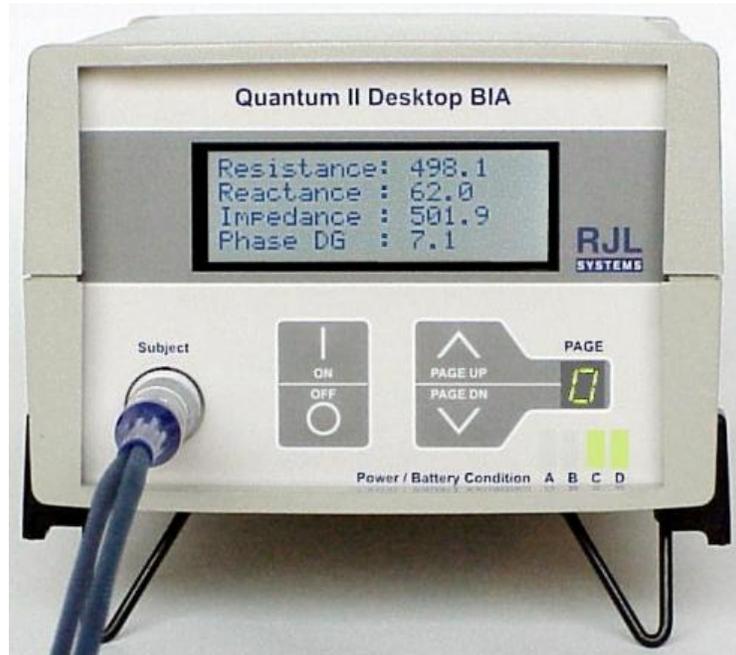## Quantum-II Desktop

Introduction

The purpose of the Q-II Desktop is to create a safe operating environment that displays and communicates with heterogeneous self contained modalities which measure and monitor physiological events in real time. The most fundamental aspect is fast high resolution (16 bits) data acquisition sub-system coupled to a powerful micro-controller operating at 16 MHz including a real time clock/calendar. The micro-controller unit (MC68HC812A4) is a 16-bit device composed of standard on-chip peripheral including external flash and battery powered RAM memory. The system is programmed entirely with the C programming language where run time objects are saved in 128KB or 512KB of flash memory.

Instrument design - safety and resolution

Isolation - safety

A safe electrical isolation barrier between the subject/patient and earth ground must exist, eliminating the possibility of any form of electrical shock. A leakage current across this barrier from a possible 120 VAC source should ideally be below 10 micro-amps, as defined by The Association for the Advancement of Medical Instrumentation (AAMI). Without this isolation, a medical device can not be connected to computers or a recording device that is connected to a 120 VAC source (plug). Safety (electrical isolation) of the Q-II Desktop has been built into the entire instrument with 2500 volt isolation from the subject input to external computers and the actual 120/240 volt line connection. This exceeds UL-544 and most CE requirements. The main power supply operates from a step-down toroidal transformer with 4500 volts of isolation.

In addition, the BIA modality is transformer-coupled at the subject interface and has been tested with a high-resistance meter (HP 4329A). An applied voltage of 1000 VDC was placed between the subject and the analog ground for 2 minutes. The resistance recorded was 10,000 Megohms or greater, resulting in a leakage current of 0.1 micro-amps.

LCD display

The display is back-lit with four ultra bright white light emitting diodes (LEDS). This creates a white gray back ground that is contrasted with bright blue characters. Readability is excellent at any viewing angle or ambient light level. The display is updated at a viewing rate that is comfortable to read without any LCD flicker. The display can be reversed with a dark blue background and white characters, as an option.

Organization of heterogeneous modalities

The availability of high speed micro-controllers and analog to digital converters make it possible to establish a communications interface to todays personal computers and workstations. In addition, a simple user interface can be layered into a multiple modality product that allows the instant display of information over many pages and retrieve simultaneous dynamic information for filtering, analyzing and recording on your PC. The key components of this design are safety, resolution, and sampling rate.

Quantum Desktop and Real Time BIA Architecture
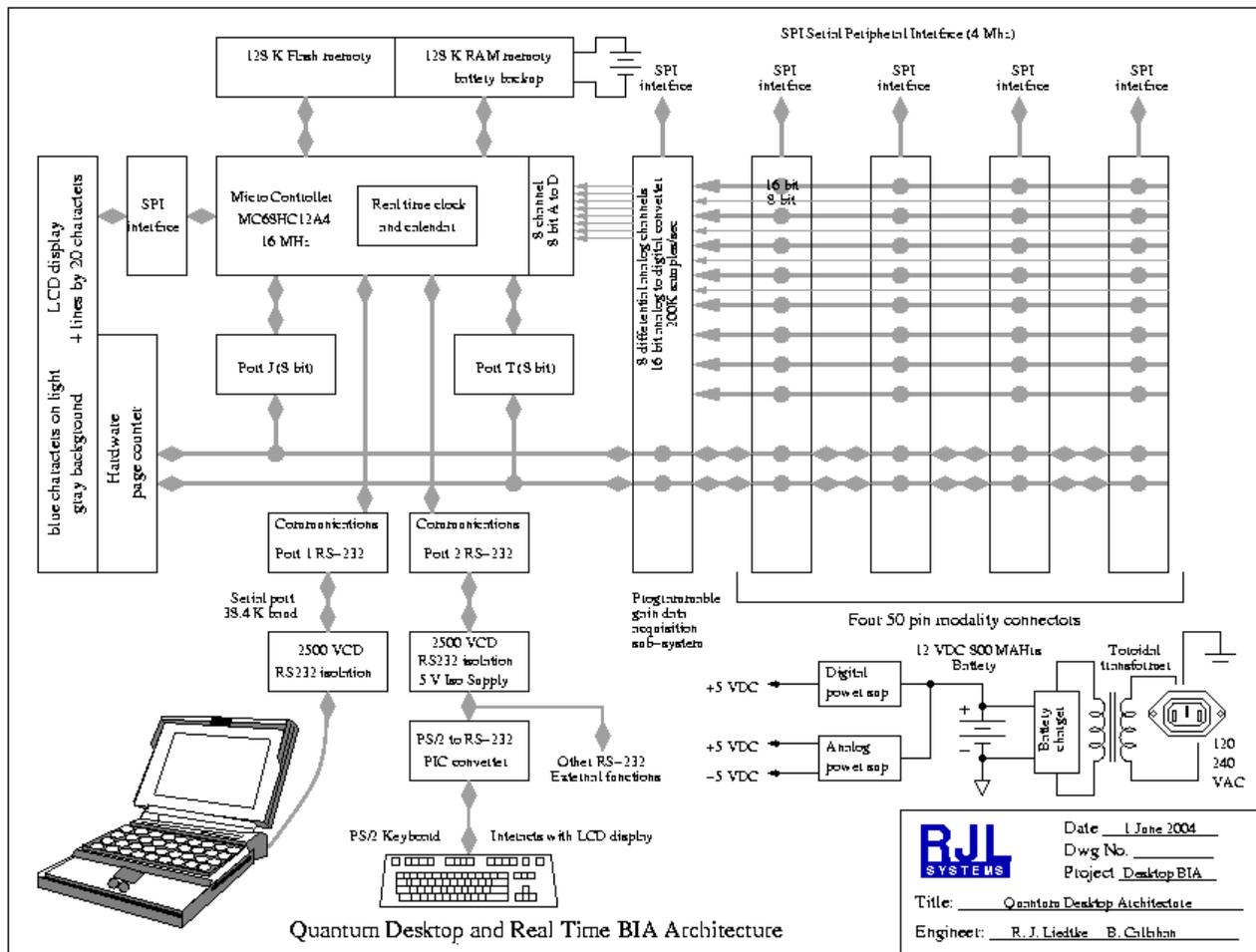
Modality modules return analog signals with a full scale of 2.00 volts with excellent stability and repeatability allowing full 16 bit conversion. The analog to digital conversion rate can exceed 100K samples/second, which allows high-speed events to be followed in real time and saved in battery backed RAM (128K standard, 512K optional). The data acquisition module also contains dual programmable gain instrumentation amplifiers to improve sensitivity and resolution and is scaled to decimal for direct readings.

Resolution

The fundamental instrument specification assumes a direct linear measurement of resistance and reactance originating from zero. In addition, the instrument must have a high common mode rejection ratio at the operating frequency where background noise is rejected or attenuated to virtually zero. Only a direct measurement of resistance and reactance makes real-time BIA possible. Computed resistance and reactance results from impedance and phase angle measurements are only as accurate as the resolution of the micro-controllers A/D converter and can rarely operate at zero impedance. Therefore, a direct analog output of simultaneous resistance and reactance that can measure zero ohms is the best and only solution.

The analog output signal must have an extremely high signal to noise ratio (SNR), or resolution, because of the small signal changes that are due to the parallel effect of the physiological event. The baseline resistance and reactance values may be 10,000 times larger than their respective changes. Designing the instrument as a pure analog device will achieve the highest possible resolution. The BIA modality is an analog circuit which can achieve a SNR of 10,000 to 1. With modest filtering, this ratio can be improved to 100,000 to 1 and maintain excellent frequency response of the event (segmental blood flow).

Assuming a SNR of 10,000 to 1 implies that if the instrument has a range of 0 to 1000 Ohms, the actual resistance or reactance being measured could change by as much as 0.1 Ohm without being detected. When the events being measured produce a change of only a few tenths or hundredth of an Ohm, resolution must be greatly improved. Therefore, it may be necessary to incorporate an analog-to-analog digital nulling subsystem to subtract the resistance and reactance baseline from the event. Digital subtraction would create a calibrated analog signal without a baseline, making the error produced by the SNR inconsequential. Digital subtraction would only be necessary when events range from a 0.1 to 0.01 Ohm change, such as cardiac events and/or rapid fluid mobility.

The BIA modality LCD display

LCD page 1 (series model)

```
Resistance : 500.0
Reactance  : 50.0
Impedance  : 502.5
Phase DG   : 5.7
```

LCD page 2 (parallel model)

```
Par Res   : 505.0
Par Ract  : 5050
Cap (pF)  : 630.6
Imp Indx  : 1152
```

The BIA modality is electrically identical to the Quantum II and Quantum X. The difference is the analog outputs are filter with a 1 Hz second order active filtered. This eliminates the cardiac circulatory effect caused by each heart beat. Without this filter the 0.1 resolution would be unstable and difficult to read. The filtered output is coupled directly to the 16 bit data acquisition sub-system for processing by the micro-controller then displayed on the LCD readout. All of the bioelectrical values are illustrated on two LCD pages. The BIA parameters are toggled by the front panel paging buttons. These values are not related to any anthropomorphic measurements. The subject weight and height are not considered in any calculation. The series equivalent model of resistance and reactance is read directly by the BIA modality, all other information is calculated from fundamental formulas of electrical engineering. All values except the **Cap (Pf)** (parallel capacitance - picofarads) and **Imp Indx** (impedance index) are expressed in Ohms.

Blood flow (Digital subtraction modality)

The main BIA modality has optional blood flow modality (second PC board) which increases the resolution from 0.1 Ohms to 0.01 Ohms, and decreases the subject maximum range to 200 Ohms full scale. The subject 50 Khz detection signal is multiplied by 10.0 with a 50 Khz resonant circuit, thereby, reducing background noise because of the narrow bandwidth of the tuned amplifier. When the tuned BIA modality is interfaced to a separate 16-bit digital-to-analog subtracter, the base line resistance and reactance signals are eliminated leaving only their calibrated changes with respect to time. The high signal-to-

noise ratio of the tuned BIA detector and the digital subtracter will create a real time plethysmograph that can quantify resistance and reactance changes due to blood flow.

Virtually any segment of human, animal or plant can be measured, displaying fast resistance and reactance changes simultaneously on a serially coupled PC or workstation. Sampling rates in the microsecond range are stored locally on the micro-controllers 128 KBytes of battery powered RAM (512 KBytes optional) or for slower sampling rates, data is sent directly to the PC at 38400 KBaud. The subtraction technique is built around a very stable 16 bit digital to analog converter that can hold its subtracted value from milliseconds to months. There are two 16 bit digital subtracters on the blood flow modality board for simultaneous recording of resistance and reactance changes due to circulating blood.

Specifications: BIA modality

Isolation barrier	Nominal:	10,000 Megohm at 1000 VDC
		subject leads to analog ground

Constant current accuracy	Nominal:	425 microamp at 50 Khz ± 1 %
	Regulation:	better than 0.1 %
	Range:	0 to 10,000 Ohms, resistive or capacitive

Resistance accuracy	Nominal:	1.0 Ohm
	Range:	0 to 1000 Ohms (**Blood flow** 200 Ohms)
	Resolution:	0.1 Ohm (**Blood flow** 0.01 Ohm)

Reactance accuracy	Nominal:	1.0 Ohm
	Range:	0 to 1000 Ohms (**Blood flow** 200 Ohms)
	Resolution:	0.1 Ohm (**Blood flow** 0.01 Ohm)

Power supply, monitor and self diagnostics

The Q-II Desktop can operate both from the power line (120/240 VAC) or its internal battery. This feature is implemented as a true **uninterruptible power supply (UPS)** with 4 hours of battery life, once the line voltage is in a "brown out" or "black out" condition. When the instrument is operated from the line, the battery is charged and the internal electronics is run independent of the battery. The battery is, therefore, charged at its maximum safe rate, without any leakage back to the internal electronics. Battery charging is part of a constant voltage (13.8 volts) current limited (170 Ma) power supply, keeping the battery from being over charged. When the battery is discharged to its minimum state the system will automatically turn off with an appropriate warning, keeping the battery from being completely discharged. Therefore, the Q-II Desktop's internal battery should have many years of trouble free operation including recording events independent of power line conditions.
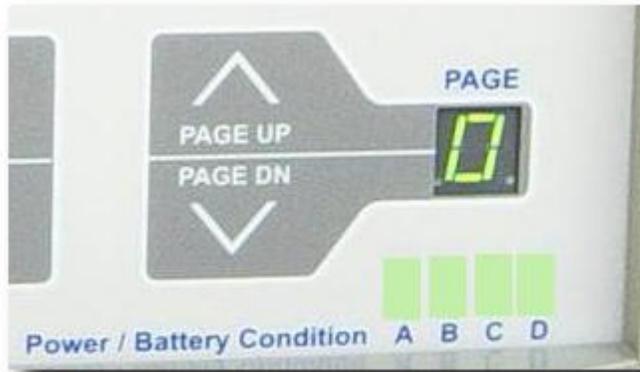
On the lower right hand corner there are four green LED's that continuously monitor the conditions of the power supply and battery. *Light A* indicates the instrument is powered from the 120/240 line. *Light B* indicates the battery if fully charged (trickle charging). *Light C* blinks when the battery is discharged to its minimum level, then automatically turns the instrument off. *Light D* indicates that all power supplies are within their specifications.

Page 9 of the LCD display is dedicated to self diagnostics to aid in fast servicing of the Q-II Desktop. The first line indicates the internal temperature of the instrument. There is virtually no heat radiated from any of the instruments components, therefore, the temperature reading indicates the ambient (room) temperature of the Q-II Desktop. This is very useful when the outside temperature related to weather conditions is desirable, such as measuring and monitoring the resistance and reactance of cold blooded animals, trees and plants.

LCD page 9 (self diagnostics)

```
Inter Tmp  : 25.0 C
PS Dig +5V : 4.98
PS Ana +5V : 5.00
PS Ana -5V : 5.04
```

There are three internal switching power supplies powered from the battery or line. All digital components including the micro-controller are operated by a 5 volt digital supply, indicated by line 2 of the LCD display. The voltages of the ± 5 volt analog supplies are indicated by lines 3 and 4. ALL modalities and the data acquisition sub-system require the analog supplies because of its low noise and temperature stability. The LCD display readings are continuous and reflect the instantaneous true power supply voltages.

Serial communications

Located on the rear panel is an isolated (2500 VDC) 9 pin RS-232 compatible serial connection to a local PC or workstation. Communication rates are at 38,400 bits/sec or higher. Programmed within the memory of the micro-controller is a "serial command interpreter" where specific simple requests are sent to the Q-II Desktop for analysis. Once a request is sent, the Q-II Desktop it will immediately send the appropriate information back to the caller (PC or workstation). All internal Q-II Desktop data are stored as signed 16 bit words. The data word is delivered back to the caller in a communication wrapper requiring three (3) bytes to complete the transfer of the 16 bit word. There are no control or escape characters transfered to the caller, therefore, most communication protocols will work reliably. Considering a baud rate of 38.4 KBaud, a 16 bit word requires 781 micro seconds for a complete transfer. Real time data that requires faster sampling can be saved in the micro-controllers 128K (512K optional) battery backed RAM for later transfer to the caller.

BC is fully compatible with this protocol, allowing resistance and reactance values to be read directly into the body composition program to 0.1 ohms. In addition, data logging software is also available that can set sampling rates from micro seconds to hours. The Q-II Desktop is insensitive to its ambient temperature allowing it to be used in winter and summer outdoor conditions. This can open new BIA studies of small plants or large trees observing the action of daily photosynthesis, growth and plant disease.

Applications

There have been thousands of BIA instruments sold since 1980 by RJL Systems and other companies. These devices were primarily used to predict the body composition of humans based on prediction equations using resistance and reactance values. Peer review literature indicates that these electrical values are, indeed, excellent predictors of body composition as a

total body (hand to foot) measurement. Total body composition equations are all based on stature height assuming that tall or short people have long or short arms and legs. The true specificity and sensitivity of BIA has not been fully demonstrated on well defined geometrical structures. Examples include all small animals with spinal electrode arrays [9,10], fish[11], human arms[12] and thighs (upper leg)[13]. When the segment or subject has a geometry that is simple and consistent across its species, an equation of

$$Volume\ or\ Mass = \frac{Length^2\ (Distance\ between\ detecting\ electrodes)}{Resistance_{series},\ Reactance_{series},\ Resistance_{parallel},\ Reactance_{parallel}}$$

can be used to predict water, muscle mass, ash, protein and fat by knowing the distance between the detecting electrodes. Correlations of greater than .96 can easily be achieved on large or small human segments and animals.

The segmental composition of human limbs and animals should be completed by observing the quantitative circulation of blood that is perfused into a specific muscle or organ resulting from each beat of the heart.
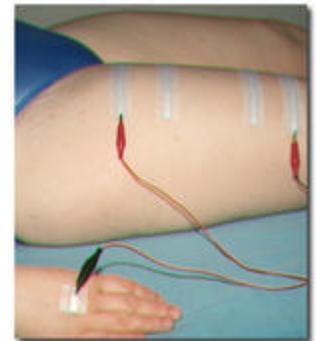
Q-II Desktop modalities under development

The following list is just a sample of the information which can be collected by the Q-II Desktop with the proper modality boards installed:

- Real time bioelectrical impedance analysis (Impedance Plethysmography). Quantitative blood flow on virtually any segment of the human or animal body.

- Electrical Impedance Tomography (resistance and reactance)

- Electro-cardiograph (ECG)

- Galvanic Skin response (GSR)

- Infrared peripheral blood flow (skin and wound blood flow)

- Blood pressure and volume monitoring from inflated cuffs

Regulatory

The applications described in this manuscript are for investigational (research) purposes and have not been approved by the FDA for commercial use. The RJL Systems Quantum series of instruments have been approved for use as body composition analyzers only. However, they may be used for other applications as investigational devices. RJL Systems welcomes the mutual collaboration of commercial and/or academic organizations to further the advancement of BIA sciences that may lead to patents and FDA approval of new specific applications using real-time BIA. The Quantum and Q-II Desktop series of instruments have been submitted to US and world patent offices.

History of BIA

In 1887, the first demonstration of electromotive (voltage) changes synchronized to heart beats using surface electrodes was done by A. D. Waller on humans. Dutch physiologist Willem Einthoven was awarded the 1924 Nobel Prize for his discovery of the electrical properties of the heart. His invention of the Einthoven galvanometer (string galvanometer) was able to graphically record electrical potentials of the heart muscle. In 1939, J. Nyboer[1] and S. Bagno built the first tetrapolar (4 electrode) impedance cardiograph and recorded the impedance changes over the heart. Later, in 1950, Nyboer quantified these changes as a numerical parallel impedance model defining arterio-venous volume changes. Traditional impedance plethysmography can be applied to most areas of the human body to record arterial and venous blood flow changes[8], as pioneered by Jan Nyboer.

The concept of introducing a safe radio frequency current into the body and detecting resistance and reactance change has led to the science of Bioelectrical Impedance Analysis (BIA) for assessing body composition in health and disease. The science of BIA is based on the static observation of wrist-to-ankle resistance and reactance. There are, however, a very large number of quantitative dynamic events which can be observed by a regional (segmental) measurement of parts of the human body, including muscles, organs, glands and circulation. These phenomena are fluid and circulatory shifts, which result in resistance changes as small as 0.01 Ohms, depending on the event and its time duration. For example, placing electrodes over the stomach could easily illustrate expansion and contraction due to ingesting and digesting fluids and solids[2,3]. The measured impedance will decrease rapidly as the stomach fills, then slowly return to its baseline value as the food is digested. Displaying this event would require instrument resolution of .01 Ohms implying a very high signal-to-noise ratio. Other examples would include respiration changes (apnea monitoring) and extracellular water accumulating in the right lung due to heart disease [4].

Impedance Cardiography has been well documented by R. Allison [5] and many others. The single characteristic that stands out with real-time BIA or Impedance Plethysmography is that the measurements are quantitative, expressed as volume changes, following the same principles outlined by Nyboer in the 1950's. However, there have been mathematical advances in defining intracellular and extracellular volume with parallel reactance, both dynamically and statically. Paul Schloerb[6] demonstrated a very high correlation (R=.99) of resistance volume changes compared to draining ascetic fluid during a paracentesis on liver cancer patients with cirrhotic ascites. Detecting physiological events by impedance has been well documented by L. A Geddies and L.E. Baker[7], including bladder filling to cerebral edema. Today, most impedance plethysmography devices are used to assess cardiac output. Real-time BIA instruments have improved the resolution and accuracy of biological measurements that can be applied to critical areas of all living things, including humans, animals, and living plants.

Unlike Electrocardiography, where a signal originates from within the body, real-time BIA introduces a safe radio frequency signal and quantifies changes due to the mobility of fluids, solids, and circulation. These changes may take milliseconds or years, and can be monitored by BIA with the proper instrument. The difference between real-time BIA and impedance plethysmography is the simultaneous measurement of resistance and reactance and their changes vs. the the magnitude of impedance (vector sum of resistance and reactance) and its change due to physiological and biological events. Real time simultaneous records of resistance and reactance allows new modeling of how changes are related to intracellular and extracellular distribution of rapidly changing fluids such as blood.

The history of Impedance Plethysmography and Bioelectrical Impedance Analysis dating back to the 1960's is now implemented in an integrated instrument know as a Quantum-II Desktop or Q-II Desktop. The architecture and the possibilities of the Q-II Desktop's real time ability to capture physiological events were discussed comprehensively in hopes that it is useful.

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