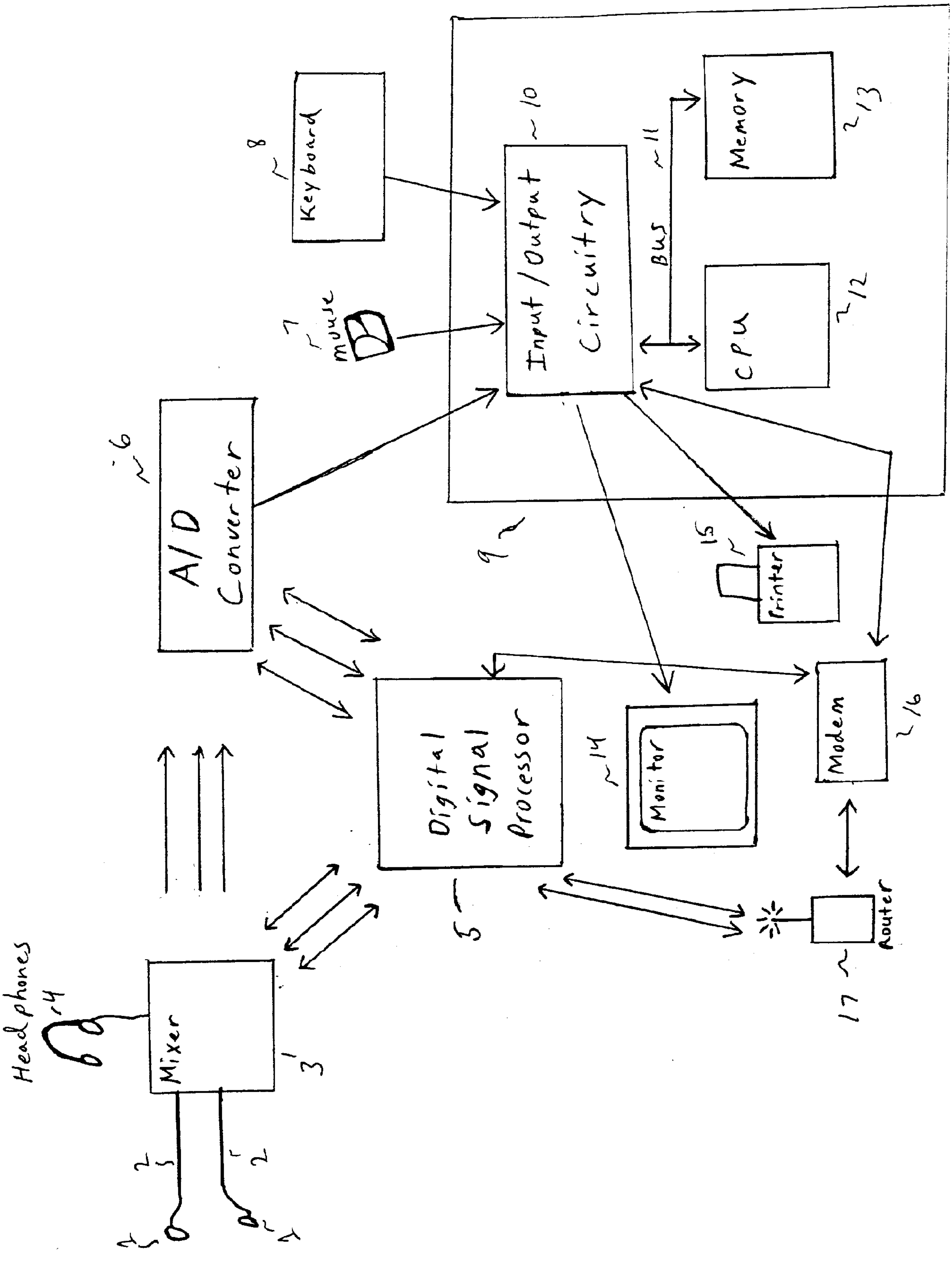
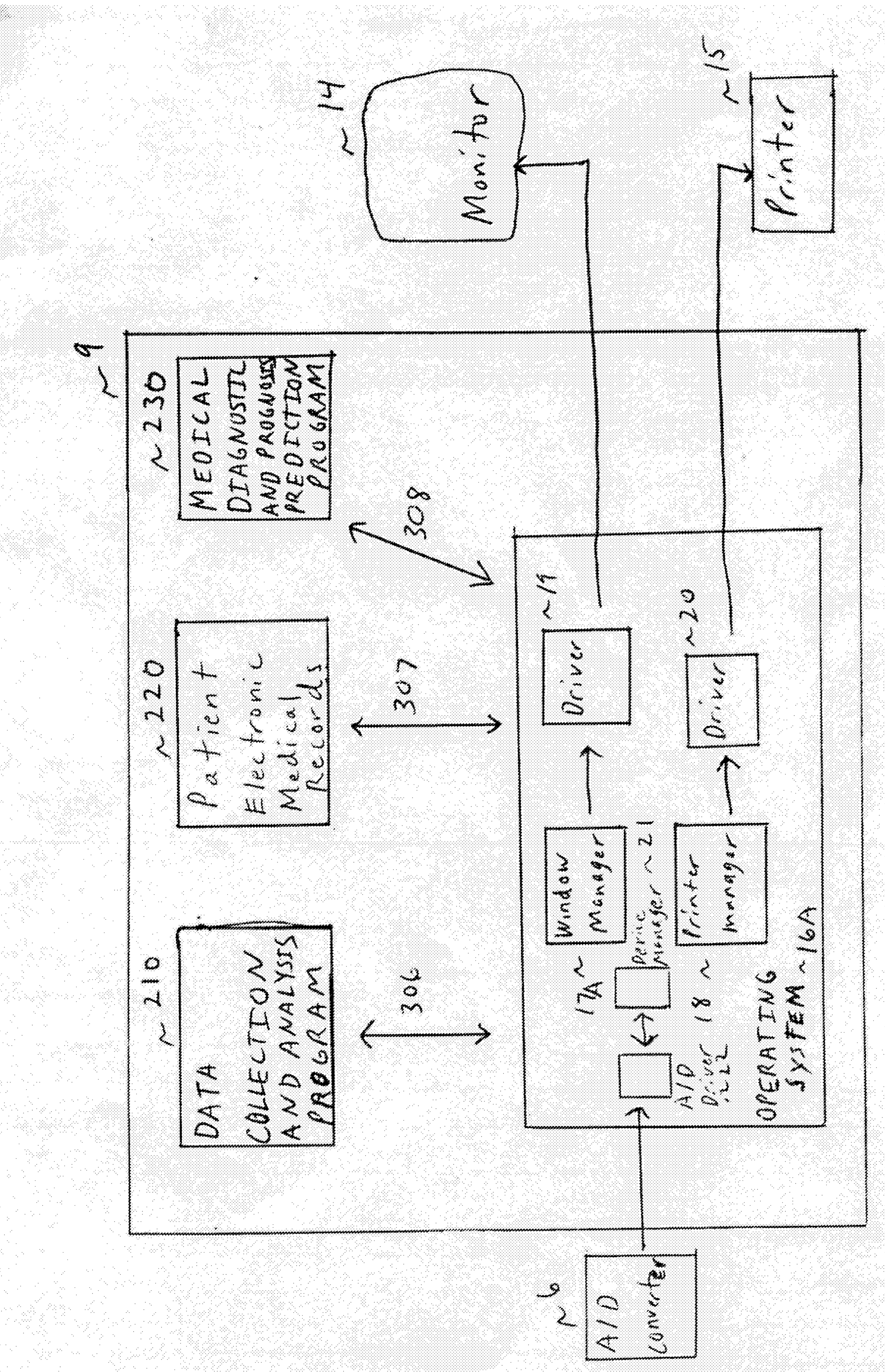

Keyboard
8
mouse
7
Input / Output Circuitry
10
BUS
11
Memory
13
CPU
12
A/D Converter
6
9
Printer
15
Digital Signal Processor
5
Monitor
14
Modem
16
Router
17
Headphones
4
Mixer
3
2
2
1
1

Figure #2


~9
~210
DATA COLLECTION AND ANALYSIS PROGRAM
~220
Patient Electronic Medical Records
~230
MEDICAL DIAGNOSTIC AND PROGNOSIS PREDICTION PROGRAM
306
307
308
~19
Driver
~20
Driver
Window Manager
Printer Manager
Device Manager ~21
17A
18
A/D Driver ~22
OPERATING SYSTEM ~16A
~14
Monitor
~15
Printer
~6
A/D Converter

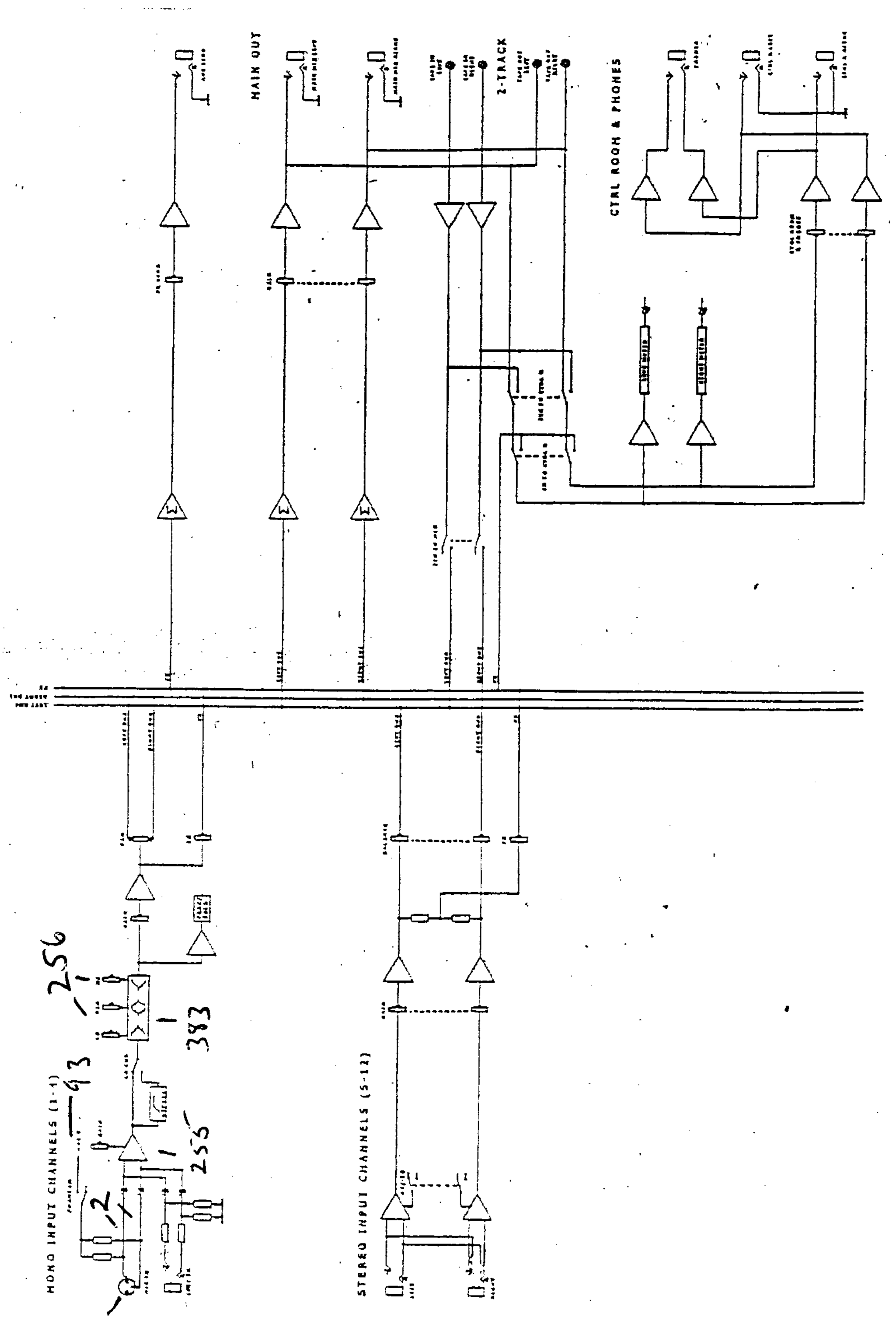

MAIN OUT
2-TRACK
CTRL ROOM & PHONES
MONO INPUT CHANNELS (1-4)
STEREO INPUT CHANNELS (5-12)
97
2
93
256
383
255

Figure 3A

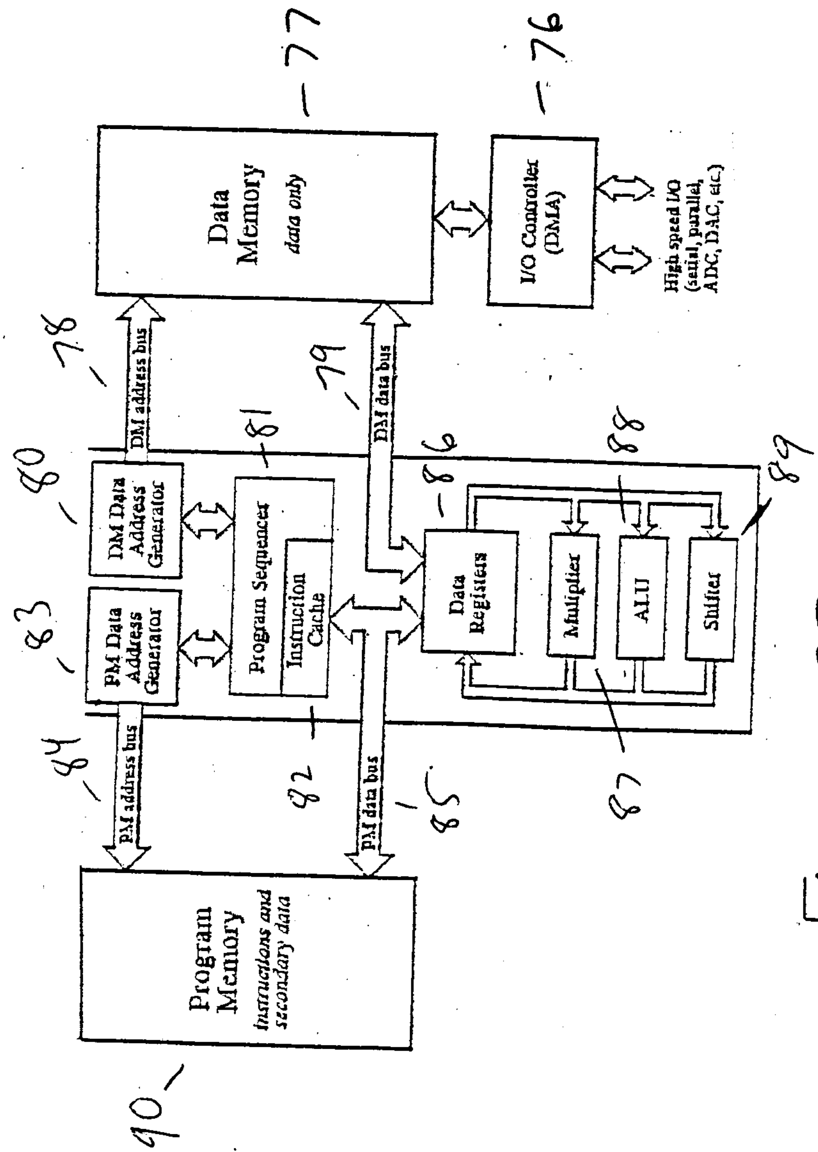

Data Memory
data only
77
I/O Controller (DMA)
76
High speed I/O (serial, parallel, ADC, DAC, etc.)
DM address bus
78
DM data bus
79
DM Data Address Generator
80
Program Sequencer
81
Instruction Cache
82
PM Data Address Generator
83
PM address bus
84
PM data bus
85
Data Registers
86
Multiplier
87
ALU
88
Shifter
89
Program Memory
instructions and secondary data
90

Figure 3B

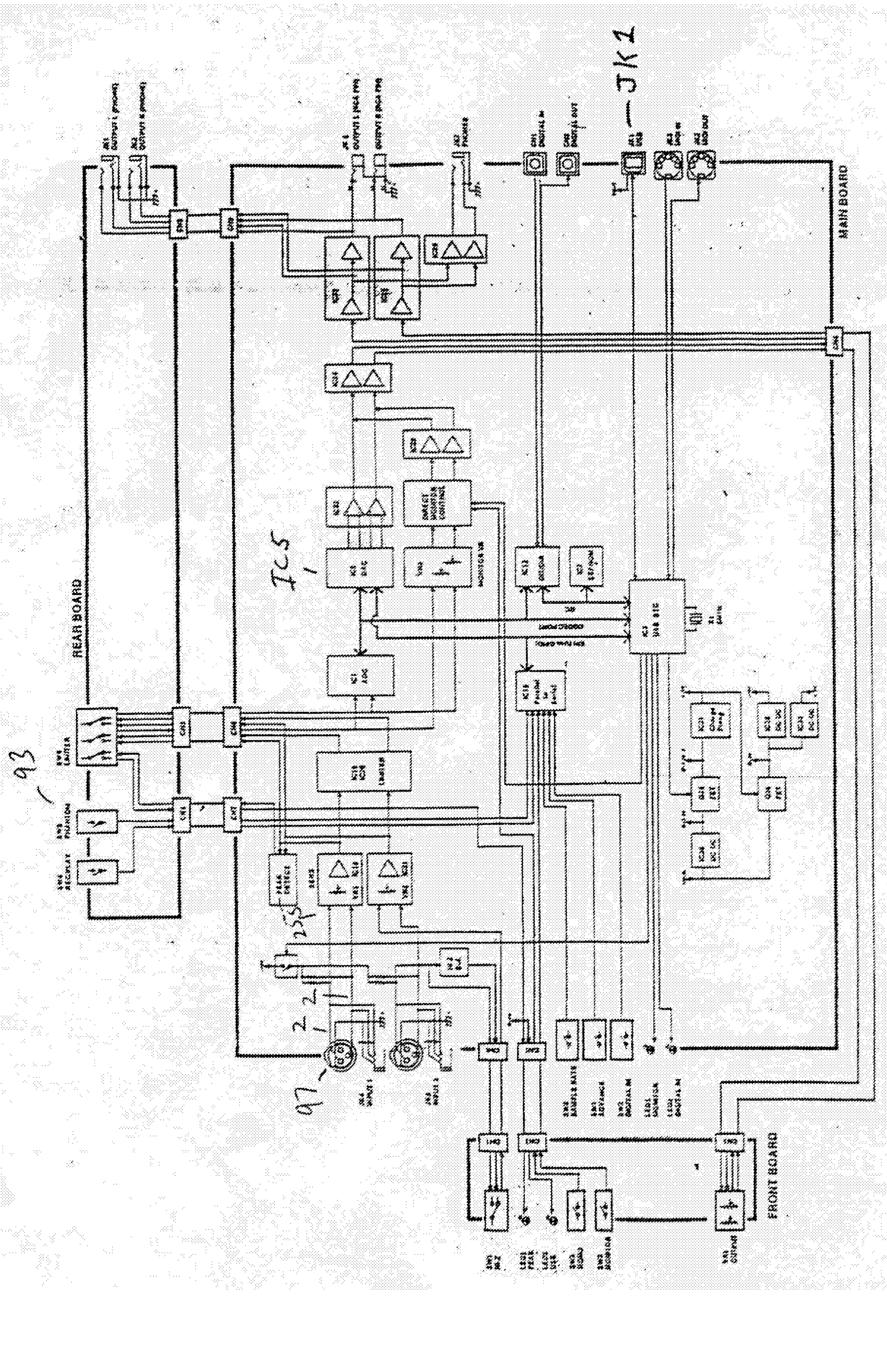


Figure 3C

MENU STRUCTURE

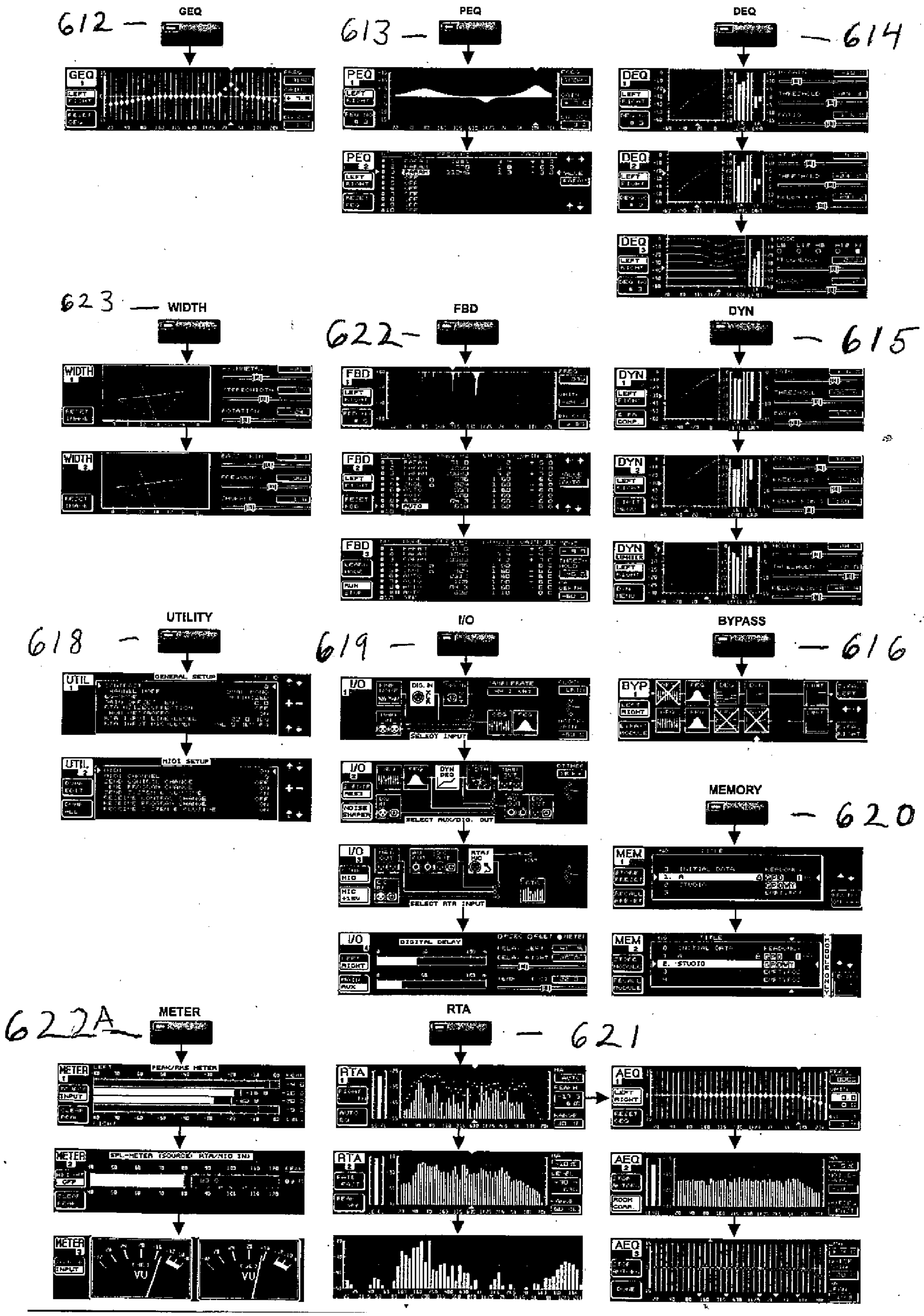
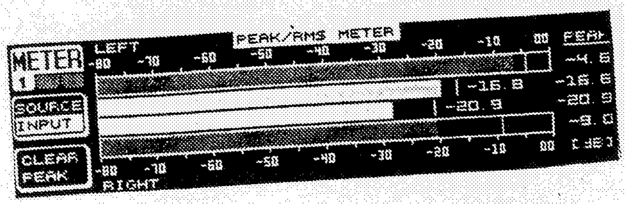
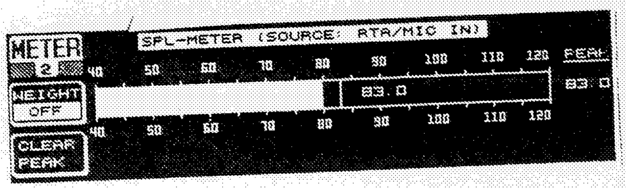


Figure #5


METER 1
SOURCE INPUT
CLEAR PEAK
LEFT
PEAK/RMS METER
-80 -70 -60 -50 -40 -30 -20 -10 00
PEAK
-4.6
-16.8
-20.9
-9.0
[dB]
-16.8
-20.9
RIGHT


METER 2
WEIGHT OFF
CLEAR PEAK
SPL-METER (SOURCE: RTA/MIC IN)
40 50 60 70 80 90 100 110 120
PEAK
83.0
83.0

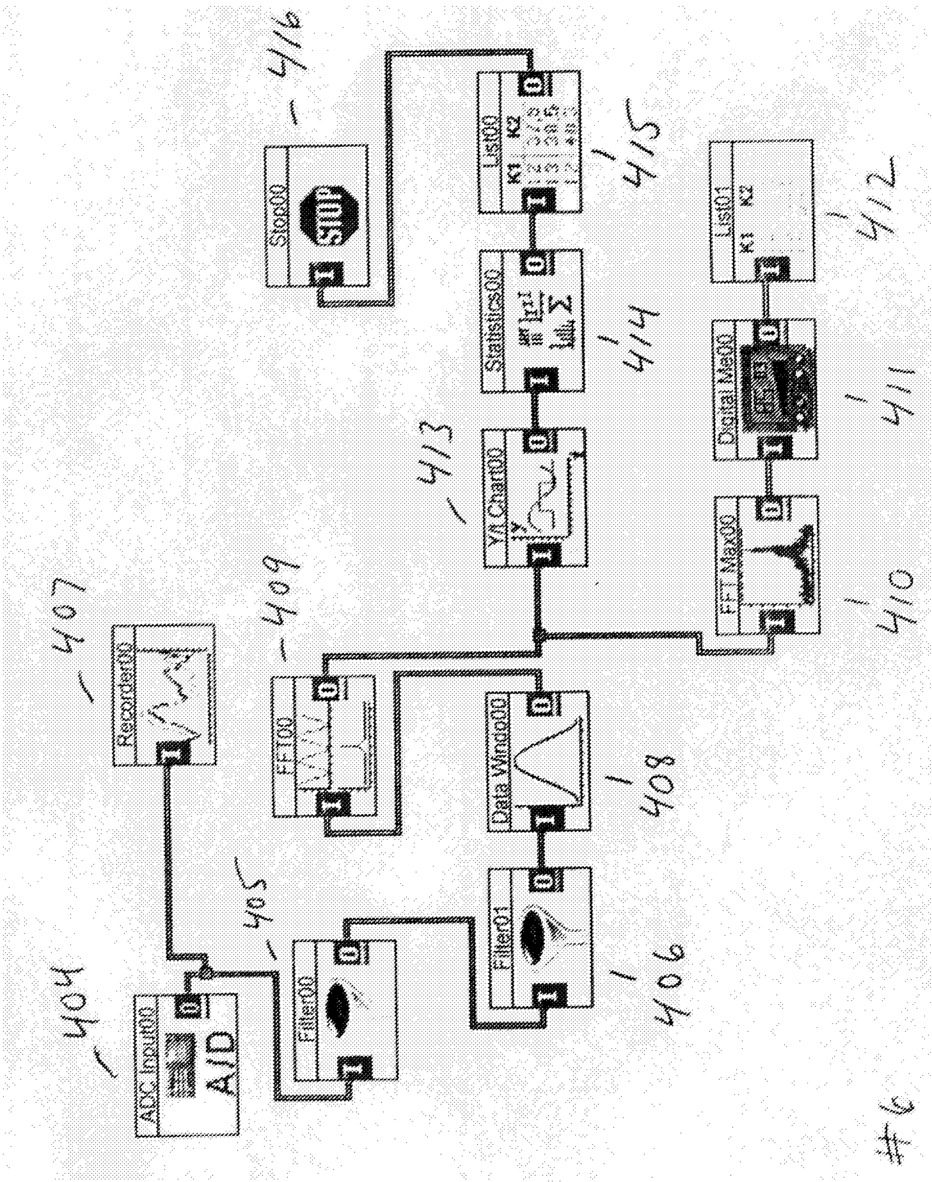

ADC Input00
A/D
Filter00
Filter01
Recorder00
FFT00
Data Windo00
Y/t Chart00
Statistics00
List00
Stop00
STOP
FFT Max00
Digital Me00
List01
K1
K2
404
405
406
407
408
409
410
411
412
413
414
415
416

Figure #6

Figure #7A

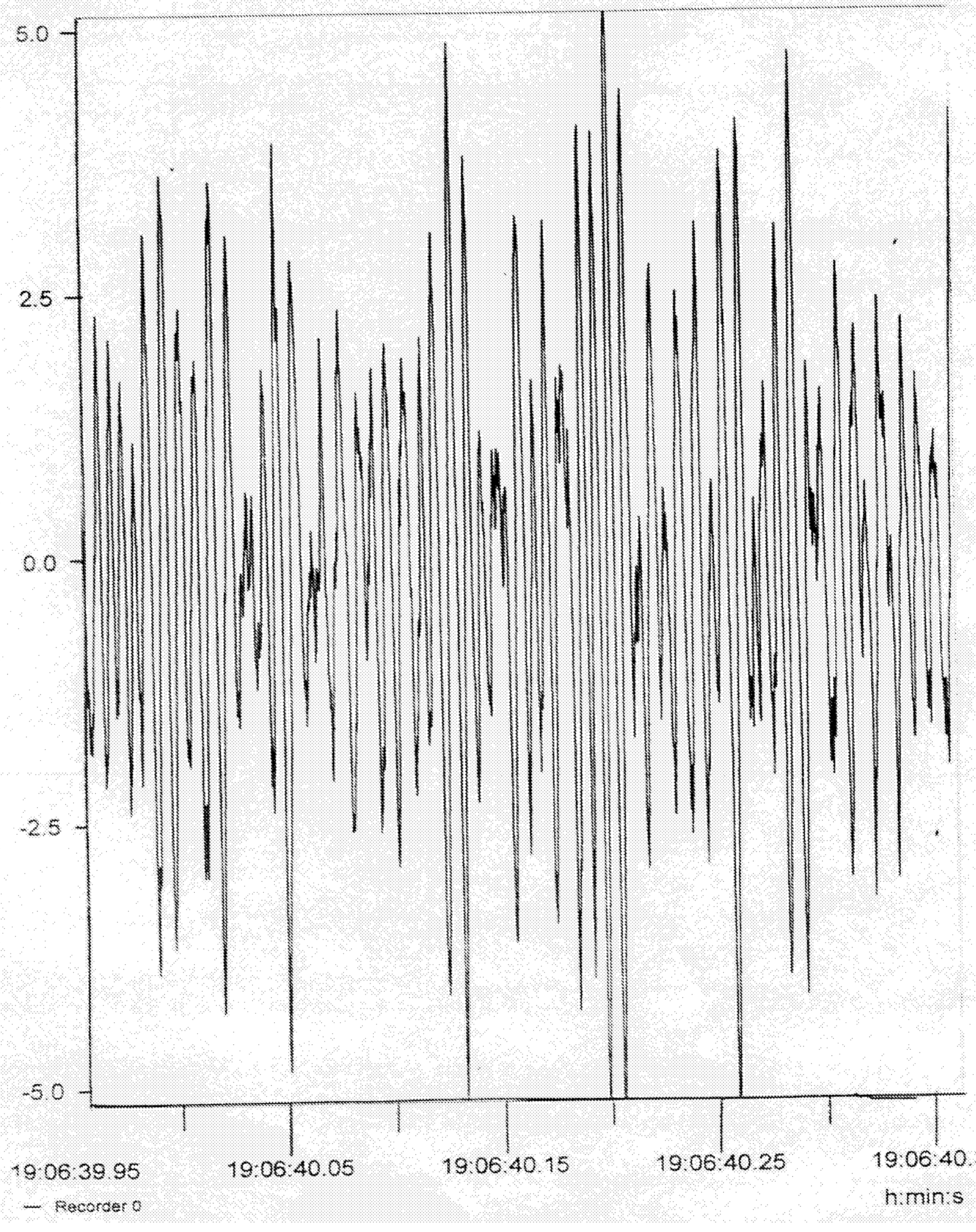

5.0
2.5
0.0
-2.5
-5.0
19:06:39.95
19:06:40.05
19:06:40.15
19:06:40.25
h:min:s
Recorder 0

Figure #78

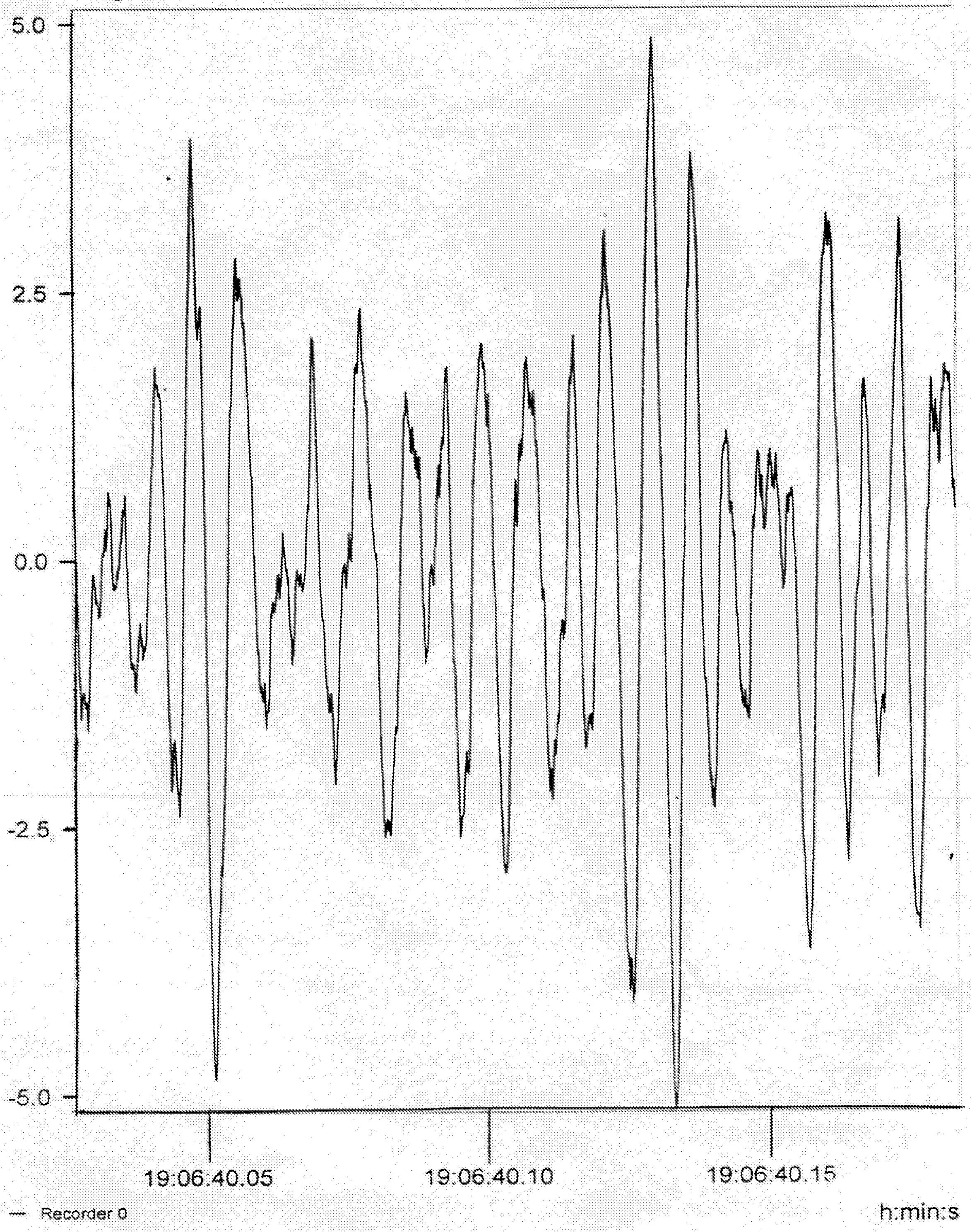


Figure #8

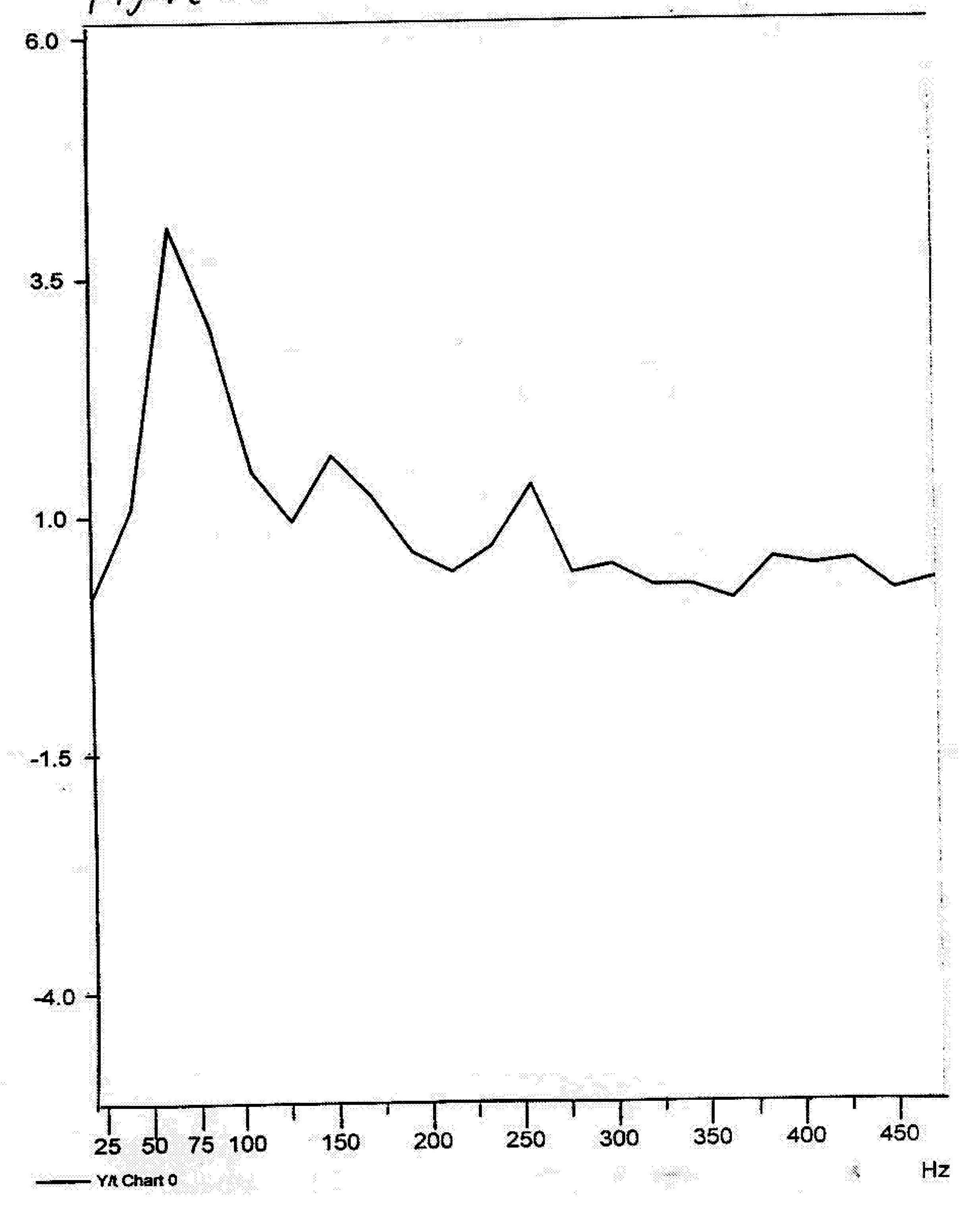

6.0
3.5
1.0
-1.5
-4.0
25 50 75 100 150 200 250 300 350 400 450
Hz
Y/t Chart 0

Figure #9

Number	List 0
0	0.32416
1	0.24833
2	0.26159
3	0.38564
4	0.39383
5	0.27714
6	0.33288
7	0.28556
8	0.36188
9	0.39170
10	0.41769
11	0.37412
12	0.28504
13	0.31108
14	0.30409
15	0.30258
16	0.24723
17	0.30873
18	0.44627
19	0.40087
20	0.33600
21	0.31696
22	0.39488
23	0.38666

Figure #10

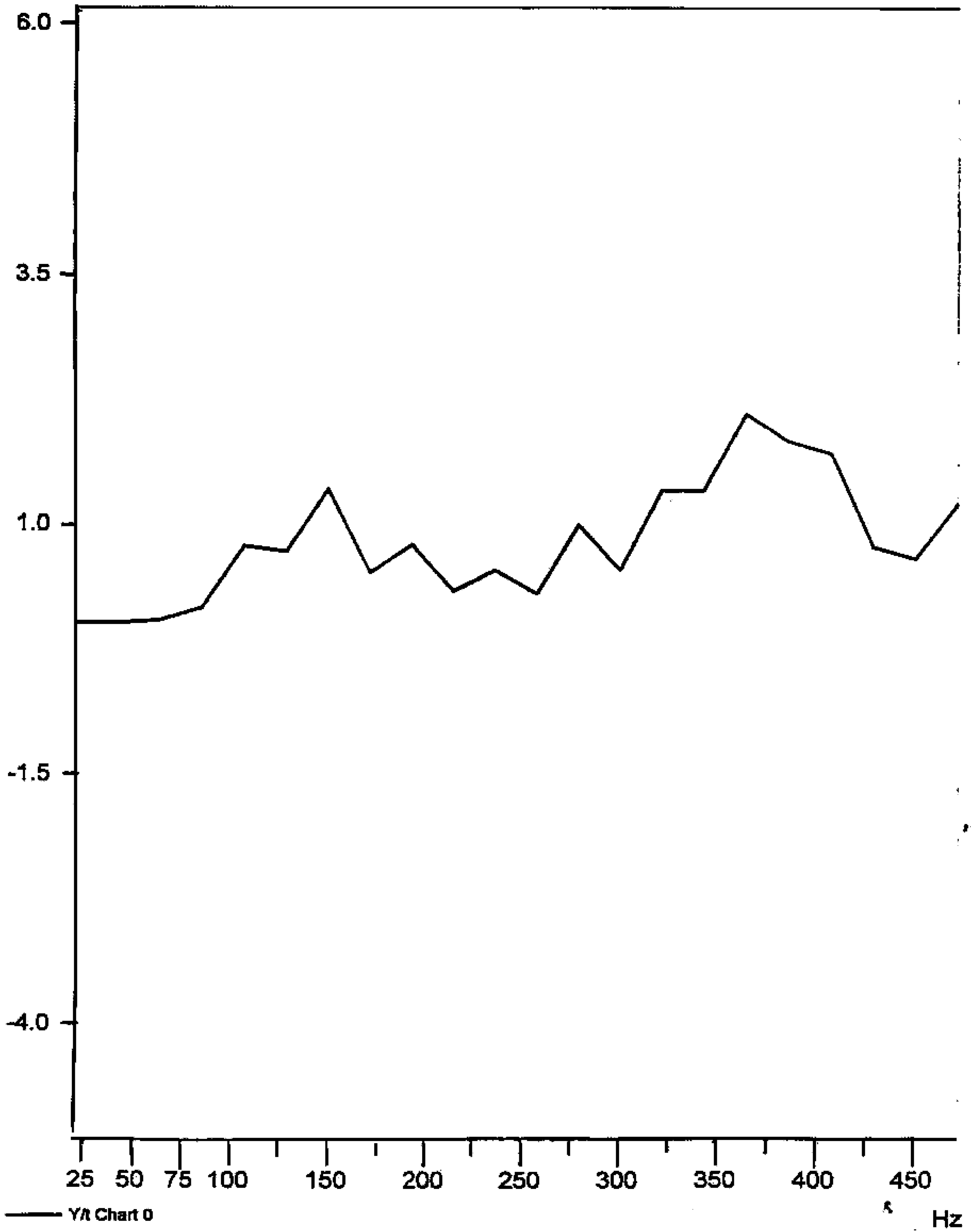

6.0
3.5
1.0
-1.5
-4.0
25 50 75 100 150 200 250 300 350 400 450
Y/t Chart 0
Hz

Figure # 11 A

Number	List 0
144	0.16453
145	0.19866
146	0.25353
147	0.30213
148	0.27350
149	0.32605
150	0.38357
151	0.38844
152	0.39335
153	0.40621
154	0.36097
155	0.36865
156	0.34936
157	0.35348
158	0.37133
159	0.38622
160	0.37478
161	0.35564
162	0.37702
163	0.36008
164	0.36676
165	0.36367
166	0.34848
167	0.34179
168	0.35888
169	0.31170
170	0.34592
171	0.36733
172	0.35863
173	0.34091
174	0.33474
175	0.36267
176	0.36828
177	0.34860
178	0.35901
179	0.36568
180	0.34046
181	0.33658
182	0.34959
183	0.29098
184	0.33565

Figure #11B

Number	List 0
185	0.32099
186	0.30145
187	0.34859
188	0.34272
189	0.37439
190	0.32083
191	0.31364
192	0.17720
193	0.29043
194	0.34371
195	0.36921
196	0.37567
197	0.38466
198	0.36238
199	0.35867
200	0.34770
201	0.33068
202	0.35571
203	0.29219
204	0.32458
205	0.36456
206	0.34355
207	0.38699

Figure #12 A

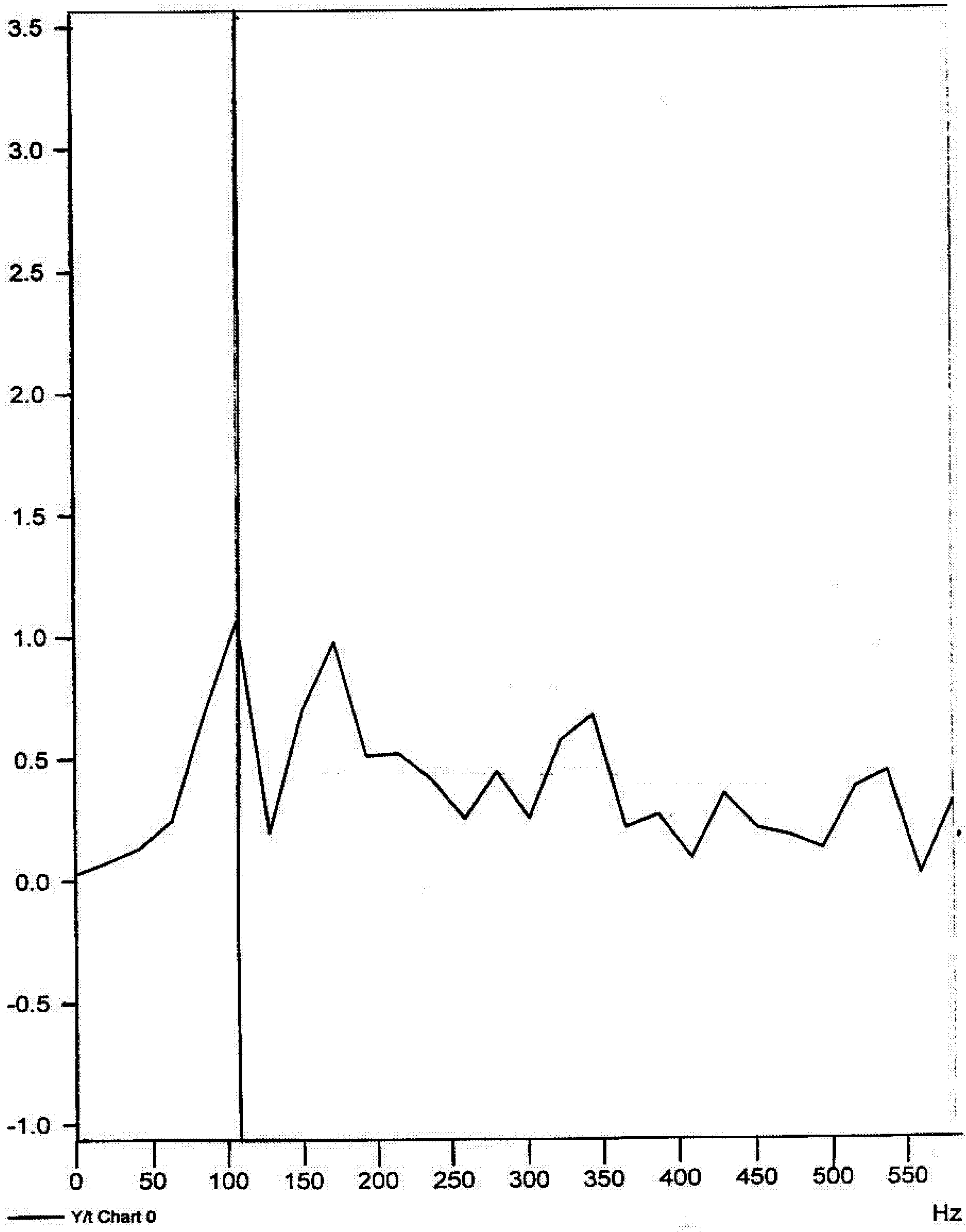

3.5
3.0
2.5
2.0
1.5
1.0
0.5
0.0
-0.5
-1.0
0
50
100
150
200
250
300
350
400
450
500
550
Hz
Y/t Chart 0

Figure #12 B

Number	List 0
24	0.578
25	1.728
26	1.008
27	0.558
28	0.880
29	0.944
30	1.019
31	0.602
32	0.532
33	0.850
34	1.071
35	1.244
36	0.553
37	0.601
38	0.550
39	0.637
40	1.164
41	0.548
42	0.682
43	1.525
44	2.146
45	1.216
46	0.462
47	0.429
48	0.199
49	0.407
50	0.629
51	0.589
52	0.803
53	0.596
54	0.473
55	0.239
56	0.699
57	1.176
58	1.875
59	0.982
60	0.267
61	0.854
62	1.341
63	0.253
64	0.584

Figure #12C

Number	List 0
65	1.380
66	1.579
67	0.614
68	0.793
69	0.249
70	0.626
71	0.517
72	0.692
73	0.843
74	0.237
75	0.996
76	0.536
77	0.344
78	1.064
79	1.493
80	0.816
81	0.100
82	0.440
83	1.676
84	0.877
85	0.423
86	0.724
87	1.066