XITRON

TECHNOLOGIES, INC.
San Diego, CA, USA

HYDRA ECF/ICF (Model 4200)

Bio-Impedance Spectrum Analyzer
For Measuring Intracellular And Extracellular Fluid Volumes

OPERATING MANUAL
REVISION 1.03

Device Warranty

This Xitron Technologies instrument is warranted against defects in material and workmanship for a period of two years after the date of shipping. Xitron Technologies agrees to repair or replace any assembly or component (except system cables which are guaranteed to be free of workmanship defect at the time of shipping) found to be defective, under normal use, during this period. Xitron Technologies obligation under this warranty is limited solely to repairing any such instrument which in Xitron Technologies sole opinion proves to be defective within the scope of the warranty when returned to the factory or to an authorized service center. Transportation to the factory or service center is to be prepaid by the purchaser. Shipment should not be made without prior authorization by Xitron Technologies.

This warranty does not apply to any products repaired or altered by persons not authorized by Xitron Technologies, or not in accordance with instructions furnished by Xitron Technologies. If the instrument is defective as a result of misuse, improper repair, or abnormal conditions or operations, repairs will be billed to the customer at cost. Xitron Technologies assumes no responsibility for its product being used in a hazardous or dangerous manner, either alone or in conjunction with other equipment. Special disclaimers apply to this instrument, Xitron Technologies assumes no liability for secondary charges or consequential damages and, in any event, Xitron Technologies' liability for breach of warranty under any contract or otherwise, shall not exceed the original purchase price of the specific instrument shipped and against which a claim is made.

Any recommendations made by Xitron Technologies, or its' representatives, for use of its products are based upon tests believed to be reliable, but Xitron Technologies makes no warranty of the results to be obtained. This warranty is in lieu of all other warranties, expressed or implied, and no representative or person is authorized to represent or assume for Xitron Technologies any liability in connection with the sale of our products other than set forth herein.

Instrument Serial Number: _____

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Corrections, Notes and Added Information Added to

Hydra ECF/ICF Bioimpedance Analyzer (Model 4200)
Operation Manual Revision 1.02, Updated August 30th, 2001

Chapter 3. Changing Setup Parameters

Format Time and Units

(***Reduced Confusion***) The correct heading of this section is "Set Date and Units." The word Date replaces the word Time for this is a Date function of the device. When the USA Date format is selected, the date will be displayed in all printouts, etc., as MM - DD - YY. When the International Date format is selected the date will be displayed as DD / MM / YY. Note that the USA format uses a "dash" and International format a "slash." This enables the user to always know what form the date was in when the measurement was performed.

(***Reduced Confusion***) When the Units are set, they will be pounds-inches for USA units and centimeters-kilograms for International units.

Predict Fat-Free Mass Option

(*New Function*) As described in Appendix B Volume Equations, the device predicts Fat-Free Mass by the following: $(d_{ECF} \times V_{ECF}) + (d_{ICF} \times V_{ICF})$, where, d_{ECW} and d_{ICW} are the mean densities of the ECF and ICF and their associated materials. We have updated the device so if improved constants are discovered, the user can update their device in the field. The following sequence replaces the instructions previously provided.

1. The display will ask the user if they wish to "Set FFM Option."

2. Press Enter to Set FFM Option or MENU key to go to the next option.

3. When Enter is pressed the display will ask "Use FFM" or "Do Not Use FFM" when the arrow keys are pressed. If "Do Not Use FFM" is selected, FFM will no longer be included as an output.

4. If "Use FFM" is selected, the device will ask for "Use User's Value" or "Use Default" . When "Use Default" is selected the device will compute FFM with the factory default constants.

5. If "Use User's Value" is selected, the user will be asked to input new male and female d_{ECF} and d_{ICF} values.   Do not change these parameters arbitrarily. Refer to this Addendum for information on how to compute new d_{ECF} and d_{ICF} constants. Refer to *Chapter 6. Hydra Utilities Software, Data Model_Vol Utility, Computing ECF and ICF Density.*

Chapter 4. Measurement Operation

Accuracy Considerations - Cole Model

(***Improved Model Fit Rating Detection***) As discussed in this section, the device can have difficulty solving the Cole model when the subject has very little cell membrane capacitance or a very high characteristic frequency (F_C). We have updated the device so when there is less then 25% of the frequencies are beyond F_C, the device will rate the fit as "Marginal." When there is less than 10% of the frequencies beyond F_C, the device will rate the fit as questionable. When there is less than 2% of frequencies beyond F_C, the device will display "Bad Fit", beep for five seconds and then abort the data. No results will be displayed. If the user wishes to obtain data on such subjects, they should collect the data using a computer and the Hydra Utilities Software. The same ratings will be produced by the external modeling program but will allow "Bad Fit" results to be obtained.

Performing A Measurement

(***Improved Convenience***) When performing a single measurement, the display will now read "Measurement in Progress." The measurement will take approximately 15 seconds. Once the measurement has been successfully completed, the device will make a "beep" sound and begin fitting the data to the Cole model. The display will now read "Modeling in Progress." At this point the subject can be disconnected or allowed to relax. Previously the subject had to remain motionless throughout the entire process. Under normal conditions, results will be displayed in approximately 45 seconds. If solving the model takes longer, the solution is more complex than normal. Refer to the *Measurement Operation, Accuracy Considerations, Cole Model* section for details.

Chapter 6. Hydra Utilities Software

Data Model-Vol Utility

External Modeling Saved Impedance Data

(***Files not compatible***) The files produced by the Data Model-Vol Utility are not compatible with those produced by the Hydra Data Acquisition Utility. Do not attempt to "Append" files .MDL and .PLO created by Data Model-Vol Utility to files .MOD and .VOL created by the Hydra Data Acquisition Utility. It can crash the program with all data lost.

Computing Volume Following Modeling

(*New Program Function*) A new function has been added to the Data Model-Vol Utility so the user can compute extracellular fluid (ECF) and total body water (TBW) for multiple subjects when the data are in a spreadsheet. This program also allows the user to compute new ECF and ICF apparent resistivity and density constants when reference data are available (e.g., dilution and DEXA). Discussion on how the ECF and ICF apparent resistivity constants are computed is found in Appendix B Volume Equations. How density is computed is found in this Addendum under *Appendix B. Equations, and Chapter 6. Hydra Utilities Software, Data Model-Vol Utility, Computing ECF and ICF Density*.

Multiple Case Volume Computation

Thus function allows the user to compute ECF and ICF volume automatically on multiple subjects. The user should save their data in the following format in a spreadsheet:

Required Row Fields

1. Subject ID without space or Tab characters
2. Gender (Male = 0, Female = 1)
3. Height in centimeters
4. Weight in kilograms
5. R_E from Cole modeling
6. R_I from Cole modeling

The user should then convert this spreadsheet into a text (.txt) file.

Go into the Data Model-Vol program. With the mouse Open the text file. Then highlight the data with the mouse as shown in the figure below:

```
HydraUtility - [Dilut.txt]
File  Edit  View  Online  Offline  Settings  Window  Help

ID    Sex    Ht      Wt     Re      Ri
75    0      179.0   74.6   526.2   965.0
76    0      179.5   67.1   665.8   1101.6
77    0      168.0   71.7   610.0   875.1
78    0      183.5   84.7   535.1   1030.9
79    0      171.5   72.7   568.6   933.2
80    0      174.5   67.5   585.6   961.6
81    0      172.5   72.9   614.6   1059.8
82    0      185.0   84.6   568.6   1086.6
83    0      167.5   67.8   524.2   1034.9
84    0      170.0   62.6   634.3   1097.3
85    0      184.0   79.4   597.7   964.4
86    0      168.0   67.5   510.6   1202.4
87    0      168.0   77.2   539.3   991.9
88    0      182.5   96.9   607.4   981.2

Ready
```

Now Go into Off-line and Click on "Resistivity Regression" with the left mouse button. The predicted ECF (ECF_P) and TBW (TBW_P) volumes will be computed and displayed immediately as shown in the figure below:

```
HydraUtility - [Dilut.txt]
 File  Edit  View  Online  Offline  Settings  Window  Help

ID      Sex     Ht      Wt      Re      Ri              ECF_P    TBW_P
75      0       179.0   74.6    526.2   965.0           19.99    48.58
76      0       179.5   67.1    665.8   1101.6          16.56    42.44
77      0       168.0   71.7    610.0   875.1           16.43    45.46
78      0       183.5   84.7    535.1   1030.9          21.32    50.52
79      0       171.5   72.7    568.6   933.2           17.78    45.77
80      0       174.5   67.5    585.6   961.6           17.41    44.79
81      0       172.5   72.9    614.6   1059.8          17.03    42.71
82      0       185.0   84.6    568.6   1086.6          20.69    49.23
83      0       167.5   67.8    524.2   1034.9          17.77    41.60
84      0       170.0   62.6    634.3   1097.3          15.54    38.92
85      0       184.0   79.4    597.7   964.4           19.45    50.52
86      0       168.0   67.5    510.6   1202.4          18.13    38.96
87      0       168.0   77.2    539.3   991.9           18.28    44.35
88      0       182.5   96.9    607.4   981.2           20.34    52.80
Regression for male not performed (No or incomplete dilution data)!
Regression for female not performed (No or incomplete dilution data)!

                Before Regression       After Regression
Pecf_Male:      40.50                   40.50
Picf_Male:      273.90                  273.90
Pecf_Female:    39.00                   39.00
Picf_Female:    264.90                  264.90

Ready
```

Computing ECF and ICF Resistivity

(New Function) This function allows the user to compute new resistivity constants when dilution ECF and TBW volumes are available. As above, the spreadsheet data should be converted into a text file arranged in the following format. Note dilution ECF and TBW have been added as required fields.

Required Row Fields

1. Subject ID without space or Tab characters
2. Gender (Male = 0, Female = 1)
3. Height in centimeters
4. Weight in kilograms
5. R_E from Cole modeling
6. R_I from Cole modeling
7. ECF volume by dilution or equivalent
8. TBW volume by dilution or equivalent

Go into the Data Model-Vol program. With the mouse Open the text file. Then highlight the data with the mouse. Now Go into Off-line and Click on "Resistivity Regression" with the left mouse button. ECF and TBW volumes as well as new ECF and ICF resistivity constants will be computed and displayed immediately as shown in the figure below:

Save this file. The user can the use these new constants to predict ECF, ICF and TBW if so desired. How to change the default resistivity constants used in the Data Model-Vol Utility is described in *Chapter 6 Hydra Utilities Software, Data Model-Vol, Changing Resistivity Constants*. The constants used by the device to compute ECF and ICF can be modified as described in *Chapter 3. Changing Setup Parameters, Set Resistivity Section.*

Computing ECF and ICF Density

This function is exactly the same as Computing ECF and ICF Resistivity except reference fat-free mass (FFM) data (e.g., DEXA) is added along with dilution ECF and TBW as a required field.

Required Row Fields

1. Subject ID without space or Tab characters
2. Gender (Male = 0, Female = 1)
3. Height in centimeters
4. Weight in kilograms
5. R_E from Cole modeling
6. R_I from Cole modeling
7. ECF volume by dilution or equivalent

8. TBW volume by dilution or equivalent
9. FFM by DEXA or equivalent

The results will appear as follows:

HydraUtility - [Import-2.txt]

File Edit View Online Offline Settings Window Help

ID	Sex	Ht	Wt	Re	Ri	VECW	VTBW	FFM	ECF_P
75	0	179.0	74.6	526.2	965.0	20.61	49.29	67.06	20.00
76	0	179.5	67.1	665.8	1101.6	16.47	43.90	59.73	16.56
77	0	168.0	71.7	610.0	875.1	17.86	42.70	58.10	16.44
78	0	183.5	84.7	535.1	1030.9	22.81	48.84	66.45	21.33
79	0	171.5	72.7	568.6	933.2	16.91	44.33	60.31	17.79
80	0	174.5	67.5	585.6	961.6	17.41	43.71	59.47	17.41
81	0	172.5	72.9	614.6	1059.8	16.22	42.60	57.96	17.03
82	0	185.0	84.6	568.6	1086.6	20.21	49.40	67.21	20.70
83	0	167.5	67.8	524.2	1034.9	17.19	43.43	59.09	17.78
84	0	170.0	62.6	634.3	1097.3	15.23	40.28	54.80	15.55
85	0	184.0	79.4	597.7	964.4	20.52	51.42	69.96	19.46
86	0	168.0	67.5	510.6	1202.4	18.71	41.19	56.04	18.14
87	0	168.0	77.2	539.3	991.9	17.25	42.81	58.24	18.29
88	0	182.5	96.9	607.4	981.2	19.41	52.78	71.81	20.35

Decf_Male: 1.872
Dicf_Male: 1.015
Decf_Female: 0.000
Dicf_Female: 0.000
Regression for female not performed (No or incomplete dilution data)!

          Before Regression   After Regression

Ready

The density constants used in the device to compute FFM can be modified as described in *Chapter 3. Changing Setup Parameters, Predict Fat-Free Mass Option.* The Model_Vol Utility does not at this time provide a prediction of FFM or %Fat. However, once ECF and ICF volumes are determined, FFM and %Fat can easily be computed as described in Appendix B. Volume Equations.

Program Limitations

For computing volume, resistivity and density through a spreadsheet, a number of limitations are enforced by the program. They are as follows:

1. Column headings or labels must be used (e.g., height, weight , etc.)
2. When there are less than five subjects, the program will not compute new resistivity or density constants.
3. When there are five or more subjects for one gender but not the other, volume and resistivity will only be computed for the five or more subjects.
4. When no reference data are available (e.g., dilution and DEXA) place a zero in column headings ECF, TBW and FFM. The columns can be left blank but this helps avoid confusion.

5. To compute density, reference ECF, TBW and FFM data must be available.
6. When there is a zero in any of the data, the program will not regress for resistivity or density but will compute ECF and ICF using the default resistivity constants.

Appendix B. Volume Equations

Computing The Wrist-Ankle Constants

(Additional Information) Although the default d_{ECF} and d_{ICF} constants used by the device for predicting FFM were theoretically derived, they can also be computed from reference ECF and TBW (dilution) FFM (DEXA) data. When computed form reference data, d_{ECF} and d_{ICF} are computed by obtaining the best fit using FFM predicted from dilution volumes, against a densitometry or DEXA determined FFM.

Manual Additions, August 30th, 2001

Page 16,18: Add the following to the end of each the paragraph's for the Section's Labeled

HOST COMPUTER PORT/ CONNECTOR:

-Attention-
At no time shall the operator touch the patient and the computer at the same time while the Hydra ECF-ICF product is connected through this connection. Please ensure that the supplied screw-secured cover is placed over the Host computer port when the unit is not connected to the Computer through the RS-232 interface cable.

Page 26: Add the Following Paragraph between the sections labeled Effect of Other Devices and Power Cord

Interference:
If this equipment causes harmful interference with other devices, which can
be determined by turning the equipment on and off, the user is encouraged to
try to correct the interference by one or more of the following measures:
- reorient or relocate the receiving device
- increase the separation between the equipment
- connect the equipment into an outlet on a circuit different from that to which the other device(s) is connected

Chapter 1. Introduction

Xitron Technologies

Pioneer and Leader

Xitron Technologies, Inc. is a leading manufacturer of low frequency signal analysis instrumentation, and one of few companies with full DSP 18 bit multi-channel measurement technology. The products produced by Xitron's Test and Measurement Division are used by most of the major Aerospace, Computer, Defense and Appliance companies. Xitron personnel also has over 20 years experience designing the type of impedance phase-gain instrumentation used in advanced materials research and biophysics.

Xitron personnel have designed leading bio-impedance instrumentation and conducting impedance-body water research since 1985. In fact, the device selected for the NIH HAINS III National Nutrition Survey was designed and validated by Xitron personnel. Xitron was the first company to introduce a multifrequency device with a measurement range of 1KHz to 1MHz and full Cole modeling software. Xitron's technology also produced the first successful prediction of intra and extracellular water volume *in vivo* on humans using a biophysical model. This was accomplished using a volume equation derived from advanced dielectric mixture theory.

Certified Quality Manufacturing

Xitron is certified to meet the quality and procedural standards set forth by ISO 9002. ISO 9002 is a global certification provided to those companies meeting the accepted standard for quality.

Hydra ECF-ICF Features

Advanced Electronic Measurements

The HYDRA ECF/ICF Bio-Impedance Analyzer (Model 4200) represents the latest in electronic technologies for the medical community. This instrument uses the latest in microprocessor, signal conversion, and digital signal processing technologies to produce a flexible, accurate and reliable instrument. The scope of measurement options enables the device to be used routinely as well as for research.

Validated Scientific Basis

Xitron's Bio-Impedance Spectroscopy (BIS) technology has been validated on a number of populations by a variety of leading body composition research institutions dating back to 1992. These studies have primarily focused on comparing the predicted ECF and ICF volumes measured wrist-ankle to dilution and other reference methods. The HYDRA ECF-ICF has been designed to enable ECF and ICF to be measured easily and routinely. The HYDRA ECF-ICF device has substantially improved high frequency performance, thus, providing improved ICF prediction accuracy and repeatability.

Easy to Use

All other multifrequency systems require the use of a computer, Although the HYDRA ECF/ICF device can be controlled from a computer using the system utilities software, the HYDRA ECF/ICF features extensive data processing capabilities, thus, the Cole model and ECF and ICF volume can be computed internally without use of a computer.

When quality data has been measured, a calculation of ECF-ICF will take approximately 45 seconds. The calculation of solely ECF will take approximately 15 seconds. For continuous measurements, the initial values will take the same time as above but the following result for ECF-ICF and ECF will be displayed approximately every 5 and 2 seconds, respectively.

Flexible Measurements

Most bioimpedance research has employed a wrist-ankle electrode arrangement and this was the method used to validate the HYDRA ECF/ICF technology. The device enables the user to perform wrist-ankle measurements routinely following data entry.

Research has indicated that a segmental measurement may provide adequate information about fluid and nutritional status. Therefore, HYDRA ECF/ICF has been designed to also allow body segments to be measured routinely.

A number of recent investigations have reported the HYDRA ECF/ICF technology to be sensitive to the change in ECF and ICF, and that the ability to measure ECF and ICF continuously would be useful to several fields of medicine. So as to facilitate such applications, HYDRA ECF-ICF has been designed to allow for a continuous measurements of ECF and ICF.

Data Storage Memory

When the power is turned off, the base product will save the last "single" measurement performed. When the device is shipped with the Data Storage Memory Option (MEM4200), the device will save up to 250 single measurements. At any time the user can print individual subject data or download the data to a computer using the provided utility software. This feature allows the user to use the device for several days or weeks without connecting it to a printer or computer.

Continuous Measurement Memory

While the device remains on, the device provides for approximately 20 hours of continuous ECF-ICF measurements and 8 hours of ECF measurements. When the device memory gets full, the device will no longer perform measurements and the device will inform the user that the Memory is Full. The user can printout a plot of those data that have been saved. When the power is turned off, data collected continuously will be deleted from memory.

Communication With Host Computer

The Hydra ECF/ICF device comes equipped with an RS232 Serial Port so the user can transmit the raw, modeled and volume data to a computer. For advanced users wishing to integrate the device into a larger system, the RS232 Command Set is listed in Appendix D. For the normal user simply wishing to save the data to a computer for post analysis or data base records, the user can accomplish this by using the Data Acquisition Utility Software on a computer with Windows® 95 installed.

Real Time Data Analysis and Plotting

The user can monitor real time volume changes either digitally on the device display or on a computer screen, using the provided HYDRA Plotting Utility Software (Windows 95®).

- Attention -
The user is strongly advised to read this entire manual before attempting to use the HYDRA ECF/ICF device. In particular, the user is urged to pay special attention to the *Safety and Accuracy Considerations Sections.* This instrument has been designed to meet the accepted safety standards for medical equipment. However, its use involves inducing an electrical current into the body, thus it should be used only for its intended purposes and only by well trained and qualified personnel.

Specifications

Impedance Measurement

Hydra ECF-ICF measures resistance (R) and reactance (X) and calculates the reciprocal impedance (Z) and phase angle (θ) at each measured frequency.

Measurement Frequencies

The device provides a measurement of complex impedance at different frequencies in a range according to the following modes:

Extra and Intracellular Fluid

A spectrum of the following 50 programmed frequencies spaced throughout a 5KHz to 1MHz range:

5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 20, 23, 25, 28, 31, 35, 39, 43, 50, 54, 60, 67, 75, 83, 93, 100, 115, 128, 143, 159, 177, 200, 220, 245, 273, 304, 339, 378, 421, 469, 500, 582, 649, 723, 806, 898, 1000.

All frequencies are accurate to within 0.05% of the selected frequency.

Extracellular Fluid

A spectrum of the following 20 programmed frequencies spaced throughout a 5KHz to 200KHz range:

5, 6, 7, 8, 10, 12, 14, 16, 20, 25, 31, 35, 43, 50, 67, 83, 100, 128, 159, 200.

All frequencies are accurate to within 0.05% of the selected frequency.

Electronic Measurement Accuracy

The following equations indicate the expected accuracy of the HYDRA ECF-ICF instrument excluding the independent time delay effects caused by contact, conductor length and transmission line effects. The time delay effects caused transmission line effects can be effectively removed by modeling (**Appendix A;** De Lorenzo 1997).

All frequencies (F) are expressed in KHz, all impedance's (Z) in ohms, all phases (P) in degrees.

Impedance Accuracy:

Accuracy (ohms) = (0.005 * Z) + 0.4 + (0.01 * Z / F) + (0.00001 * Z * F) + (0.001 * F)

Phase Accuracy:

Accuracy (degrees) = 0.25 + (A) + (1.0 / F) + (0.001 * F) + (B)

where

A =   (10 / Z) if Z > 1ohm

else A = 10

B =   0.02 * F / Z if Z < (0.002 * F)
        else B = 10

Applied Current

Never exceeding the IEC601-1 and U. L. 2601 safety standards, all measurements are performed using a variable current between 50µA and 700µA RMS dependent upon frequency output and load.

Resolution

Impedance: 0.01Ω
Phase: 0.01°
Volume: 10mL

Volume Prediction Accuracy

Validation research using our former device (model 4000B) on young to middle age subjects has shown the correlation between predicted and dilution determined ECF to range between 0.96 to 0.89, and SEE's ranging between 0.97 L to 0.88 L, respectively (Van Loan 1993; Patel 1995; De Lorenzo 1997). The prediction of ECF on children renal patients, ranging in age 4-18 years, was $r^2 = 0.94$ with a mean difference of 0.29 L (Bradbury 1997). Validation research on young to middle age subjects has shown the correlation between predicted and dilution determined TBW to range between 0.89 to 0.99, and SEE's ranging between 2.50 L to 1.26 L, respectively (Van Loan 1993; Patel 1994; De Lorenzo 1997). On hemodialysis patients pre and post dialysis, the correlation between the predicted and deuterium determined TBW was r = 0.95 and 0.92, and SEE's of 1.64 and 2.50 L, respectively (Ho 1994).

The change in ECF compared to bromide dilution on critically ill patients was reported to be r = 0.89, SEE 2.8 L (Plank 1996). On hemodialysis patients, the predicted loss in TBW was reported to be within 0.8 kg of body weight loss (Ho 1994). For continuous measurements, the relationship between change in ECF and body weight during dialysis was found to be r = 0.83-0.99, and 0.76-0.99 for ECF and ICF, respectively (Jabara 1995).

> **- Note -**
> The HYDRA ECF-ICF technology has been validated numerous times but this research was conducted on specific populations with well designed protocols and under controlled conditions. The validation research reported is only applicable to those subject populations studied and may not be applicable to other subject groups. The user is advised to read the referenced papers, as well as, the *Accuracy Considerations Section.*

Volume Prediction Repeatability

The repeatability of the volume prediction is dependent on the resolution of the measurement, modeling accuracy and the susceptibility of the electronic measurements to and interference. Repeatability is also influenced by electrode placement and biological variations such as volume distribution, temperature and ion concentration change. Under ideal test conditions, our former 4000B device had an ECF and ICF repeatability of ≈50 mL and ≈250 mL, respectively. However, in non-ideal conditions, where the cabling was not properly routed, the repeatability of ICF (high frequency) could be much worse. The Hydra ECF/ICF device have dramatically improved resolution and reduced sensitivity to noise and interference.

Internal testing has shown the repeatability of both ECF and ICF to be ≈50 mL when the measurements are performed repetitively.

Physical Characteristics

Size :   4.1" wide x 6.3" high x 9.7" deep
                                  104mm wide x 160mm high x 246mm deep.
Weight :   4lbs. in use, 9lbs. shipping.
                                  1.8Kg. in use, 4.09Kg. shipping.

Warm-Up Time

The specifications are valid immediately after setting the power switch to the *ON* position.

Environmental

Operating :   0°C to +50°C, less than 70% R.H. at 40°C (non-condensing).
Storage :   -30°C to +65°C, less than 95% R.H. at 40°C (non-condensing).

Interface

RS232 :   Full Talk/Listen capabilities. Selective baud rates: Up to 57.6 Kb. Isolated from output circuitry: Up to 500V RMS.

Subject Leads

The *five foot* (30.48cm) subject leads are connected to the HYDRA ECF-ICF by means of a connector located on the rear panel. Each cable set terminates to a pair of small "alligator" clips, enabling connection to an appropriate electrode (Refer to the *Specifications and Accuracy Considerations Sections*, for further details and for information on Xitron's IS4000 Disposable Electrodes). All measurements are made using a 4-wire technique.

USA Power Cord Requirements

The 10 ft power cord is a grounded medical grade (Beldon, USA, part no. 820) power cord with a C13 style receptacle that plugs into the Hydra ECF/ICF device.   Per the IEC601-1 and U.L. 2601 standards, the power cord comes with a Ferrite attached to reduce electromagnetic emissions. Use of power cords not meeting these specifications will cause the device to no longer comply with the applicable USA medical device standards.

International Power Cord Requirements

Per the standards set for by the European Medical Device Directive (CE Mark), a standard European Cenelec approved harmonized power cord must be used, and the provided Ferrite must be attached to reduce electromagnetic emissions. See instructions for the attachment of the provided Ferrite to the user purchased harmonized power cord in **Figure 1**. Use of power cords not meeting these specifications will cause the device to no longer comply with the applicable EC medical device standards.

AC Power Source Requirements

The HYDRA ECF/ICF is powered from an 85-250V 47-63 Hz AC power supply.

Chapter 2. Getting Started

Unpacking

If the shipping carton is visibly damaged when delivered, request that the carriers' agent is present when the instrument is unpacked. If the instrument appears damaged when unpacked, notify the carriers' agent, who should then authorize repairs before the instrument is returned to Xitron Technologies. Even if the instrument appears undamaged, it may have suffered internal damage in transit that may not be apparent until the instrument is operated. If the instrument fails to achieve its' published accuracy specifications (as shown in the *Specifications Section*) then notify the carriers' agent and Xitron Technologies or an authorized service center and retain the shipping carton for the carriers' inspection.

The identification of the HYDRA ECF-ICF instrument is listed on a label attached to the rear panel of the instrument. This label should be checked, along with any other options shipped with the instrument, against the original order and any discrepancy should be brought to the attention of Xitron Technologies or its authorized agent.

<div style="border:1px solid black">

- Recommendation -
Save the box and shipping material that was used to ship the device. These materials have been designed specifically for HYDRA ECF-ICF to prevent damage during shipping. These materials will be needed if the device ever needs to be returned.

</div>

Main System Components

Hydra ECF-ICF

The HYDRA ECF-ICF (Model 4200) is the basic measurement instrument.

Subject Cables

The MC4200 option is the subject measurement cables. One set is supplied with each instrument. It should be noted that the accuracy specifications are only valid when using this cable set, thus the user should only use this cable set and should not attempt to modify or repair the cables.

Power Cord

USA Power Cord

The CP4200 option is a USA medical grade power cord. This cord is designed to plug directly into the line and the device. One USA power cord is supplied with the instrument. This power cord has been labeled to ensure other power cords are not used with the device. Use of other power cords can cause the product to no longer meet the applicable safety standards.

International/European Power Cord

As discussed in the Specifications Section, the European Community Medical Device Directive (CE Mark) requires use of a Cenelec approved harmonized power cord with the provided Ferrite attached. A harmonized power cord is a standard European power cord that can be purchased at most electronic supply retail entities. Purchase an approved Cenelec power cord and attach the Ferrite as shown in **Figure 1** below.

Harmonized Power Cord
Ferrite Attachment for CE Mark

(NOT PROVIDED)

(PROVIDED)

Ferrite Clamp
Figure 2

Wire-Tie
Figure 3

Harmonized Power Cord
Figure 1

(Front View, Open)
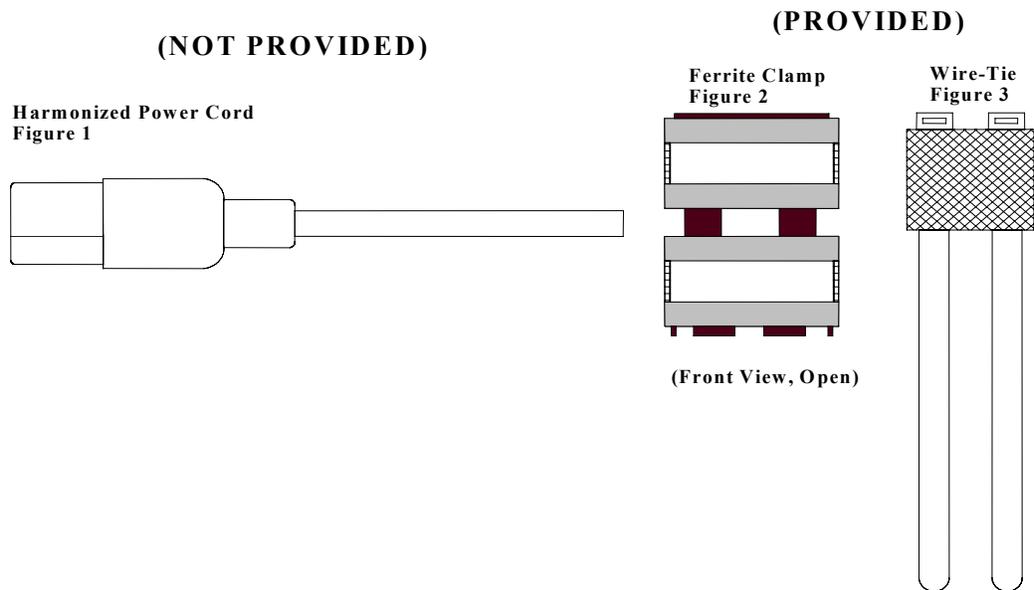
ASSEMBLY INSTRUCTIONS

1. Attach the Ferrite (Figure 2) as close to the Receptacle (Figure 1) as possible.

2. Fasten securely with the provided wire-tie (Figure 3) as shown

3. Cut the excess wire-tie tabs so they are flush with the fastner's.

Figure 2

Figure 1

Figure 3

C-13 Style
Receptacle
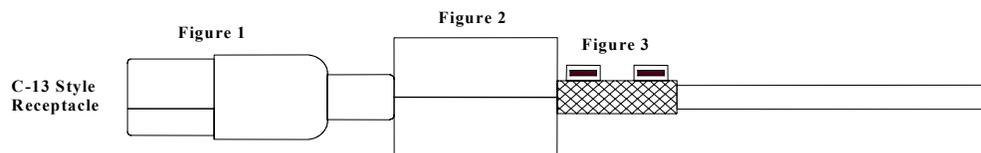
Host Computer Port

The host computer port (RS232 Interface) enables the device to communicate with a computer. The port must only be connected to a computer.

RS232 Interface Cable

The RC4200 option is a female-female file transfer cable to interface to a standard IBM AT® 9-pin RS232 connector. One cable is included with the system.

Parallel Printer Port

A standard IBM™ 25 pin parallel printer port enables the device to communicate to a text or graphical (HPGL) printer. The user is required to provide their own parallel printer cable. This port must only be connected to a printer.

Utilities Software

The HYDRA ECF/ICF system comes with the BIS4200 Utilities Windows 95® Utilities Software. One of these utilities (**Hydra Acquisition.exe**) enables the device to be controlled by a host IBM PC® (or compatible) computer, thus allowing the frequency, modeled and volume data collected from the device to be saved electronically. Another utility (**Hydra Plotting.exe**) enables the continuous measurement data to be saved, converted into a text file and plotted versus time and viewed real time on a host PC® computer monitor. The third (**Data Model-Vol.exe**) allows measured raw frequency data to be externally fit to the Cole model for model fit verification if necessary. This utility also produces a file that can be used for plotting measured data. This utility can also be used to externally compute ECF and ICF volume. A forth utility (**Hydra Memory Utility**) is provided to those users who purchased the MEM4200 Data Storage Memory Option. The third display screen when the device is turned on indicates if the Hydra ECF/ICF device has been fitted with this option. To run these programs requires a PC® with a minimum of 8mb of RAM and Windows® 95 installed. Refer to the *HYDRA Utilities Software Section* for details of operation. One copy of each utility is supplied with the instrument.

Verification Module

The TS4201 option is an equivalent electronic test circuit that simulates the typical skin contact resistance, and the resistance and capacitance values obtained wrist to ankle. The user can at any time verify that the device is performing correctly by comparing the results obtained to the expected results. One TS4201 is included with the system package. Refer to the *Product Maintenance Section, Device Performance Verification Section* for instructions

Operation Manual

The MO4200 option is the HYDRA ECF-ICF operation manual. One copy is supplied with each instrument.

Options and Accessories

Data Storage Memory

The MEM4200, Data Storage Memory Option automatically saves up to 250 single measurements. The MEM4200 Option also comes with a computer software utility for downloading the saved data to a computer and clearing the device memory of saved data.

Disposable Electrodes

The IS4000 option provides disposable electrodes designed and specified for use with the HYDRA ECF-ICF product. Contact Xitron Technologies for pricing and delivery details. A sample is provided with the instrument.

Carrying Case

The CC4200 option is a padded soft carrying case designed specifically for the HYDRA ECF-ICF device. The flap opening in the front allows the device to be used while in the case, and the storage area at the rear and side of the bag allows for cables, electrodes, etc. to be carried along with the device.

Roll Stand

This option is not yet available from Xitron. However, a roll stand for the device can be ordered directly from GCX Corporation, 3875 Cypress Drive Petaluma, California, USA, 94954-56335, Phone: 707 773-1100, FAX: 707 773-1180. Contact GCX Corporation for details and mention the roll stand is for the Xitron Technologies, Hydra ECF/ICF Bio-impedance Analyzer.

Rear Panel Controls and Connections

Setup Switch

The "Setup" Switch (**Figure 2**), located on the right side of the rear panel between the "Host Computer" and "Parallel Printer" labels, allows the user to change the mode of the device for changing the device Setup (Maintenance) parameters (e.g., date, time, baud rate, etc.) or to perform a measurement (Normal). When the rear panel Setup Switch is in the down or "Maintenance" position, the device is in the Setup Mode. When the Rear Panel Mode switch is in the up or "Normal" position, the device is in the Measurement Mode. Turn off the device to change modes.

Power Cord Connector

The power cord connector, located at the bottom of the rear panel, is the receptacle for the female end of the power cord (**Figure 2**). See the *Powering the Device* Section for further details.

Subject Cable Connector

The "Subject Cable" Connector, located on the left side of the rear panel (**Figure 2**), is the receptacle for the subject lead set provided with the instrument.

+---+
| **- Attention -** |
| The provided subject cables have been specifically designed and tested for the HYDRA ECF-ICF. Use of any other subject leads cables will result in severe inaccuracies. |
+---+

Host Computer Port Connector

The "Host Computer" RS232 serial interface connector is located at the top right-hand corner of the rear panel (**Figure 2**). This connector connects to a female 9-pin to female 9 pin, D-sub, RS232 serial file transfer cable (Comp USA No. 130246).

Parallel Printer Port Connector

The "Parallel Printer" interface connector "Parallel Printer" is located at the bottom right hand corner of the rear panel (**Figure 2**). This connector accepts a standard 25 pin D-sub parallel printer cable.

Circuit Protection Fuse

The circuit protection "Fuse", located in the middle of the rear panel (**Figure 2**) protects the unit from failure of the internal power supply or a power surge. The replacement fuse should be a 0.5Amp 250VAC, Type T, 5 x 20mm, slow blow fuse (manufacturer: Littlefuse 218.500). Although not visible, an internal 0.8Amp 250VAC, Type T, 5 x 20mm, slow blow fuse (manufacturer: Littlefuse 218.800) is connected in series with the neutral wire.

> **- Attention -**
> Although a power surge can cause the fuses to blow, a blown fuse may also suggest internal power supply problem. Thus, it is recommended that the external fuse be replaced only once and only with a specified fuse. Contact Xitron Technologies for further information if needed.

Attention Symbol

The "Attention" symbol, located on the middle left side of the rear panel, reminds the user to consult accompanying documents before use.

CE Mark Symbol

This symbol indicates that the Hydra ECF/ICF device meets the standards set forth by the European Community, Medical Device Directive (MDD), thus bears the symbol for CE Mark.

Type Applied Part Classification

This symbol indicates that the Hydra ECF/ICF device has been classified as a Type BF Applied Part. A BF-Type Applied Part complies with specified requirements of the EN-60601-1 (1988) standard to provide a higher degree of protection against electric shock than that provided by Type B Applied Parts and is marked with the symbol above. Note: Type BF Applied Parts are not suitable for direct cardiac application.

Protection Class

This indicates that the Hydra ECF/ICF device has been classified according to the criteria set forth in the European Community, Medical Device directive as a Class I device with measuring function. Class I equipment with measuring function does not rely on basic insulation only but provides an additional safety precaution in that means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the

installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.
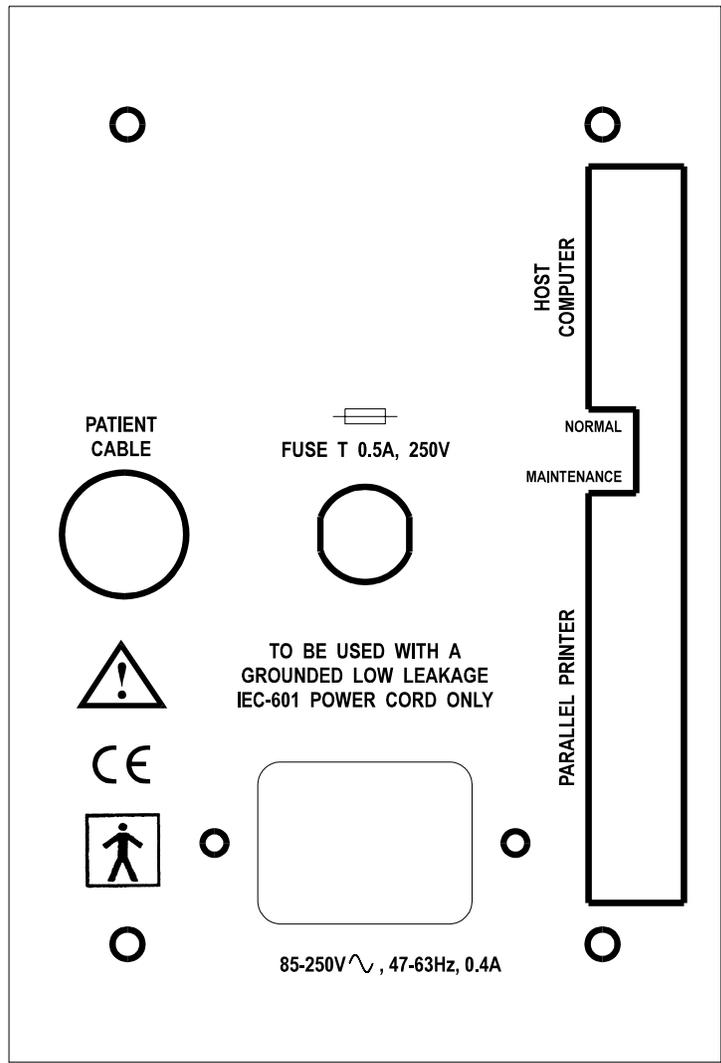
Figure 2

Front Panel Controls

This chapter discusses the basic use of the various controls, connectors and indicators on the front panel of the HYDRA ECF/ICF instrument. For a complete discussion of the methods used to perform specific tasks, the user is referred to the *Changing Setup Parameters and Performing A Measurement Sections.*

Display

The display used in the HYDRA ECF-ICF instrument is a 16 character, double line back-lit Liquid Crystal Display (LCD) (**Figure 3**). This display is used to indicate the request of input data, the status of the instrument and the measurement results. During interactive sequences, the display is used to prompt the user with the available choices (during selection type entries) or to indicate the progress of a numeric entry.

Power Switch

The "Power" switch (**Figure 3**), controls the power applied to the circuitry in the instrument. When this switch is in the ON or "**I"** position, the microprocessor and analog circuitry is powered and the instrument may be operated normally. When this switch is in the OFF or "**O"** position, the device is disabled.

Menu Key

As described in the *Rear Panel Controls and Connections, t*he "MENU" key is used to select or change various maintenance Setup functions (e.g., baud rate), or to select the measurement parameters (**Figure 3**). Simply press the "Menu" key until the desired function is displayed.

Setup "Maintenance" Mode

When the Rear Panel "Mode" switch is in the down or "Maintenance" position, the available Setup choices through the Menu Key and their description are as follows:

Update Main Software

This feature allows the user to update the device from a computer with any new code (functions or equations) Xitron may produce without needing to return the device to the factory. Contact Xitron Technologies from time to time for update information.

Update Boot Software

This function allows the user to update the basic circuitry check and bring alive software without needing to return the device to the factory. Contact Xitron Technologies for additional information.

Format Time And Units

This function allows the user to change the format of time and units of measurement in either USA or international form. The device is shipped with the time and units set in international form.

Format Date and Time

This function allows the user to change the date and time programmed in the device. The device is shipped with the date and time set at west coast USA.

<u>Set Serial Port</u>

This function provides baud rates of 1,200, 2,400, 9,600, 19,200, 38,400, 57,600. The other parameters for serial port are fixed. They are 8 data bits, none parity, 1 stop bit, hardware flow control. The device is shipped with the baud rate set at 19,200.

<u>Select Printer</u>

The device has the capability of printing "directly" to a dot matrix (text), ink jet or laser printer (graphical). Plots of continuous measurements can be printed directly to a dot matrix printer but for more attractive direct graphical printing, use of a higher level ink jet or laser (graphical) printer that supports HPGL language is recommended. Host computer controlled operation may allow for graphical printing on moderate level ink jet and laser printers. Refer to the *Utility Software Sections* for details. The device is shipped with a text printer selected.

<u>Set UF Options</u>

This function allows the user to select or disable inclusion of ultrafiltration (UF) volume when continuous ECF or ECF-ICF measurements are performed. If the UF option is enabled but a UF rate of zero is used, UF rate will not appear in the plot provided. The device is shipped with the UF function disabled.

<u>Set Resistivity</u>

This option allows the user to set the default ECF and ICF resistivity constants or modify them according to results provided by future research. The device is shipped with the Default resistivity coefficients enabled. The male and female default ECF and ICF resistivity values used are as follows:

	Male	Female
ρ_{ECF}	**40.5**	**39.0**
ρ_{ICF}	**273.9**	**264.9**

The "Default Values" and the "Users Values" will be the same until the "User Values" are changed by the user.

> It is to be noted that these constants dramatically affect the size (scaling) of the predicted ECF and ICF volume and should "NOT" be changed arbitrarily but rather after extensive and thorough research. Refer to the *Scaling of Resistivity Section* for details.

<u>Set Measurement Interval</u>

This feature allows the user to set the time interval between continuous measurements. For filtering purposes, measurements should be made as frequent as possible (zero interval or feature disabled). However, so as to allow the user to extend the device memory or reduce the amount of data to analyze, this feature has been provided. An interval of up to 9 minutes, 55 seconds can be implemented. When the measurement interval has been disabled, it will no longer be displayed as an input parameter. The device is shipped with the measurement interval disabled.

<u>Set Predict Fat-Free Mass (FFM) Option</u>

Because the prediction of FFM requires the assumption that the FFM is 73% water, which would be inappropriate for some settings, the device enables this predicted variable to be removed as a printed result. If the predicted FFM option is disabled, it will no longer be printed. The device is shipped with the FFM option disabled. Although second order, %Fat, can be calculated by the equation shown in Appendix B.

Measurement "Normal" Mode

When the Rear Panel "Mode" switch is in the up or "Normal" position, the available measurement mode choices through the Menu key are provided:

Case Number

This function allows the user to input the desired case number (from 1 to 99999) for the subject being measured. The initial Case Number displayed will be 00001.

Object

This function requests the user to select whether they wish to measure the ECF, ECF and ICF, or the ECF-ICF ratio. The initial Object displayed will be ECF and ICF.

Mode

This function requests the user to select whether they wish to make a single measurement of volume or measure volume continuously. The initial mode displayed will be Continuous Measurement.

Method

This function requests the user to select whether they wish to predict whole body (WB) water volume from a wrist-ankle measurement or the water volume in a segment. When a continuous measurement is selected and the UF function enabled, the user can also predict change in whole body water volume from a scaled segment measurement. The initial Method displayed will be Wrist-Ankle.

Data Entry

Once Object, Mode and Method are selected, the user will be requested to input the data required (e.g., height, weight, etc.) to complete the selected functions. The user will perform this task by scrolling with the ARROW Keys to find the desired selection and pressing the ENTER Key to select it.

Arrow Keys

The arrow keys (**Figure 3**) are used for selecting desired entries into the instrument, such as measurement mode, height, weight, gender, etc. For the entry of numbers (e.g., weight), holding down an Arrow Key for 5 seconds switches the units changed from 0.1 increments to increments of 1. This feature allows for numbers far apart to be reached more quickly. By releasing the Arrow Key, the increment of change reverts back to 0.1.

Enter Key

The "Enter" key (**Figure 3**) is used to select the displayed or input data. For multiple choice questions (e.g., height), this key is used to select the choice found with the Arrow Keys. The user can also use the MENU Key as the Enter Key.

Start/Stop Key

The "Start/Stop" key (**Figure 3**) allows the user to start the measurement after input of requested data entry. During continuous measurement, this key also allows the user to stop the measurement, adjust ultrafiltration (UF) rate if enabled, and then re-start the measurement when the key is pressed again. Refer to the *Stopping or Terminating a Measurement Section* for details.

Mark Key

During continuous measurements, the "Mark" key (**Figure 3**) allows the user to mark on a plot when an event took place. The provided print-out plot will included this Mark for analysis.

Print Key

The "Print" key (**Figure 3**) allows the user to printout either a plot of continuously measured parameters versus time or a report including time, date, water volume, etc., when a single measurement has been performed. When the measured results are shown on the display, the user can print current results by pressing the Print key. Turning off the power before printing will delete the continuously measured data. Only the last single measurement will be saved in memory when the power is turned off.

Printing Stored Data

The following is for devices equipped with the Data Storage Memory Option MEM4200 (See *Options and Accessories Section* for details). To print the "Current" results directly, simply press the print key when a single measurement result is shown on the screen or when the Stop Key has been pressed during continuous measurements. To print stored data, get into the data entry mode (e.g., case number) through the Menu Key and press the Print Key. The display will ask the user if they wish to print the "Current" data or "Stored" data. Use the Arrow Keys to select "Current" or "Stored" data. Press the Print Key to print the "Current" data, or use Arrow Keys to locate the "Saved" data you wish to print. Press the Menu Key to return to the data entry mode if printing is not desired. Refer to the *Changing Setup Parameters, Select Printer Section* for additional details on printers.

      The MEM4200 Option saves up to 250 and only single measurements (not continuously measured data) according to data and time. When 250 has been reached, the last measurement performed will be deleted and the latest will become number one. At any time, download the stored data to a file using the *Hydra Data Memory Utility*.

Attention Symbol

As discussed previously, this "Attention" symbol reminds the user to consult the accompanying documents for the device before its use.

UF/ECF Difference

The UF/ECF difference verbiage and its associated light is a future option for the dialysis field that has been disabled, thus, is non-functional.
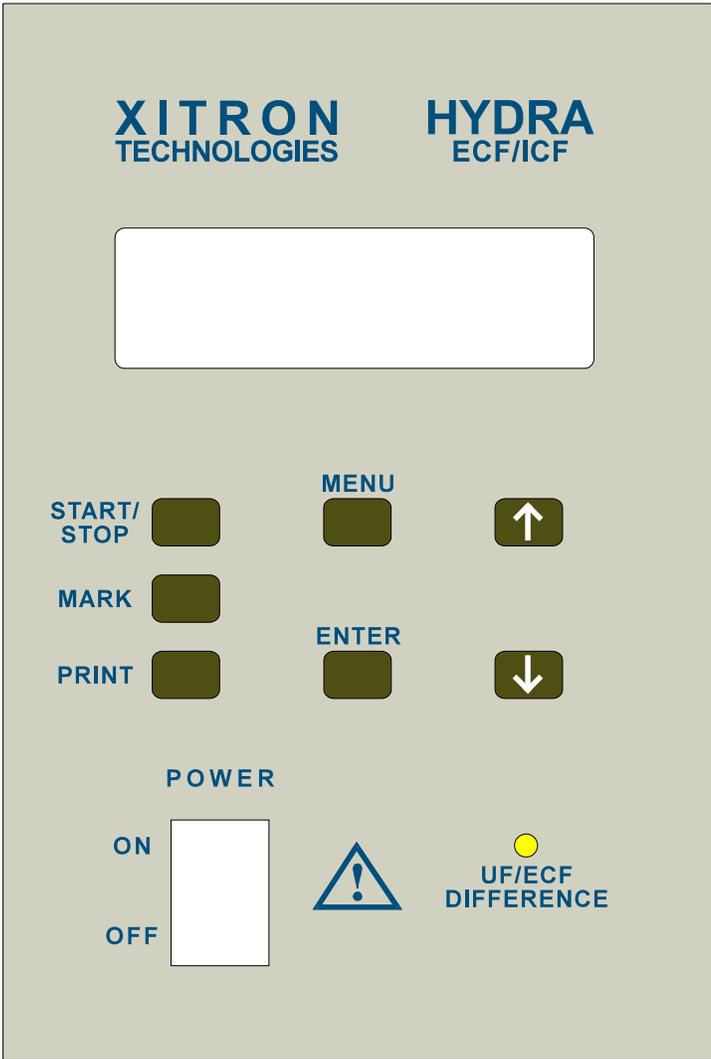
Figure 3

Safety Considerations

Product Compliance

The HYDRA ECF-ICF has been certified by a European Community (EC) notified body to meet the safety and other applicable standards stipulated in the EC Medical Device Directive (MDD), thus, bears the CE Mark. The IEC601-1-2 safety standard required by the MDD is effectively equivalent to the Underwriters Laboratory 2601 safety standard.

Effect Of Other Devices

At no time should the patient leads come into direct contact with the heart or great vessels, or be intended (as part of) to be used in conjunction with other devices which have such pathways. The HYDRA ECF-ICF uses a measurement current that never exceeds the safe current limit standards established by U. L. 2601 and IEC601-1

Although there has been no risk or contraindications reported, it is recommended that measurements "NOT" be performed on patients with implanted defibrillators, pacemakers, stents or with metal suture material in the heart or great vessels.

It is also recommended that at no time should the device be used in conjunction with other devices that inject a measurement current, including but not limited to impedance cardiography instrumentation. Use of such other devices in conjunction with the HYDRA ECF-ICF device may cause the safe current limits to be exceeded.

The HYDRA ECF-ICF device injects a current at very small voltage levels. Electrocardiography (ECG) equipment is designed to detect very small voltage levels, thus, an impedance measurement may interfere with the ECG result. Although further research is needed, the user is advised NOT to perform a measurement while ECG measurements are being performed.

Power Cord

In compliance the accepted safety standards, at no time should measurements be performed in the USA with any other power cord connected to the device other than the one supplied by Xitron or an equivalent. In Europe, at no time should measurements be performed with any other power cord connected to the device other than a Cenelec approved harmonized power cord with the provided Ferrite attached. Refer to the *Specifications, and Getting Started Sections* for details on power cord equivalency and the proper attachment of the Ferrite.

Product Circuitry Self-Check

If at any time prior to or during a measurement, the device detects that the current or voltage is too low or high, the device will stop functioning and the message "Warning! Current To Low or High" or "Warning! High Voltage Sensed" will appear on the display. A low or high current or voltage can be caused by either an internal fault or by one of the alligator clips or electrodes becoming disconnected. When either the black-current (I) alligator clip or the electrode used to inject current become disconnected, a warning that the current is too low will appear. When either the red-voltage (V) alligator clip or the electrode used to detect voltage become disconnected, a warning that the current is too "High" will appear. If either of these messages do appear, check the subject connections and press start. If the problem was only a disconnected lead or electrode, the device will conduct another self-check and if OK will resume measuring. If the self-check continues to detect a low or high current or voltage, the device will not function. Do not attempt to use the device and contact Xitron for returning the device for repair.

Circuit Protection Fuses

The circuit protection "Fuse", located in the middle of the rear panel (**Figure 1**) protects the device from failure of the internal power supply or a power surge. The replacement fuse should be a 0.5Amp 250VAC, Type T, 5 x 20mm, slow blow fuse (manufacturer: Littlefuse 218.500). In addition, an internal 0.8Amp 250VAC, Type T, 5 x 20mm, slow blow fuse (manufacturer: Littlefuse 218.800). is connected, internally, in series with the neutral wire.

Periodic Device Inspection

It is recommended that the HYDRA ECF-ICF device, cables and power cord be tested or inspected periodically by qualified personnel throughout its life to confirm that the device continues to perform properly and is free of faults or defects.

Qualified And Trained Personnel

The HYDRA ECF-ICF device is a professional device designed to be used by trained and qualified health practitioners. In addition to having a appropriate educational background, the user is advised to read and comprehend this manual thoroughly prior to use of this equipment.

Important Note:

For additional safety information on the meaning of symbols and device classification, refer to the *Rear Panel Controls and Connections Section*.

Powering The Device

The HYDRA ECF/ICF is powered from an internal medically approved 85-250V, 47-63 Hz power supply. Powering the device is accomplished by inserting the female end of the provided power cord into the connector located in rear panel of the instrument, and then plugging the male end of the provided power cord into a suitable AC power outlet. The user should always ensure that the voltage rating of the local AC power source is within the tolerances specified for the device, and an approved power cord has been used.

- Attention -

HYDRA ECF-ICF should only be powered using the power cord provided by Xitron or an equally equivalent power cord described in the *Specifications Section*. When initial unpacking the instrument, the user should ensure that the correct power cord has been provided. Use of an unapproved power cord will void compliance to the accepted U.S. and International electrical safety standards for medical devices. Refer to the *Specifications, and Getting Started Sections* for details.

Initial Power Application

Shortly after the user switches the "Power" switch located on the front of the instrument (**Figure 2**) to the ON or "I" position, the internal microprocessor performs tests upon the internal circuitry. The display will show Test RAM, KB Tested. Should any faults be detected a message describing the fault will be displayed. Depending on the nature of the fault, the instrument will either hold the displayed message (no further operation of the instrument being possible until the fault has been corrected), or the message will be displayed for approximately 2 seconds prior to the instrument continuing with normal operation.

Following successful completion of these tests the display will then momentarily display the device model (HYDRA ECF/ICF) and if memory option has been fitted (MEM4200 Yes or No). Next the display will show the Boot and Main Firmware Versions programmed in the device. The device will then display the Date and Time. The device is shipped with the rear panel "Setup" Switch set in the Up-Normal operation. If the "Mode" switch is in the Down-Maintenance setting (**Figure 2**), the display will show Testing RAM, KB Tested then Set_Up Menu, Update Software. These messages indicate that the instrument is functioning correctly and ready to be used. Allow the device to warm-up for several minutes before performing a measurement. When not in use, turn the HYDRA ECF-ICF off.

Chapter 3. Changing Setup Parameters

Refer to *Rear Panel Controls and Connections Section* for details about Setup-Maintenance parameters. Turn off the device to change modes. When the Rear Panel "Mode" Switch is in the "DOWN" position, the available "Setup" choices and their operation are as follows:

Update Software

1. The display will ask the user if they wish to "Update Software" from a computer. Press the ENTER Key to select option, or MENU Key to ignore this option and go to the next option.

2. If the ENTER Key is pressed, the display will ask the user to confirm "Yes" or No" to Update Software. Use the Arrow Keys to select Yes or No.

3. If "No" is pressed, the display will go to the next MENU option. If "Yes" is pressed the device will accept a Software Update from a computer at only a 19,200 baud rate.

Update Boot ROM

1. The display will ask the user if they wish to "Update Boot ROM". Press the ENTER Key to select option, or MENU Key to ignore this option and go to the next option.

2. If ENTER Key is selected the display will ask the user to confirm "Yes" or No" to Update Boot ROM. Use the Arrow Keys to select Yes or No.

3. If "No" is pressed, the display will go to the next MENU option. If "Yes" is pressed the device will wait to accept the Boot Codes from a computer at only a 19,200 baud rate.

Format Time and Units

1. The display will ask the user if they wish to set format of time and measurement units to USA or international standards. Press the ENTER Key to select option, or MENU Key to ignore this option and go to the next option.

2. If selected, use the Arrow Keys locate the desired display of time and press ENTER. Follow the same procedure to change the units of measurement.

3. When time and units have been changed, the next option will be displayed.

Format Date And Time

1. The display will ask the user if they wish to change the date and time. Press the ENTER Key to select option, or MENU Key to ignore this option and go to the next option.

2. If selected, use the ARROW Keys to locate the desired date and press ENTER. Follow the same procedure to change the time.

3. When date and time have been changed, the next option will be displayed.

Set Serial Port

1. The display will ask the user if they wish to change the baud rate. Baud rates of 1,200, 2,400, 9,600, 19,200, 38,400, 57,600 are available. Press the ENTER Key to select a new baud rate or MENU Key to ignore this option and go to the next option.

2. If selected, use the Arrow Keys to find the desired baud rate and press ENTER.

3. When the baud rate has been selected, the next option will be displayed.

Select Printer

1. The display will ask the user if they wish to change the printer type of Text or Graphics. The printers with HP-GL/2 language are considered graphical for HYDRA. Otherwise it will be considered text.

2. Use the Arrow Keys to find the desired printer type and press ENTER.

3. When the printer type has been selected, the next option will be displayed.

Set Ultrafiltration Options

1. The display will ask the user if they wish to "Set UF Options" to use or disable the inclusion of ultrafiltration (UF) volume during continuous ECF or ECF & ICF whole body wrist-ankle or whole body segmental measurements. Press ENTER Key to use or disable the UF function , or the MENU Key to ignore this option and go to the next option..

2. If selected, use the ARROW Keys to select "USE UF" or "DO NOT USE UF" option.

3. Once the user has selected to include or not to include the UF function, press ENTER and the display will go to the next option. If disabled, UF will no longer be included as a data input parameter.

Set Resistivity

1. Do not change this parameter arbitrarily. Refer to the *Front Panel Controls, Set resistivity or Accuracy Considerations, Scaling Resistivity Sections* for details. The display will ask the user if they wish to "Set Resistivity" for the male and female ECF and ICF resistivity constants used to predict volume. Press the ENTER Key to change or set resistivity, or the MENU Key to ignore this option and go to the next option..

2. If the Enter Key is pressed, the display will ask if the user wishes to "Use Default" or "Use User's Value." Use the ARROW Keys to select the option desired.

3. If the user selects "Use Default" by pressing ENTER, the device will set resistivity to the factory default values and go to the next option. For the factory default values refer to *Front Panel Controls, Set Resistivity*.

4. If the user selects "Use User's Value", the device will display (WARNING! Volumes Will be Affected) for three seconds, then display Pecf_M (Male ECF resistivity). Use the Arrow Keys to adjust Pecf_M to the desired value and press ENTER to select.

5. The device will then display Pecf_F (Female ECF resistivity). Use the Arrow Keys to adjust Pecf_F to the desired value and press ENTER to select.

6. The device will then display Picf_M (Male ICF resistivity). Use the Arrow Keys to adjust Picf_M to the desired value and press ENTER to select.

7. The device will then display Picf_F (Female ICF resistivity). Use the Arrow Keys to adjust Picf_F to the desired value and press ENTER to select.

8. The device will then display Exit, press ENTER to exit or the MENU Key to return to the menu selections.

<div style="border:1px solid black">

- Warning -

Resistivity is a scaling term, thus, changing resistivity will affect the size of the predicted volume. As discussed in the *Accuracy Considerations, Scaling To Reference Methods Section,* the default resistivity constants have been determined from dilution methods and cross- validated on independent populations. These terms should not be changed arbitrarily but rather based on validation to known and accepted reference methods. The user can select the "Use Default" to return to factory values at any time. Refer to the *HYDRA ECF-ICF Utility Software Manual* for how to compute new resistivity terms from dilution ECF and TBW data. Refer to De Lorenzo et al , J Appl Physiol 82(5) 1997, for compete discussion.

</div>

Set Measurement Interval

1. The display will ask the user if they wish to "Set Measurement (Mea) Interval."

2. Press ENTER to Set or Change the Measurement Interval or the MENU Key to go to the next option.

3. When ENTER is pressed the display will ask "Set Mea Interval" "Yes" or "No. " Select Yes to change measurement interval from 0 to up to 9 minutes, 55 seconds. The default setting is zero. If No is pressed to SET MEA INTERVAL, this parameter will no longer be included as a data input parameter.

Predict Fat-Free Mass

1. The display will ask the user if they wish to "Set Fat-Free Mass (FFM) Option"

2. Press ENTER to Set FFM Option or MENU Key to go to the next option.

3. When ENTER is pressed the display will ask "Use FFM" or "Do Not Use FFM. Use the Arrow keys to select desired option. If "Do Not Use FFM" is selected, FFM will no longer be included as an output.

4. Although second order and prone to error, %Fat, can be calculated by the equation shown in **Appendix B**. FFM will be displayed as L (lean body mass).

Chapter 4. Measurement Operation

Rationale For Measurement Options

This chapter provides the user with the rationale for the options provided by the HYDRA ECF-ICF device.   Applications that have been validated, cross-validated and published in respected medical journals are labeled as (Validated Application). Those application having shown validity and utility but require more research are labeled as (Additional Research). Those applications that are provided solely for research applications are labeled as (Research Only). Functions not available are labeled (Not Provided). The user is advised to read the *Safety and Accuracy Considerations Sections* before performing a measurement.

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┌─────────────────────────────────────┐
│       ┌─────────────────┐            │
│       │     OBJECT      │            │
│       │  ECF-ICF Ratio  │            │
│       │       ECF       │            │
│       │     ECF-ICF     │            │
│       └─────────────────┘            │
│                │                     │
│                ▼                     │
│         ┌─────────────┐              │
│         │   METHOD    │              │
│         │ Wrist-Ankle │              │
│         │   Segment   │              │
│         └─────────────┘              │
│                │                     │
│                ▼                     │
│         ┌─────────────┐              │
│         │    MODE     │              │
│         │ Continuous  │              │
│         │   Single    │              │
│         └─────────────┘              │
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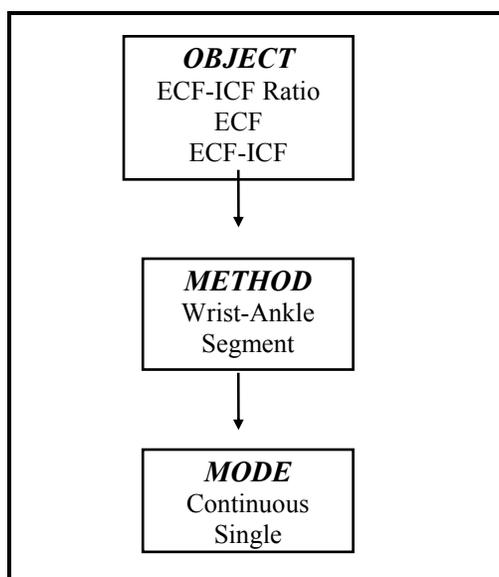
ECF-ICF Ratio Measurements

Single ECF-ICF Ratio

(Additional Research) The ECF-ICF ratio has been suggested as an index of health because many conditions result in loss in ICF and a gain in ECF volume (Pierson 1986). Recently, the HYDRA technology has shown to be a good indicator of overhydrated dialysis patients (Katzarski 1996; Lopot 1996). An ECF-ICF ratio measurement requires no additional subject information such as height, weight, etc, is electrode placement independent and can be applied wrist-ankle or on a segment at any time. Refer to the *Accuracy Considerations Section* for information concerning limitations to an ECF/ICF ratio measurement.

Continuous ECF-ICF Ratio

(Research Only) Since the device is capable of measuring continuously in all modes, a continuous ECF-ICF ratio has been provided as a feature. This feature presently has no validated application. Refer to the *Measurement Protocol and Accuracy Considerations Sections* for further information.

Whole Body Wrist-Ankle Measurements

Whole Body Wrist-Ankle ECF-ICF

(Validated Application) A single measurement of total ECF-ICF volume using a wrist-ankle electrode arrangement is the standard or conventional method. This application has been successfully validated on a variety of subject populations (Van loan 1993; Patel 1994; Ho 1994; Van Loan 1996; Finn et al 1996; Bradbury 1997; De Lorenzo 1997). Refer to the *Accuracy Considerations Section* for additional information on subject selection criteria.

Whole Body Wrist-Ankle ECF

(Validated Application) Under and over hydration primarily affects the ECF compartment, thus, there are several important applications whereby only ECF volume may be required (Katzarski 1996). As above, the measurement of ECF has been validated numerous times. Refer to the *Accuracy Considerations Section* for information on subject criteria.

Continuous Whole Body Wrist-Ankle ECF-ICF

(Additional Research)   The HYDRA ECF-ICF technology has shown to be highly sensitive to the change in ECF and ICF volume during dialysis (Jabara 1995; Jaffrin 1996). The measurement of ECF has been shown to closely follow ultrafiltration (UF) volume, and the rate of ECF change has shown to be highly predictive of hypotension (Zaluska 1996). Because investigators are interested in measuring ECF and ICF continuously over time, the device provides a continuous measure of these parameters. If an ultrafiltration (UF) volume (when enabled) is included, the device will continuously display ECF, ICF and UF versus time. The device will also compute the ECF rate of change. The device will also save the data for post plotting ECF, ICF and UF (if enabled) versus time. The user can also use the "Mark" Key to indicate on the plot when an event needs to be recorded. The provided plot can be printed at any time or viewed real time when the device is connected to a computer and using the *HYDRA ECF-ICF Plotting Utility Software*. These device features will greatly facilitate the knowledge and understanding of fluid dynamics in a variety of fields. Refer to the *Accuracy Considerations Section* for information on subject criteria.

Continuous Whole Body Wrist-Ankle ECF

(Additional Research)   As above, the rate of ECF change has shown to be highly predictive of hypotension (Zaluska 1996). When this function has been selected, the product will function as above but only ECF will be measured and displayed.

Segment Measurements

Segment ECF-ICF

(Additional Research)   Research has shown that hydration status can be adequately determined from a segmental measurement (Kouw 1992). More recent research (Hemysfield 1996) has suggested that nutritional status may also be adequately determined from a body segment measurement. To facilitate the clinical applications of the segmental approach, the device enables segmental measurements to be performed. This function has been primarily designed for limb measurements because their shape can be more closely approximated and the system volume equations employed. Refer to the *Accuracy Considerations Section* for information on subject criteria.

Segment ECF

(Additional Research) As discussed, there may be applications for only ECF. This feature is intended for those health practitioner interested only in a segmental ECF measurements. When this feature is selected, the device will function as above but only ECF will be measured and displayed. Refer to the *Accuracy Considerations Section* for information on subject criteria.

Continuous Segment ECF-ICF

(Research Only) Because the device is configured to provide a continuous measurements in all modes, the product enables the health practitioner to continually measure the ECF and ICF in a limb or segment. As with continuous wrist-ankle measurement, this function also allows for the plotting of the continuous measurement. Refer to the *Accuracy Considerations Section* for information on subject criteria.

Continuous Segment ECF

(Research Only) As above, there may be applications for only ECF. This feature is provided to health practitioner interested only in continuous ECF limb measurements. As with continuous wrist-ankle measurement, this function also allows for the plotting of the data. Refer to the *Accuracy Considerations Section* for information on subject criteria.

Segment-Whole Body ECF-ICF

(Not Provided) This function is not provided because whole body absolute ECF-ICF volume can be predicted by a wrist-ankle measurement. Thus, a segmental prediction of whole body ECF-ICF volume is unnecessary.

Segment-Whole Body ECF

 (Not Provided) This function is not provided because whole body absolute ECF volume can be predicted by a wrist to ankle measurement. Thus, a segmental prediction of whole body ECF volume is unnecessary.

Continuous Segment-Whole Body ECF-ICF

(Research Only) The relationship between ECF rate of change measured wrist-ankle has been found to be predictive of hypotension during hemodialysis (Zaluska 1996). The change in ICF is also of concern during hemodialysis. A wrist-ankle measurement may be problematic for some subjects because of movement. This feature allows the change in ECF and ICF to be related through scaling, as is a wrist-ankle measurement, to UF volume using a segment measurement. As with the wrist-ankle continuous measurement, this feature will allow for the plotting of the data along with UF. Refer to the *Accuracy Considerations Section* for information on subject criteria.

Continuous Segment-Whole Body ECF

(Research Only) This feature will function as above but only ECF will be measured and displayed. Refer to the *Accuracy Considerations Section* for information on subject criteria.

Accuracy Considerations

The HYDRA ECF-ICF represents a significant advance for field of human body composition. The methodology HYDRA ECF-ICF employs has been validated by many leading body composition research institutions on a variety of populations. Although HYDRA's prediction of ECF-ICF is based on the most scientific rigorous approach ever assembled, all indirect methods are based upon assumptions, thus, subject to error. The user is advised to adhere strictly to protocol and interpret with caution the results derived on populations the technology has not yet been fully validated on.

Measurement Considerations

Cables, Subject Placement and Connection Effects

General Guidelines

The subject cables can affect measurement accuracy, and these effects vary with frequency and impedance level. Although the device performs best between the 200-800Ω impedance range (wrist-ankle), body limbs and segments can also be accurately measured. The following general guidelines are recommended.

1. A segment having a length of at least 10 cm is recommended.
2. An impedance of ≈50Ω should be measured.
3. The respective black-current injection and red-voltage sense contacts should be at least 7.5 cm apart.
4. The surface between all contacts should be clean (apply alcohol swab when necessary) and free of excessive body hair.
5. Use electrodes that have at least $5cm^2$ of contact area. A smaller electrode surface area may adversely affect the measurement accuracy.

Placement of Cable Leads

The red-voltage detector connections should always be placed proximal (inside) to the black-current injection connections on the subject. Refer to the *Measurement Protocol Section* for exact protocols.

Cable Routing And Subject Placement

The accuracy of the measurement can be adversely affected by placing the subject on a conductive surface (e.g. a metallic table) or by routing the cables over (or around) metallic objects. Computers and other high voltage equipment can be a major source of interference, thus the device or cables should not be located or routed near such devices.

Cable and Connection Effects

1. The accuracy of the measurement is only specified when used with the cables designed for the HYDRA ECF-ICF. Other cables should "NEVER" be used.

2. Discontinuity in the cables can cause resonance at certain frequencies. Ensure that the connectors and cable surfaces are clean, the cables are free of tangles.

3. At high frequencies there can be large errors caused by parallel capacitance. The HYDRA ECW-ICW incorporates a technique that considerably reduces this effect (and

cable resonance). The user should ensure that the cable sets do not become twisted together.

4. Poor contact, caused by a dry electrode (due to poor storage or long term usage), exceptionally dry subject skin, excessive hair, oil or lotion can accentuate the cable effects previously mentioned. Most affected are cable capacitance and resonance. Poor contact can also cause current path to be formed between the current and voltage electrodes, resulting in very poor measurements. The user should always ensure good connections and adequate distance between the red-V & black-I electrodes.

5. Using electrodes having less than 5cm^2 of contact area may adversely affect the measurement accuracy. This is because contact resistance increases with decreasing electrode surface area. Because it is not possible for Xitron Technologies to test all brands of electrodes, Xitron has had an electrode specifically designed for these measurements (Option IS4000). The electrode is 1.90 cm (0.75") wide by 7.62 cm (3") long. By being thinner and longer, nearly double the surface area is provided.

Static Voltage Accumulation

The 4200 is sensitive to the static voltage accumulated on the patient. This will be most noticeable during extremely dry conditions and particularly when nylon carpeting on the floor is present. Simply have the patient discharge by touching something metal before attaching the patient leads to the electrodes. High static voltage accumulation on a patient can damage the device but presents no safety concerns.

Effects Of Other Devices

In accordance with the requirements for European Community CE Mark, the device has been certified to meet the accepted standards for both emissions of and immunity to electromagnetic interference.   However, in addition to that discussed in the *Safety Considerations Section*, the device predicts volume assuming the impedance is a function of body water. Implanted conductive material or devices can effect the impedance, thus, measurements should not be performed on subjects with implanted conductive material or devices.

Electrode Placement

The HYDRA ECW-ICW measures the parameters between the red-voltage contacts on the subject, thus, any variability in the actual placement of these connections will directly cause an apparent reduction in the repeatability in the actual parameters measured. Distinct "physical landmarks" should be used to determine electrode placement (particularly the voltage sense electrodes), and that care be taken to position these electrodes accurately with respect to these "landmarks" for each measurement. The important position point within the electrode is its' center, thus the accurate positioning of this point with respect to the selected "landmark" will accommodate variability in electrode size and contact area.

+--+
| **- Note -** |
| For continuous measurements, it is advised to keep the electrodes in place with |
| nonconductive standard medical adhesive tape, paying attention to the area closest to the |
| alligator connection tab. This will ensure that the electrodes do not come off unintentionally |
| during the measurement. |
+--+

Subject Positioning

Measurements are best performed with the subject positioned in the supine position (face up), with the legs and arms slightly apart **(Figure 3)**. Extreme abduction and adduction of the limbs, crossing the legs or touching the hands to another body part dramatically effect the results (Kushner 1996). The subject should remain motionless throughout the measurement.

Biological Considerations

Effects Of Geometry On Prediction of Volume

Estimating the volume of an object requires knowing the geometry of the object (Foster 1996). A wrist-ankle measurement assumes that the geometry between subjects is the same. Although this assumption is tenuous, prediction of volume at the extremes of geometry have not been significantly effected (Withers 1995; Van Loan 1996, Bradbury 1997). The scaling effect of geometry on resistivity has been estimated (De Lorenzo 1997).

The impedance measured wrist-ankle is dominated by the arm and leg because the trunk has a large cross-sectional area (Foster 1996). As such, the relationship between a wrist-ankle measurement and total body water is a function of the body water being evenly distributed. Obviously this is not always the case (Kushner 1996). In cases of suspected uneven fluid distribution, wrist-ankle data should be interpreted with caution. The geometry of a limb is more easily accounted for, thus, segmental measurements may have utility.

Conduction Path Of Measurement

The characteristic frequency of tissue varies, depending on the tissue measured. All tissues display different characteristic frequencies that depend upon their physical structure. As reported (Vereheij 1996), the measurement performed 5KHz-1MHz is mainly determined by the presence of skeletal muscle tissue. However, the current is not fully conducting through the ICF of all cells and tissues with higher characteristic frequencies. The error caused by the current not fully conducting through all the cells of the various tissues appears to be small.

The Cole Model

Although modeling is essential for the interpretation of an impedance measurement and the overwhelming majority of data has corresponded well to the Cole model, it cannot be assumed that the Cole model is a perfect representation of physical reality. This is particularly true for the translating Cole model terms R_E and R_I into ECF and ICF volume, respectively.

In rare instances, the data has not fit the Cole Model well. For septic patients, the progression of the disease appears to reduce the high resistive properties of the cell membrane, resulting in very little difference between low and high frequency impedance (Scheltinga 1995). With little or no dispersion, it is virtually impossible to compute the Cole model, particularly R_I. However, as reported by (Finn 1996), the calculation of ECF does not appear to be affected. Therefore, the predicted ICF on septic patients should be interpreted with caution. The device will indicate when a poor fit has been obtained, will display a "BAD FIT" and will not provide any final result. The user is advised to collect the data using a computer so the raw data can be cross checked through external modeling.

Extremely high characteristic frequencies (F_C) (>1MHz) have been observed in severely dehydrated malnourished infants (Mazariegos 1996). High F_Cs have also been observed in a small number of critically ill surgical patients. With an observed F_C greater or near the limit of measured high frequency data, it is very difficult to accurately compute ICF. Again, the measurement of ECF does not appear to be effected by high F_Cs (Finn 1996). The device will indicate when a poor fit has been obtained, will display "BAD FIT" and will not provide any final result. The user is advised to collect the data using a computer so the data can be cross checked through external modeling.

Evaluating The Quality of Fit To The Cole Model

As discussed in **Appendix A**, the modeling program evaluates the weighted least square error of both Z and θ, where the weighting was established by the published accuracy specifications of the HYDRA ECF-ICF instrument and removes any frequency that would significantly decrease the total weighted least square error. The device utilizes the following ratings for judging the accuracy of fit to the Cole Model.

        0 =   Excellent fit to model
        1 =   Good fit to model
        2 =   Marginal fit to model
        3 =   Questionable fit to model
        4 =   Bad fit to model

      For any fit rated Questionable or Bad, the volume data will not be computed by device. For, results rated Marginal, the display will warn the user that the data is "Marginal". If data cannot be modeled or the results provided become in question, the user is recommended to judge the quality of fit to the Cole model by manually collecting the data with a computer using the *HYDRA Data Acquisition Utility* and modeling the data using the *HYDRA Modeling Utility Software*. For additional information on "Evaluating the Quality of Fit To The Cole Model", the user is referred to the *Data Model-Vol Utility Software Section* in this Manual. Remember, ECF is computed using data measured 5KHz-200KHz and ECF and ICF with the full 5KHz-1MHz spectrum.

Hanai Dielectric Mixture Theory

The equations shown in Appendix B have been validated numerous times (Van Loan 1993; Patel 1994; Ho 1994; Plank 1996), and the exact exponent predicted by the Hanai theory has proven to be the best volume predictor (De Lorenzo 1997). However, the user is reminded that this equation has not been tested on all populations nor under all conditions. When measurements are performed on populations that the device has yet to be fully validated on, the user should interpret the results with caution. Furthermore, the user is reminded to follow the protocol utilized by the quoted validation studies closely.

Orthostatic Fluid Shifts

Upon recumbence from standing, there is a ≈3% increase in low frequency impedance (decrease in ECF volume) and an additional ≈2% increase at 10 minutes (Kushner 1996). Over four hours, there is an additional ≈4% increase. With a proximal electrode arrangement (forearm and lower leg) (Scheltinga 1991), the percentage change was reported to be roughly half of that measured with distal electrodes (wrist-ankle). The effect at high frequency (ICF) was roughly half for both distal and proximal electrode arrangements. For an average 70 kg man with roughly 42 L TBW, 17 L ECF and 25 L ICF, after 10 minutes, this is roughly a 0.68 L and 0.75 L error for ECF and ICF, respectively. Thus, for the prediction of absolute volume, subjects should always be measured at the same time or after 5 minutes following recumbence.

Ion Concentration Changes

It has been found that a 5 mmol change in ion can affect the predicted ECF 1-2%, and ICF 4-5% (Scharfetter 1995). This can be attributed to the fact that the ICF is 4-5 to 1 less conductive than the ECF, thus, a small change in ion has a larger effect on ICF. Nevertheless, a 2% and 5% error on ECF and ICF, represents 0.34 L and 1.2 L error, respectively, for the standard 70 Kg man with 17 L ECF, and 25 L ICF. For the prediction of

absolute volume in liters, the error caused by ion is small on ECF and moderate for ICF. For such applications as hemodialysis, the patients can be measured post dialysis after ion concentration has been normalized. Fortunately, since resistivity is purely a scalar term, the ion effects on resistivity are linear and thus could be accounted for.

Skin And Core Temperature

As discussed in the *Changes in Vascular Perfusion and Exercise Sections*, changes in skin temperature caused by a variety of health conditions, changes in environment, blood flow and heat dissipation can affect the measurement adversely (Kushner 1996). In addition to these effects, changes in core temperature can also effect the prediction. To estimate ECF and ICF volume requires the assumption that resistivity is known, and if known, constant. The temperature coefficient for tissue below 1GHz is 2%/ °C, thus, a 1° change in core temperature causes a 2% change in resistivity, which is a 0.34 L and 0.50 L error for a subject with 17 L and 25 L of ECF and ICF volume, respectively. As such, results should be interpreted with caution when either skin or core temperature is suspected of significantly changing form baseline.

Dehydration

There is evidence to suggest that when a subject becomes dehydrated due to insufficient water intake, the ion concentration changes 3-5 mmol/L. As discussed in the *Ion Concentration Changes Section*, a 5 mmol change in ion has been found to affect the prediction of ECF ≈1% and ICF ≈4%. Unless the change in ion is accounted for, it is advised to fully rehydrate the subject before performing a measurement.

Exercise

 Moderate to strenuous exercise can affect the measured impedance (Kushner 1996). This is caused by increased blood flow to the skeletal muscles, increased skin blood flow and temperature and fluid and electrolyte loss. The effect will vary depending upon the muscle groups involved, intensity of exercise, skin blood flow and heat production, and amount of fluid lost. The errors caused by exercise have been in the 3-5% range. To reduce errors, measurements should not be performed within several hours of moderate to strenuous exercise, and hydration status should be completely corrected. On the other hand, if qualitative rather than quantitative information is desired, significant ECF and ICF difference have been found between untrained and trained subjects (Kanai 1987).

ECF-ICF Ratio Measurements

Cause For Change In Ratio

Once absolute ECF and ICF volume is known by either a wrist-ankle or segmental measurement, an ECF-ICF ratio measurement provides a convenient measure of the change in this ratio. However, an ECF-ICF ratio provides no information as to the cause for the change in ratio.   For those situations where the directional change in compartment volume is well understood, a ECF-ICF ratio may be very useful because it is electrode independent and requires no input of height or weight.

Comparing Ratio's Between Groups

For discerning ratio differences between patient groups, the user is reminded that even healthy, normally hydrated subjects have variation in there proportion of ECF to ICF.

Wrist-Ankle Measurements

Geometry and Fluid Distribution

A wrist-ankle measurement assumes the body is one perfect cylinder when if fact the body is comprised of five imperfect cylinders (arms, legs and trunk), with the arms an legs contributing 90% to the measurement. As discovered (De Lorenzo 1997), fluid volume tends to be evenly distributed in healthy subjects, thus, a wrist-ankle measurement can provide accurate and useful information (Jaffrin 1996). However, there are conditions and populations where assumed even fluid distribution is invalid. The relationship between a single side wrist-ankle measurement and total ECF and ICF volume is dominated by the arm (typically 250Ω) and leg (typically 200Ω), with the trunk contributing very little to the total impedance measurement (typically 20Ω). As such, any variable causing localized changes in the limbs or trunk can lead to an inaccurate prediction of ECF and ICF volume. Under such conditions, a limb measurement may be useful.

Changes In Vascular Perfusion

A reduction or increase in limb blood flow can be caused by any number of conditions. Results derived wrist-ankle on subjects where changes in vascular perfusion is suspected should be interpreted with caution (Kushner 1996)

Consumption of Food And Beverage

A wrist-ankle measurement is insensitive to fluid changes in the abdominal cavity (Kushner 1996). Several studies have shown that consumption of food and water is not detected immediately but following absorption is. It is also possible that fluid would also shift to the gastrointestinal tract post food consumption. Therefore, it is advised that measurements be performed while the subject is in a 6 hour fasted state.

Proximal Versus Distal Electrode Placement

Some investigations have reported that the prediction of body water is more accurate using a proximal electrode arrangement (elbow-knee) versus the traditional wrist-ankle approach (Scheltinga 1991; Hannan 1996). However, others have found little difference (Ho 1994).
The argument that a measurement using proximal electrodes would be more sensitive to changes in the trunk is invalid because only a measurement solely of the trunk would be insensitive to the extremities. The advantage of a proximal electrode arrangement may be that it is less sensitive to orthostatic fluid shifts. However, following 10-15 minutes, the effects of orthostatic fluid shifts are small. The disadvantage of proximal electrodes is that the landmarks are less accessible than a wrist and ankle and no study has yet reported repeatability for proximal electrode arrangement.

Scaling of ECF & ICF Resistivity

The ECF and ICF resistivity constants used in HYDRA ECF-ICF have been scaled to measurements made wrist-ankle (De Lorenzo 1997). As shown in **Appendix B**, resistivity can be scaled according to body geometry (De Lorenzo 1997), but at the present time, there are no resistivity constants available that have been scaled to dilution ECF and ICF volumes and impedance measured with proximal electrodes. Refer to the *Scaling to Reference Methods Section* for further details.

Segmental Measurements

Repeatability And Electrode Placement

The reproducibility of repeated measurements is dependent upon instrument accuracy and precision of the device as well as biological variation (Kushner 1996).   Wrist-ankle measurements taken repeatedly over several minutes have ranged from 1-2%, and daily or weekly 2-5%. Although one would expect some change even in the same day due to normal variation in hydration, the most direct reduction in repeatability is electrode placement. If a 1cm difference in electrode placement causes a 1% variation in predicted volume measured wrist-ankle with a 200cm length, a 1cm difference for a segment 20cm long would be a 10% error. The major error caused by electrode placement has not been fully considered for segmental measurements (Matthie 1995A).   Electrodes need to be placed in the exact previous location around the "entire" segment if band electrodes are used (**Figure 6**). Actually marking the site around the entire segment using a measured distance from a landmark is advised.

Current Distribution

Over a longer distance, the current can fully distribute throughout the conductive tissue. For segment measurements, band electrodes are normally used because they ensure complete current distribution.   Although more research is required, preliminary internal research suggests that spot electrodes might provide the same information as band electrodes if consistently placed on a conductive portion of the segment (**Figure 7**). This is worthy of further investigation because spot electrodes are less expensive and their use might improve repeatability.   Consistently placing a long electrode exactly in the same place around an entire segment will not be easily performed.

Accounting For Mixture Effects

Mixture effects have not generally been considered by those conducting segmental research (Kouw 1992; Kushner 1996). To accurately account for the mixture effects, the total volume of the body or segment must be known (Matthie 1995; De Lorenzo 1997). For the wrist-ankle method, total body volume is provided by weight/body density. To account for the mixture effects on a segment requires knowing the total segment volume.   To estimate segment water volume, HYDRA requires input of total segment volume, which is derived from two segment circumferences and length between the voltage-detector electrodes. The segment is considered to be cone in shape. Therefore, a limb segment that most approximates a cone in shape should be measured. It is estimated that a 10% error in estimating segment geometry is a 6% error in estimating volume.

Problems Measuring The Trunk

Investigators advocating a segmental approach have not considered the problems a trunk measurement introduces (Matthie 1995). The trunk is much more heterogeneous than is a limb, having many different tissues with different characteristic frequencies and resistivities. There is evidence that low frequency current cannot pass the peritoneal cavity, this, it may never be possible to associate fluid accumulated in the trunk to ECF space. Secondly, it is uncertain how to best input the current so as to create an even distribution of current flow. Some have suggested a band electrode around the neck and abdomen but this is not a measure of the trunk but rather of the space between the electrodes. Other methods suggested may have promise (Organ 1995) but with these methods it is impossible to associate the measured tissue with a measured length, which is required to compute volume. Accounting for the

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mixture effects in a trunk measurement may also prove to be extremely difficult because accurately measuring the total trunk volume from circumference and length measurements would be difficult and tedious. Additionally, the sum of the segments has not improved the prediction of total water volume over the wrist-ankle prediction. If both the arm and leg are measured with 1% accuracy but the trunk with 10%, the overall prediction will be dramatically reduced since the trunk accounts for 1/3 of the prediction. Although a trunk measurement can be performed, its accuracy will be less than for a limb.

Segment Volume Relationship

Segmental measurements may prove to be adequate for estimating total body hydration and nutritional status. However, segmental measurements, as do wrist-ankle measurements, assume a relationship between the measured segment and the total body. This may not always be valid.

General Considerations

Scaling To Reference Methods

The standard 70 kg man is 15% body fat and 60% water, with roughly 60% being ICF and 40% being ECF. As shown in Appendix B, the volume equation uses two scaling constants (k_{ECW} and k_ρ), which can also be expressed as resistivity ECF (ρ_{ECF}) and resistivity ICF (ρ_{ICF}), respectively. As described in Appendix B under "Computing the Constants", the constants were derived by regressing the Cole model terms R_E and R_I against a Bromide ECF, and Deuterium TBW minus the Bromide ECF (Van Loan 1993; De Lorenzo 1997). Both different dilution methods as well as different protocols will produce different size volume spaces (Forbes 1987). Fortunately, ρ_{ECF} and ρ_{ICF} are scalars thus, have no affect on the scientific relationship (i. e., correlation and SEE) between the impedance predicted and dilution measured volumes (De Lorenzo 1996). However, it is of practical concern that the size of predicted space match the expected physiological volumes. HYDRA ECF-ICF has been programmed with validated resistivity constants that appear to give the most physically plausible sized ECF and ICF spaces (De Lorenzo 1997). To compute new resistivity constants from dilution ECF and TBW data, the user should contact Xitron Technologies for information. Because the provided constants are scalars, it would have validity to manually adjust them until the predicted ECF and TBW volumes match the desired size space but changing resistivity should "not" be done arbitrarily. Refer *to Front Panel Controls, Menu Key, Set "Maintenance" Mode, Set Resistivity* for default values used.

- Note -

So as to maintain the integrity of the measurement, Xitron allows the user to use selected resistivity constants but they should not be arbitrarily changed. When changed, a warning that they have been changed will always appear on the display for several seconds before a measurement can be performed. Additionally, at any time the user can retrieve the original resistivity constants by selecting the default values. Refer to the *Changing Setup Parameters Section* for details.

Absolute Versus Change In Volume

Although the efficacy of any new method requires its validation to a known and accepted standards, the user is reminded that a dilution ECF measurement under ideal conditions is considered to have a methodological error 4.2% (Lukaski 1987), which is 0.7L for a standard man with 17 liters of ECF. The methodological error under ideal conditions for the various dilution methods of measuring TBW is 2.5%, which is roughly 1L for a standard man having 42 L of TBW (Lukaski 1987). The errors in the dilution method become larger under non-

ideal conditions. There is evidence that HYDRA is sensitive to very small changes in ECF and ICF, thus, the method may be most useful for measurement change (Ho 1994; Jabara 1995; Jaffrin 1996; Plank 1996). Although any scaling offset remains the same percentage error for change, the measurement of changes is normally 10 to 1 better than that of absolute volume.

Predicting Fat-Free Mass

For the average healthy adult, the percentage of Fat-Free Mass (FFM) that is TBW is 73.2%. To predict FFM by impedance one must assume the FFM to be 73.2% TBW. Although under most conditions, the mean TBW-FFM percentage will be 73.2%, there can be considerable variation, even among young healthy subjects. It also varies with age and health. Although the HYDRA technology has been used repeatedly to accurately predict FFM (Van Loan 1993; Van Loan 1996), the prediction of FFM with impedance is second order and subject to extreme error. An increase in ECF volume would result in a larger predicted FFM and higher %Fat estimation. Although FFM can be accurately predicted by impedance, it is second order and not strongly advised. Recent research suggests that when the HYDRA ECF-ICF measurement of TBW is combined with densitometry (underwater weighing), the prediction of FFM and %Fat is greatly improved.

Although second order, FFM and %Fat, can be calculated by the equation shown in **Appendix B**.

Measurement Protocol

ECF-ICF Ratio Measurements

1. Read the *Safety and Accuracy Considerations Sections* before performing a measurement.

2. Ensure the subject has not recently eaten a large meal.

3. As shown in **Figure 4**, position the subject in a supine position with the arms comfortably abducted from the body 15 degrees, and the legs comfortably separated. Ensure the subject has been in a supine position for 4 minutes. Measure between minutes 4-6.

4. Although an ECF-ICF ratio measurement is electrode placement independent, for the measurement to be representative of previous ratio measurement, the user should measure the same portion of the body consistently. As such, if a wrist-ankle ECF-ICF ratio is desired, the user is referred to the electrode placement protocol described in the *Wrist-Ankle Measurements Section*. For limb or segment measurements, the reviewer is referred to the protocol described in the *Segmental Measurements Section*.

5. Ensure that the device cables are not touching the ground, subject, metal objects or routed near high voltage equipment (e.g. computer monitor), and that the cables are not intertwined.

6. Connect the black current-injection (I) lead alligator clips to the electrodes placed distal to the red voltage-detector (V) lead alligator clips.

7. *Press Start as discussed in the Performing a Measurement Section.*

Whole Body Wrist-Ankle Measurements

1. Read the *Safety and Accuracy Considerations Sections* before performing a measurement.

2. Ensure the subject has not recently eaten a large meal.

3. Measure subject height and weight accurate to 0.1 cm/kg or inch/lb.

4. As shown in **Figure 4**, position the subject in a supine position with the arms comfortably abducted from the body 15 degrees, and the legs comfortably separated. Ensure the subject has been in a supine position for 4 minutes. Measure between minutes 4-6.

5. Using new high quality surface conductive gum based electrodes with at least 5 cm^2 in total surface area, place two current- injection (I) electrodes at the right hand and foot on the dorsal surfaces proximal to the metacarpal-phalangeal and metatarsal-phalangeal joints, respectively (**Figure 5**). Place the center of two voltage-detector electrodes (V) on the mid-line between the prominent ends of the right radius and ulna of the wrist, and mid-line between the medial and lateral malleoli of the right ankle. Ensure that the black current-injection and red voltage-detector electrodes are at least 5 cm. apart, respectively.

6. Ensure that the device cables are not touching the ground, subject, metal objects or routed near high voltage equipment (e.g. computer monitor), and that the cables are not intertwined.

7. Connect the black current-injection (I) lead alligator clips to the electrodes placed on the right hand and foot. Connect the red voltage-detector (V) lead alligator clips to the electrodes placed on the right wrist and ankle.

8. Input case number, subject height, weight and gender, and press Start as discussed in *Performing a Measurement Section.*
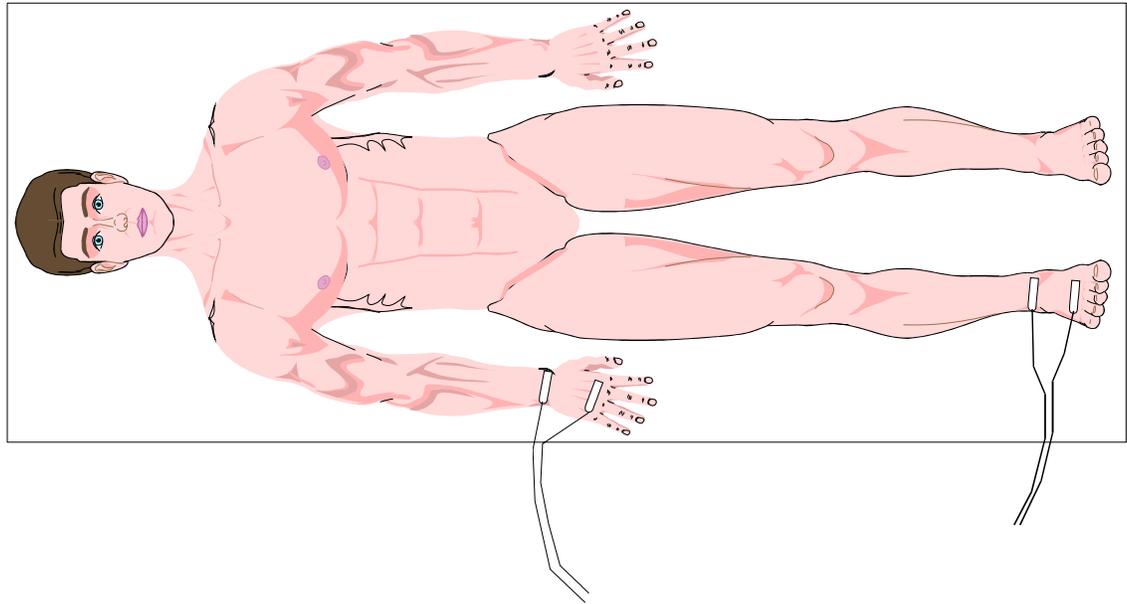

FIGURE 4
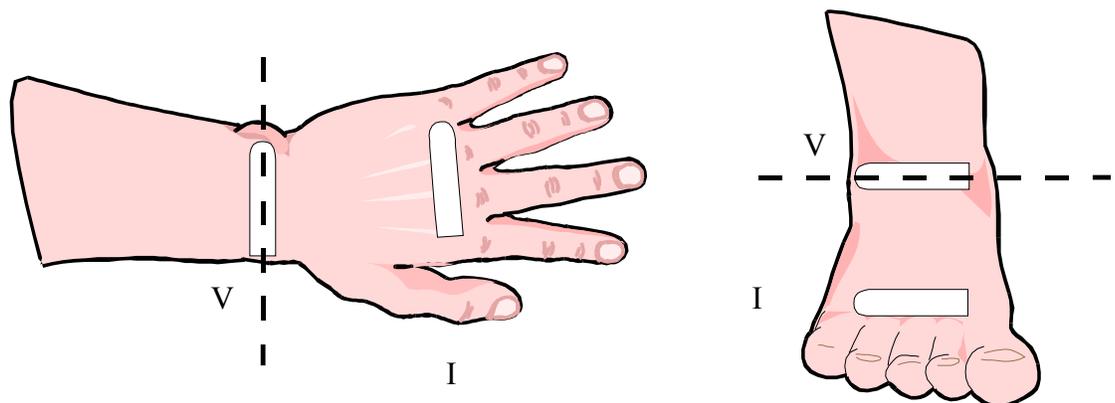
FIGURE 5

Segmental Measurements

Band Electrodes

1. Read the *Safety and Accuracy Considerations Sections* before performing a measurement.

2. Ensure the subject has not recently eaten a large meal.

3. As shown in **Figure 4**, position the subject in a supine position with the arms comfortably abducted from the body 15 degrees, and the legs comfortably separated. Before measuring, ensure the subject has been in a supine position for 4 minutes. Measure between minutes 4-6.

4. Select a body segment that is as close in shape to a cone as possible. Measure the circumferences at the site of red voltage-detector electrodes accurate to 0.1cm/inch. Measure the distance-length between the center of the red voltage-detector electrodes accurate to 0.1cm/inch.

5. Using fresh high quality gum based band electrode with at least 5cm^2 in total surface area (Equip, Maasslluis, The Netherlands, phone: 311-059-31399; Electro-Diagnostic Instruments, Burbank, California, USA, phone: 213 849-7701) place the center of two voltage-detector electrodes (V) on the "exact" location where circumferences have been measured (**Figure 6**). Additionally, place two current-injection (I) band electrodes at least 5cm distal to the voltage-detector (V) electrodes.

6. Ensure that the device cables are not touching the ground, subject or metal objects, or the cables or device are not next to high voltage equipment (e.g. computer monitor). Ensure that the cables are not intertwined.

7. Connect the black current-injection (I) lead alligator clips to the electrodes placed distally to the measured circumferences. Connect the red voltage-detector (V) lead alligator clips to the electrodes placed on the measured circumference locations.

8. Input Case Number, Circumference 1, Circumference 2 and Segment Length as discussed in *Performing a Measurement Section.*
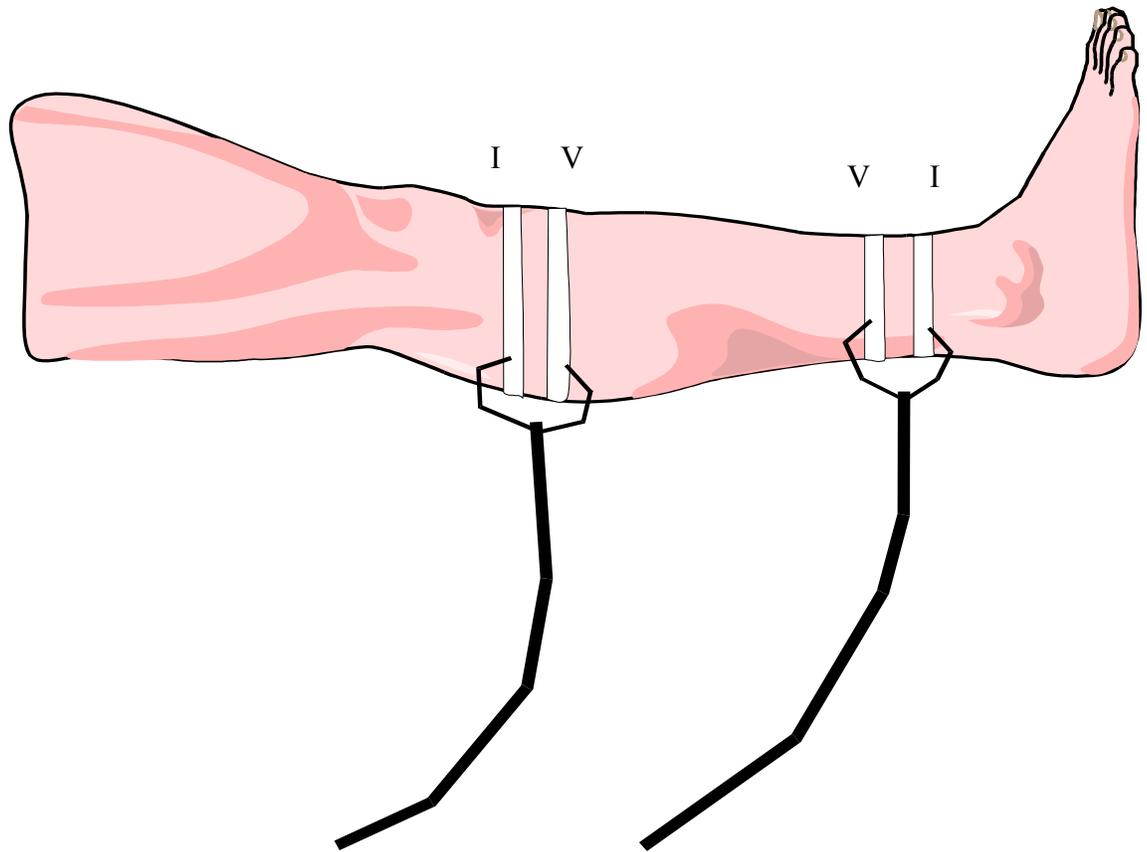
FIGURE 6

Spot Electrodes

1. Read the *Safety and Accuracy Considerations Sections* before performing a measurement.

2. As shown in **Figure 4**, position the subject in a supine position with the arms comfortably abducted from the body 30 degrees, and the legs comfortably separated. Before measuring, ensure the subject has been in a supine position for 10-15 minutes.

3. Select a body segment that is as close in shape to a cone as possible. Accurately measure the circumferences at the site of red voltage-detector electrodes to 0.1cm. Accurately measure the distance-length between the center of the red voltage-detector electrodes to 0.1cm.

4. Using fresh high quality gum based spot electrodes with at least 5cm^2 in total surface area, place the center of two voltage-detector electrodes (V) on the "exact" location where circumferences have been measured, and on a muscular area of the limb (**Figure 7**). Additionally, place two current-injection (I) band electrodes at least 5cm distal to the voltage-detector (V) electrodes.

5. Ensure that the device cables are not touching the ground, subject or metal objects, or the cables or device are not next to high voltage equipment (e.g. computer monitor). Ensure that the cables are not intertwined.

6. Connect the black current-injection (I) lead alligator clips to the electrodes placed distally to the measured circumferences. Connect the red voltage-detector (V) lead alligator clips to the electrodes centered on the measured circumference locations.

7. Input Case Number, Circumference 1, Circumference 2 and Segment Length as discussed in *Performing a Measurement Section.*
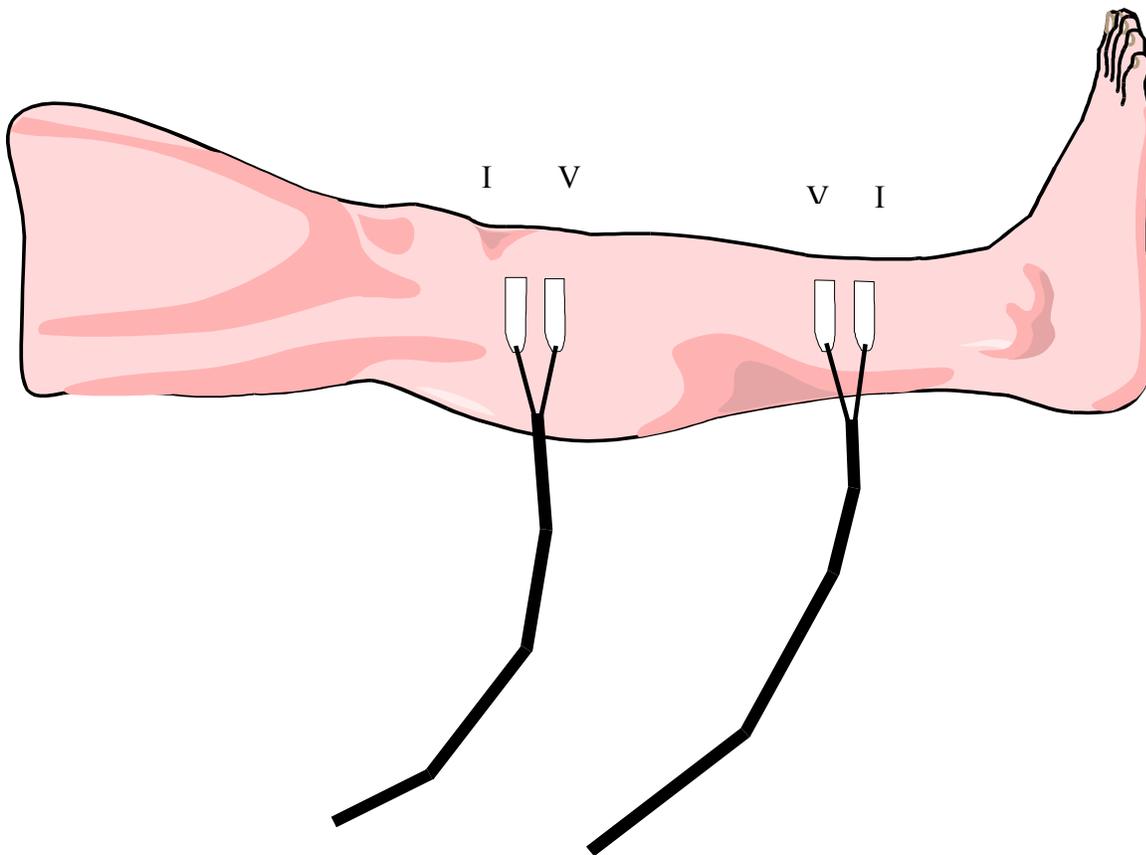
FIGURE 7

Performing A Measurement

Before attempting to perform a measurement the user should read the *Safety Considerations*, *Rationale for Measurement Options, Measurement Protocol, and Accuracy Considerations Sections*.   The user should also verify the device performance as instructed in the *Product Maintenance, Product Performance Verification Section*.

- Note -
As discussed in the *HYDRA ECF-ICF Features Section*, the data processing time needed to compute a single ECF or ECF-ICF measurement is approximately 10 seconds and 1 minute, respectively. However, these time are based on quality measurement data. Refer to the *Accuracy Considerations Section* for details.

When the Rear Panel "Mode" Switch is in the "UP" position, the display will request user input of the following measurement selections:

ECF-ICF Ratio Measurements

Single ECF-ICF Ratio

1. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

2. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

3. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF-ICF Ratio option and press ENTER.

4. The display will then ask the user to select the MODE of measuring ECF-ICF ratio. Use the ARROW Keys to find SINGLE MEAS. and press ENTER.

5. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

6. The display will then ask the user to press START to begin the measurement. If quality data has been measured, the measurement, modeling and computation of the ECF-ICF ratio will take approximately 1 minute. To terminate the measurement, press STOP and the display will return to the main menu.

7. Once the ECF-ICF ratio has been displayed, the user can print-out the results by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

```
        E:I Ratio:
          9.99
```

E:I = ECF-ICF ratio

Continuous ECF-ICF Ratio

1. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

2. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

3. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF-ICF Ratio option and press ENTER.

4. The display will then ask the user to select the MODE of measuring ECF-ICF ratio. Use the ARROW Keys to find CONTINUOUS MEAS. and press ENTER.

5. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

6. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. If quality data has been measured, the initial measurement, modeling and computation of ECF-ICF ratio will take approximately 1 minute. Following measurements will take approximately 10 seconds. To terminate the measurement, press STOP. The display will return to the main menu.

7. Once an ECF-ICF ratio has been displayed, the user can print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

```
        E:I Ratio:
          9.99
```

E:I = ECF-ICF ratio

Whole Body Wrist-Ankle Measurements

Single Whole Body Wrist-Ankle ECF-ICF

1. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

2. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

3. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF-ICF and press ENTER.

4. The display will then ask the user to select the METHOD of measuring ECF-ICF. Use the ARROW Keys to find WB (whole body) WRIST-ANKL and press ENTER.

5. The display will then ask the user to select the MODE of measuring ECF-ICF. Use the ARROW Keys to find SINGLE MEAS. and press ENTER.

6. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

7. The display will then ask the user to select the HEIGHT of the subject. Use the ARROW Keys to find the correct HEIGHT and press ENTER.

8. The display will then ask the user to select the WEIGHT of the subject. Use the ARROW Keys to find the correct WEIGHT and press ENTER.

9. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. If quality data has been measured, the measurement, modeling and computation of whole body ECF-ICF volume will take approximately 1 minute seconds. To terminate the measurement, press STOP. The display will return to the main menu.

10. Once whole body ECF-ICF volumes are displayed, the user can print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

```
   E: 99.99  I: 99.99L
  T:99.99  L: 99.99Kg
```

E = ECF in liters, I = ICF in liters, T = TBW in liters, L = lean or FFM in Kilograms

Although second order and prone to error, FFM and %Fat can be calculated by the equation shown in **Appendix B**.

Single Whole Body Wrist-Ankle ECF

1. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

2. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

3. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF and press ENTER.

4. The display will then ask the user to select the METHOD of measuring ECF. Use the ARROW Keys to find WB (whole body) WRIST-ANKL and press ENTER.

5. The display will then ask the user to select the MODE of measuring ECF. Use the ARROW Keys to find SINGLE MEAS. and press ENTER.

6. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

7. The display will then ask the user to select the HEIGHT of the subject. Use the ARROW Keys to find the correct HEIGHT and press ENTER.

8. The display will then ask the user to select the WEIGHT of the subject. Use the ARROW Keys to find the correct WEIGHT and press ENTER.

9. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. If quality data has been measured the measurement, modeling and computation of whole body ECF volume will take approximately 15 seconds. To terminate the measurement, press STOP. The display will return to the main menu.

10. Once whole body ECF volume has been displayed, the user can print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

```
E: 99.99 L
```

E = ECF in liters

Continuous Whole Body Wrist-Ankle ECF-ICF

1. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

2. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

3. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF and ICF and press ENTER.

4. The display will then ask the user to select the METHOD of measuring ECF- ICF. Use the ARROW Keys to find WB WRIST-ANKL and press ENTER.

5. The display will then ask the user to select the MODE of measuring ECF-ICF. Use the ARROW Keys to find CONTINUOUS MEAS. and press ENTER.

6. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

7. The display will then ask the user to select the HEIGHT of the subject. Use the ARROW Keys to find the correct HEIGHT and press ENTER.

8. The display will then ask the user to select the WEIGHT of the subject. Use the ARROW Keys to find the correct WEIGHT and press ENTER.

The following is displayed only if ultrafiltration (UF) volume has been enabled:

9. If UF volume "is" enabled (See "*Changing Setup Parameters-Set UF, and Rationale For Measurement Options Sections*", the display will then ask the user to select the UF Rate in liters/hour. Use the ARROW Keys to select the desired UF Rate and press ENTER.

If UF volume has "not" been enabled, the display will go directly to the following:

10. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. If quality data has been measured, the initial measurement, modeling and computation of whole body ECF-ICF volume will take approximately 1 minute. Following measurements will take approximately 10 seconds. To terminate the measurement, press STOP. The display will return to the main menu.

11. Once whole body ECF-ICF volumes have been displayed, the user can at any time print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

With Ultrafiltration Volume

```
E: +9.99  I: +9.99L
E Rate: +9.99L/H
```

Without Ultrafiltration Volume

```
E Chg: +9.99 L
I Chg: +9.99 L
```

E = ECF change (Chg) in liters, I = ICF change in liters, E Rate = ECF rate of change in liters per hour.

- Note -

The Continuous Measurement Mode and Data Plotting Utility were primarily developed for the hemodialysis field. Weight is used along with body density as a measure of total body volume and expressed in cube root form - thus a 10% error in weight is a 3% error in volume. If 3 liters were to be removed by ultrafiltration, this would represent an approximate 4% change in weight for a 70kg person, and a 1.3% error (0.195 L) in volume for a person with 15 L ECF. The program automatically subtracts the weight lost according to the input ultrafiltration volume. The user is responsible for the accurate input of UF rate. None hemodialysis applications should make periodic single measurements, accounting for change in weight manually at each time point.

Continuous Whole Body Wrist-Ankle ECF

1. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

2. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

3. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF and press ENTER.

4. The display will then ask the user to select the METHOD of measuring ECF. Use the ARROW Keys to find WB WRIST-ANKL and press ENTER.

5. The display will then ask the user to select the MODE of measuring ECF. Use the ARROW Keys to find CONTINUOUS MEAS. and press ENTER.

6. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

7. The display will then ask the user to select the HEIGHT of the subject. Use the ARROW Keys to find the correct HEIGHT and press ENTER.

8. The display will then ask the user to select the WEIGHT of the subject. Use the ARROW Keys to find the correct WEIGHT and press ENTER.

The following is displayed only if ultrafiltration (UF) volume has been enabled:

9. If UF volume has been enabled (See "*Changing Setup Parameters-Set UF,   and Rationale For Measurement Options Sections*"), the display will then ask the user to select the UF Rate in liters/hour. Use the ARROW Keys to select the desired UF Rate and press ENTER.

If UF volume has not been enabled, the display will go directly to the following:

10. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. If quality data has been measured, the initial measurement, modeling and computation of whole body ECF volume will take approximately 15 seconds. Following measurements will take approximately 3 seconds. To terminate the measurement, press STOP. The display will return to the main menu.

11. Once whole body ECF volume has been displayed, the user can print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

With Ultrafiltration Volume

> E Chg: +9.99 L
> E Rate: +9.99 L/H

Without ultrafiltration Volume

> E Chg: +9.99 L

E = ECF change (Chg) in liters, E Rate = ECF rate of change in liters per hours.

- Note -

The Continuous Measurement Mode and Data Plotting Utility were primarily developed for the hemodialysis field. Weight is used along with body density as a measure of total body volume and expressed in cube root form - thus a 10% error in weight is a 3% error in volume. If 3 liters were to be removed by ultrafiltration, this would represent an approximate 4% change in weight for a 70kg person, and a 1.3% error (0.195 L) in volume for a person with 15 L ECF. The program automatically subtracts the weight lost according to the input ultrafiltration volume. The user is responsible for the accurate input of UF rate. None hemodialysis applications should make periodic single measurements, accounting for change in weight manually at each time point.

Segmental Measurements

Single Segment ECF-ICF

1. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

2. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

3. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECW and ICW and press ENTER.

4. The display will then ask the user to select the METHOD of measuring ECF-ICW. Use the ARROW Keys to find SEGMENT and press ENTER.

5. The display will then ask the user to select the MODE of measuring ECF-ICF. Use the ARROW Keys to find SINGLE MEAS. and press ENTER.

6. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

7. The display will then ask the user to input Segment Length ("SEG LEN"). Use the ARROW Keys to find the correct Segment Length and press ENTER.

8. The display will then ask the user to select the first Circumference ("CIRCUM 1") of the segment. Use the ARROW Keys to input the correct first circumference and press ENTER.

9. The display will then ask the user to select the second Circumference ("CIRCUM 2") of the segment. Use the ARROW Keys to input the correct second circumference and press ENTER.

10. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. If quality data has been measured, the measurement, modeling and computation of segment ECF-ICF volume will take approximately 1 minute. To terminate the measurement, press STOP. The display will return to the main menu.

11. Once segment ECF-ICF volumes have been displayed, the user can print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

```
E: 99.99 L
I: 99.99 L
```

E = ECF in liters, and I = ICF in liters

Single Segment ECF

1. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

2. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

3. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF and press ENTER.

4. The display will then ask the user to select the METHOD of measuring ECF. Use the ARROW Keys to find SEGMENT and press ENTER.

5. The display will then ask the user to select the MODE of measuring ECF. Use the ARROW Keys to find SINGLE MEAS. and press ENTER.

6. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

7. The display will then ask the user to input Segment Length ("SEG LEN"). Use the ARROW Keys to find the correct Segment Length and press ENTER.

8. The display will then ask the user to select the first Circumference ("CIRCUM 1") of the segment. Use the ARROW Keys to input the correct first circumference and press ENTER.

9. The display will then ask the user to select the second Circumference ("CIRCUM 2") of the segment. Use the ARROW Keys to input the correct second circumference and press ENTER.

10. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. If quality data has been measured, the measurement, modeling and computation of segment ECF volume will take approximately 15 seconds. To terminate the measurement, press STOP. The display will return to the main menu.

11. Once segment ECF volume has been displayed, the user can print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

```
E: 99.99 L
```

E = ECF in liters

Continuous Segment ECF-ICF

1. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

2. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

3. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF and ICF and press ENTER.

4. The display will then ask the user to select the METHOD of measuring ECF and ICF. Use the ARROW Keys to find SEGMENT and press ENTER.

5. The display will then ask the user to select the MODE of measuring ECF-ICF. Use the ARROW Keys to find CONTINUOUS MEAS. and press ENTER.

6. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

7. The display will then ask the user to input Segment Length ("SEG LEN"). Use the ARROW Keys to find the correct Segment Length and press ENTER.

8. The display will then ask the user to select the first Circumference ("CIRCUM 1") of the segment. Use the ARROW Keys to input the correct first circumference and press ENTER.

9. The display will then ask the user to select the second Circumference ("CIRCUM 2") of the segment. Use the ARROW Keys to input the correct second circumference and press ENTER.

10. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. If quality data has been measured, the initial measurement, modeling and computation of segment ECF-ICF volume will take approximately 1 minute. Following measurements will take approximately 10 seconds. To terminate the measurement, press STOP. The display will return to the main menu.

11. Once segment ECF volume has been displayed, the user can print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

```
┌─────────────────────────┐
│     E Chg: +9.99 L       │
│     I Chg: +9.99 L       │
│                          │
└─────────────────────────┘
```

E Chg = ECF change in liters, and I Chg = ICF change in liters

Continuous Segment ECF

1. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

2. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number desired and press ENTER. Case numbers of 1 to 99,999 are available.

3. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF and press ENTER.

4. The display will then ask the user to select the METHOD of measuring ECF. Use the ARROW Keys to find SEGMENT and press ENTER.

5. The display will then ask the user to select the MODE of measuring ECF. Use the ARROW Keys to find CONTINUOUS MEAS. and press ENTER.

6. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

7. The display will then ask the user to input Segment Length ("SEG LEN"). Use the ARROW Keys to find the correct Segment Length and press ENTER.

8. The display will then ask the user to select the first Circumference ("CIRCUM 1") of the segment. Use the ARROW Keys to input the correct first circumference and press ENTER.

9. The display will then ask the user to select the second Circumference ("CIRCUM 2") of the segment. Use the ARROW Keys to input the correct second circumference and press ENTER.

10. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. If quality data has been measured, the initial measurement, modeling and computation of segment ECF volume will take approximately 15 seconds. Following measurements will take approximately 3 seconds. To terminate the measurement, press STOP. The display will return to the main menu.

11. Once segment ECF volume has been displayed, the user can print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

```
    E Chg: +9.99 L


```

E Chg = ECF change in liters.

Single Segment-Whole Body ECF-ICF

This function is NOT PROVIDED. Refer for Rationale For Measurement Options Chapter for explanation.

Result Display:

```
        NOT PROVIDED
```

Single Segment-Whole Body ECF

This function is NOT PROVIDED. Refer for *Rationale For Measurement Options Chapter* for explanation.

Result Display:

```
        NOT PROVIDED
```

Continuous Segment-Whole Body ECF-ICF

1. Measure the WB Wrist-Ankle ECF and ICF according to the protocol above.

2. The display will show the Date and Time. Press the MENU or ENTER Keys to proceed to data entry.

3. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

4. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF-ICF and press ENTER.

5. The display will then ask the user to select the METHOD of measuring ECF-ICF. Use the ARROW Keys to find WB SEGMENT and press ENTER.

6. The display will then ask the user to select the MODE of measuring ECF-ICF. Use the ARROW Keys to find CONTINUOUS MEAS. and press ENTER.

7. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

8. The display will then ask the user to input Segment Length ("SEG LEN"). Use the ARROW Keys to find the correct Segment Length and press ENTER.

9. The display will then ask the user to select the first Circumference ("CIRCUM 1") of the segment. Use the ARROW Keys to input the correct first circumference and press ENTER.

10. The display will then ask the user to select the second Circumference ("CIRCUM 2") of the segment. Use the ARROW Keys to input the correct second circumference and press ENTER.

11. The display will then ask the user to input the whole body (WB) ECF-ICF in liters measured by wrist to ankle. Use the ARROW Keys to input the WB ECF and ICF and press ENTER. The last measurement of WB Wrist-Ankle ECF and ICF will be displayed. If this is the measurement performed on the present subject, simply press Enter or input an ECF and ICF in liters using the Arrow Keys.

The following is displayed only if ultrafiltration (UF) volume has been enabled:

12. If UF volume has been enabled (See "*Changing Setup Parameters-Set UF, and Rationale For Measurement Options Sections*"), the display will ask the user to select the UF Rate in liters/hour. Use the ARROW Keys to select the desired UF Rate and press ENTER.

If UF volume has "not" been enabled, the display will go directly to the following:

13. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. The measurement, modeling and computation of whole body ECF volume will take approximately 1 minute. Following measurements will take

approximately 10 seconds. To terminate the measurement, press STOP. The display will return to the main menu.

14. Once whole body ECF volume has been displayed, the user can print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

With Ultrafiltration Volume

E: +9.99 I: +9.99L
E Rate: +9.99 L/H

Without Ultrafiltration Volume

E: +9.99 I: +9.99 L

E = ECF change (Chg) in liters, E Rate = ECF rate of change in liters per hour.

- Note -
The Continuous Measurement Mode and Data Plotting Utility were primarily developed for the hemodialysis field. Weight is used along with body density as a measure of total body volume and expressed in cube root form - thus a 10% error in weight is a 3% error in volume. If 3 liters were to be removed by ultrafiltration, this would represent an approximate 4% change in weight for a 70kg person, and a 1.3% error (0.195 L) in volume for a person with 15 L ECF. The program automatically subtracts the weight lost according to the input ultrafiltration volume. The user is responsible for the accurate input of UF rate. None hemodialysis applications should make periodic single measurements, accounting for change in weight manually at each time point.

Continuous Segment-Whole Body ECF

1. Measure the WB Wrist-Ankle ECF according to the protocol above.

2. The display will show the Date and Time. Press the MENU or ENTER Key to proceed to data entry.

3. The display will request the user to select the CASE NUMBER for the subject to be measured. Use the ARROW Keys to select a case number and press ENTER. Case numbers of 1 to 99,999 are available.

4. The display will request the user to select the OBJECT to be measured. Use the ARROW Keys to find ECF and press ENTER.

5. The display will then ask the user to select the METHOD of measuring ECF. Use the ARROW Keys to find WB SEGMENT and press ENTER.

6. The display will then ask the user to select the MODE of measuring ECF. Use the ARROW Keys to find CONTINUOUS MEAS. and press ENTER.

7. The display will then ask the user to select the GENDER of the subject. Use the ARROW Keys to find the correct Gender and press ENTER.

8. The display will then ask the user to input Segment Length ("SEG LEN"). Use the ARROW Keys to find the correct Segment Length and press ENTER.

9. The display will then ask the user to select the first Circumference ("CIRCUM 1") of the segment. Use the ARROW Keys to input the correct first circumference and press ENTER.

10. The display will then ask the user to select the second Circumference ("CIRCUM 2") of the segment. Use the ARROW Keys to input the correct second circumference and press ENTER.

11. The display will then ask the user to input the whole body ECF in liters measured wrist to ankle. Use the ARROW Keys to input the correct total ECF and press ENTER. If this is the measurement performed on the present subject, simply press Enter or input an ECF in liters using the arrow keys.

The following is displayed only if UF volume has been enabled:

12. If UF volume has been enabled (See "*Changing Setup Parameters-Set UF, and Rationale For Measurement Options Sections*",), the display will ask the user to select the UF Rate in liters/hour. Use the ARROW Keys to select the desired UF Rate and press ENTER.

If UF volume has "not" been enabled, the display will go directly to the following:

13. The display will then ask the user to press START to begin the measurement or MENU to return to data entry selections. The measurement, modeling and computation of modeling will take approximately 15 seconds. Following measurements will take approximately 3 seconds. To terminate the measurement, press STOP. The display will return to the main menu.

14. Once whole body ECF volume has been displayed, the user can print-out the result by pressing the PRINT Key or return to the main menu by pressing the MENU key. Refer to the *Front Panel Controls, Print Key Section* for details on printing.

Result Display:

With Ultrafiltration Volume

```
E Chg:  +9.99 L
E Rate: +9.99 L/H
```

Without Ultrafiltration Volume

```
E Chg: +9.99 L
```

E Chg = ECF change in liters, E Rate = ECF rate of change in liters per hour.

- Note -

The Continuous Measurement Mode and Data Plotting Utility were primarily developed for the hemodialysis field. Weight is used along with body density as a measure of total body volume and expressed in cube root form - thus a 10% error in weight is a 3% error in volume. If 3 liters were to be removed by ultrafiltration, this would represent an approximate 4% change in weight for a 70kg person, and a 1.3% error (0.195 L) in volume for a person with 15 L ECF. The program automatically subtracts the weight lost according to the input ultrafiltration volume. The user is responsible for the accurate input of UF rate. None hemodialysis applications should make periodic single measurements, accounting for change in weight manually at each time point.

Stopping Or Terminating A Measurement

Single Measurements

To terminate a "single" measurement and start over, press the Start/Stop key and the device will "Abort" the measurement and return to the data entry mode.

Continuous Measurements

If the Start/Stop key is pressed during a "continuous" measurement, the device will ask the user if they wish to Print "Yes" or "No?" Using the Arrow Keys select "Yes" to print and return to the Data Entry menu or "No" to directly return to the Data Entry menu. If the Start/Stop key is pressed again without changing any subject input data, the device will ask the user "Start Over." Select 'Yes" to start a new measurement from the beginning or "No" to continue with same data set. By changing any input data (case no., height, etc.), the device will assume a new subject is being made and the previous data will be erased.

With Ultrafiltration Option Enabled

When the UF option has been selected and the Start/Stop Key has been pressed during continuous measurements, the device will immediately display Print? "Yes" or "No". Using the Arrow keys select "Yes" to print and return to the Data Entry menu or "No" to directly return to the Data Entry menu. Unlike above, the device will display the UF Rate in L/Hr. If the UF Rate has changed, adjust the UF Rate L/Hr and press the Start/Stop key. The device will ask the user "Start Over." Select 'Yes" to start a new measurement from the beginning or "No" to continue with the same data set. Pressing "Yes" will erase all previous data. Press Menu to modify other variables. By changing any other input data (case no., height, etc.), the device will assume a new subject is being made and the previous data will be erased. This feature allows the user to quickly adjust UF rate and continue the measurement.

Chapter 5. Product Maintenance

Calibration

The HYDRA ECF-ICF has been fully calibrated by Xitron Technologies and by design requires no user calibration. The accuracy specifications presented assume that the device is being used in an environmental temperature within the range specified.

Internal Circuitry Self-Check

When the device is turned on, the device performs an internal circuitry self-check and will inform the user if the device has become out of calibration or has a fault. Contact Xitron if such a message is observed.

Device Performance Verification

Equivalent Electronic Circuit Testing

To easily test the device performance and functionality, the user is advised to measure, model and compute volume on the provided electronic Verification Module (option TS4201) at minimum intervals of once every two weeks. The test may of course be performed daily or at any time.

- Note -
This test result is based on the default ECF and ICF resistivity coefficients. If any other coefficients are used, the volume results will vary from the tolerance specifications shown below. However, performance tolerance is based on the result being within ± 1%. Based on this ± 1% criteria, the expected result tolerance can be established by the user if different resistivity coefficients were to be used. Deviations from this 1% criteria can occur when non ideal conditions are used. The default resistivity values can be set as discussed in the *Changing Setup Parameters Section*. Actual default resistivity values are given in the *Front Panel Controls Section*.

---

1. Ensure the "default" resistivity coefficients are being used or have been set. Refer to *Changing Setup Parameters* for details.

2. As shown below, extend cables from the device suspended or on a nonconductive surface. Connect each pair of the black current (AI & BI) and red voltage (AV & BV) alligator clips to the TS4201 as shown below.

3. Enter a case number that will not be confused with other results. This is particularly true for devices equipped with MEM4200 Data Storage Option.

4. Select ECF and ICF as Object to be measured.

5. Select WB by WRIST-ANKL as Mode of measurement

6. Select SINGLE MEAS. as Method of measurement.

7. Enter Male for Gender

8. Enter 175 cm or 68.9 inches for Height

9. Enter 70 kg or 154 lb. for Weight

10. Press START to begin measurement
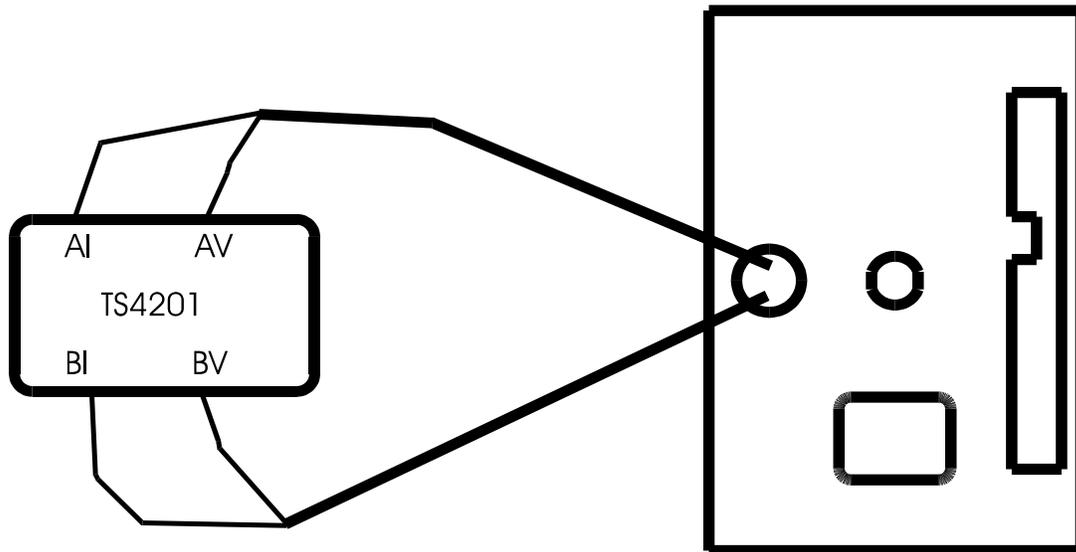
Final Result

The measured ECF should be between:

15.81 and **16.18** liters

The measured ICF should be between:

29.39 and **30.74** liters

TS4201 Construction

The TS4201 test circuit is designed with reliable components that simulate the typical values obtained *in vivo*. A series and parallel circuit orientation is used consisting of a 1% 681Ω metal film resistor in parallel with a series 1% metal film 909Ω resistor and 5% 3.3nF

capacitor. Capacitance is introduced by a 5% low dielectric absorption capacitor, axial leaded and of round construction, and made from either pollystyrene, polypropylene or teflon[tm]. To simulate contact resistance, high quality 1% 50Ω metal film resistors and 5% 100nF capacitors were placed in series with the voltage and current connection terminals. For circuit diagrams and descriptions of the equivalent electronic test circuit will be available on request by appropriately qualified personnel.

Equivalent Electronic Circuit Component Value Testing

Although the above test is easier, and tests the entire functionality of the device, users may wish to compute the component values in the TS4201 circuit. As above, the circuit consists of a 1% 681Ω resistor in parallel with a series 1% 909Ω resistor and 5% 3.3 nF capacitor. Using the *Hydra Data Acquisition Utility* measure a ECF-ICF, 5KHz to 1MHz spectrum on the TS4201 circuit as shown above and save as .DAT File. Using the Data Model-Vol.exe program, model this spectrum. The values for R_E, R_I and C_M should be within 1%, 2% and 5%, respectively.

Single Electronic Component Testing

The device was not designed to be a electronic component tester. Due to the presence of the contact resistance introduced by the skin, testing components is more complex than simply measuring components outright.

Cleaning & Inspection

Device Cleaning

Should the external surfaces of the chassis become dirty, they may be cleaned using a mild detergent and soft damp cloth. The front panel should "NOT" be cleaned with a Freon based cleaning solution, nor should excessive moisture be allowed to enter the chassis during cleaning. If the external surfaces become excessively dirty or damaged, the user is requested to contact Xitron Technologies (or one of its agents) for details as to how to rectify this situation.

Subject Leads

It is highly recommended that the subject cables and connectors be physically inspected periodically for cracks or splits in the external insulation, or for "kinks" that have become set into the cable. Cables should be replaced if any of these conditions exists. The user should also ensure that the rear panel connector "pins" are straight and connecting properly. The user should also ensure that the spring in the alligator clips that attach to the surface electrodes is functioning properly and that they close tightly on the electrodes. Periodically, the alligator clips should be cleaned and wiped free of electrode "gum" that may have collected over time. It is also advised to scrape the teeth of the alligator clips occasionally so as to removed any build up of tarnish or corrosion that inhibits conductivity.

Power Cord

The power cord and connectors should be physically inspected periodically for cracks or splits in the external insulation. The power cord should be replaced if any of these conditions exists. The user should also ensure that the rear panel connector "pins" are straight and connecting properly, and that the ends of the power cord are free of dirt and grime.

Electrodes

Obtaining accurate measurements with the HYDRA ECF-ICF requires the use of appropriate conductive electrodes. As described in the *Accuracy Considerations Section*, gum based versus gel based products with at least 5cm^2 surface area is recommended. The Xitron IS4000 Disposable Electrode, which has nearly double the surface area as conventional electrodes, has been made specifically for the device to ensure reduced contact resistance. For all electrodes, be sure to follow all manufacturers instructions and reseal the electrodes in an airtight foil bag or container. Do not reuse electrodes, or use electrodes that are out of date or that have been left out in the open air for an extended period. Store electrodes in a cool dry place.

Returning For Repair Or Maintenance

The HYDRA ECF-ICF warranty is found on page one. Prior to returning any equipment to Xitron Technologies or an authorized service center, for any reason, *"Authorization must be obtained prior to returning the device for repair."* When contacting Xitron Technologies, please provide the following information:

- The model number of the instrument (i.e., 4200, HYDRA ECF-ICF).
- The serial number of the instrument.
- The nature of the problem (include a written description of the problem with the returned instrument).

It should also be noted that attempted repair by unqualified personnel may void the warranty as determined by Xitron Technologies. Unless otherwise specified, returns should be made freight pre-paid, with the previously obtained authorization code clearly marked on the outer surface. The owner of the instrument, the name of a person to contact, the return address, phone and fax, and a description of the service required should be identified either on an external "tag," or on documentation within the packaging.

- Note -

If the instrument is to be shipped by commercial transportation for any reason, it should be repackaged in the original shipping carton, packing material and polyethylene wrap. If any of these materials are not available, or have been rendered unfit for use, then these should be replaced by equivalent materials. Disconnect, neatly pack, and return all cables and associated attachments with the instrument so that they may be reviewed at the time of repair. Failure to include all items may delay or render ineffective the repair process.

Chapter 6. Hydra Utilities Software

Introduction

The BIS4200 Utilities Software is provided so the user can collect data obtained with a Xitron Technologies HYDRA ECF/ICF Bio-Impedance Analyzer with a host computer. This documentation describes four different utilities. The *Hydra Data Acquisition Utility* is a Windows 95® program that allows for computer control of the instrument and management of data. The *Hydra Data Plotting Utility* is a Windows 95® program that allows continuously measured data to be plotted real time, as well as saved to a file. The *Hydra Data Modeling Utility* is a DOS based program that allows the user to model the raw frequency data externally if verification of the model fit is required. The *Hydra Memory Utility* is for those users who have purchased the MEM4200 Data Storage Memory Option. When you turn the device on, the third display shown will tell you if the device has been fitted with this option.

Minimum Hardware Requirements

- IBM or compatible PC^{TM} compatible with at least 386 processor (486 or Pentium preferred)
- Math co-processor (required)
- At least 8MB of RAM (16 MB preferred)
- Window 95® or Windows NT®
- A RS-232C serial communication port, and the Xitron interface cable provided.

Installing The Hydra BIS4200 Utilities

1. Open the Windows 95® program Explorer

2. Insert Disk 1 into your 3.5 floppy drive and click on the 3.5 floppy disk icon

3. Double click on Setup and a Hydra Utilities Installation window will appear. Click on Finish or change the name of the subdirectory you wish these programs to be saved and click Finish. An Installing Files window will appear indicating the program is loading.

4. A Setup window will appear asking the user to insert the next floppy disk into the 3.5 drive. As instructed, insert the next disk into the 3.5 drive and click OK. An Installing Files window will appear. Insert remaining sequentially numbered disks as instructed.

5. If installation has successfully been performed, a Utilities Installation window will appear indicating that installation was successful. Click on OK.

Hydra Data Acquisition Utility

Program Description and Use

This program is designed to allow the user to save the measured raw frequency, Cole modeling and volume data to a file for post analysis and electronic recording. This utility is very easy to use with self-explained menu items. The user is strongly advised to read the entire HYDRA manual before using this software.

Running The Program

The Hydra Data Acquisition Utility can be opened by either clicking on the icon created "Hydra Acquisition" or by opening the Window 95 Explorer® program and Hydra subdirectory, then double clicking on the icon for Hydra Acquisition.

Initial Screen - Communication Setup

Baud Rate

The baud rate can be set by clicking on the down-up arrows with the left mouse button until the desired baud rate is found. The baud rate can also be selected by simply clicking in the baud rate window using the left mouse button and then clicking the desired baud rate with the left mouse button. Be sure the HYDRA ECF/ICF device is set at the same baud rate.

COM Port Number

The COM port number can be set by clicking on the down-up arrows next to the COM port number window with the left mouse button until the desired COM port number is found. The COM port number can also be selected by simply clicking in the COM port number window using the left mouse button and then clicking the desired COM port number the left mouse button.
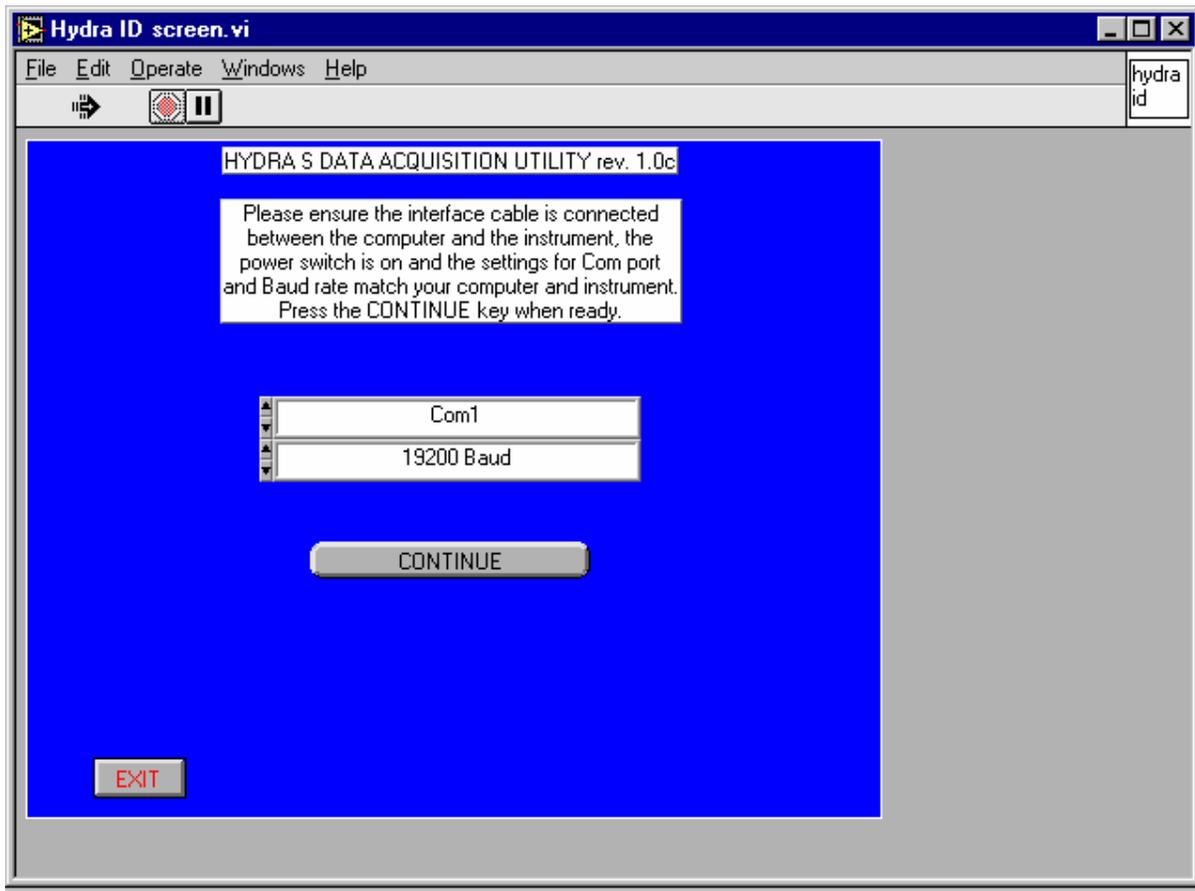
Main Screen

Once the program has been opened, the following Main Menu will appear.
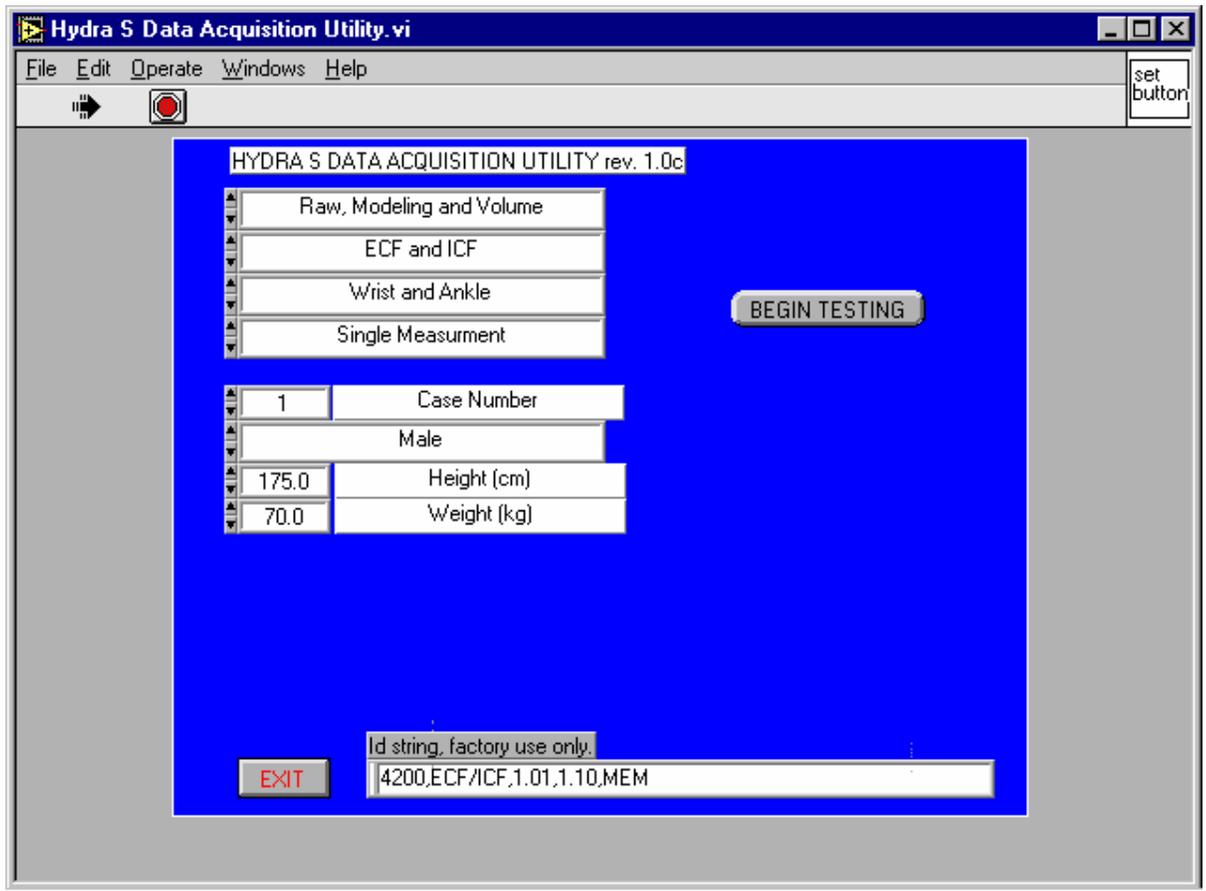
Data Collection Options

Similar to the format of the HYDRA device, the Data Acquisition Utility is arranged into similar selections. Depending upon the combination of choices selected, the program will show or not show certain data entry parameters.

Measurement Data Requested

Raw data only.	Provides measurement of raw frequency data only
Raw and Modeling data.	Provides both raw frequency and modeled data
Raw, Modeling and Volume.	Provides raw, modeling and volume data

Measurement Object Requested

ECF only:	Provides ECF using 5KHz-200KHz spectrum
ECF and ICF:	Provides ECF & ICF using 5KHz-1MHz spectrum

Measurement Method Requested

WB Wrist-Ankle	Provides a WB ECF or ECF and ICF measurement wrist-ankle
Segment	Provides ECF or ECF and ICF measurement of a segment
WB by Segment	Provides a WB ECF or ECF and ICF measurement by segment

Measurement Mode Requested

Continuous measurement:	Provides continuous measurement of selected parameters

Single measurement.   Provides single measurement of selected parameters

Measurement Mode Numbers

<u>Continuous Measurements</u>

ECF-ICF, WB Wrist-Ankle, Continuous:	8
ECF, WB Wrist-Ankle, Continuous:	3
ECF-ICF, Segment, Continuous:	11
ECF, Segment, Continuous:	6
ECF-ICF, WB-Segment, Continuous:	9
ECF, WB-Segment, Continuous:	4

<u>Single</u>

ECF, WB Wrist-Ankle, Single	2
ECF-ICF, WB Wrist-Ankle, Single	7
ECF, Segment, Single	5
ECF-ICF, Segment, Single	10

Performing a Measurement

The user is reminded to make careful notes as to what measurement protocol was used. The program has no means of knowing if the data were collected wrist-ankle, lower leg, etc. It is recommended that case number be associated with each subject and protocol used.

First put the Hydra in the Data Entry Mode (e.g., case number displayed). Then from the above selections, choose the desired data parameters to be measured and input the required data entry parameters. Single window parameters can be set by clicking on the down-up arrows shown next to the window with the left mouse button until the desired setting is found. The settings can also be selected by simply clicking in the window of interest using the left mouse button and then clicking the desired setting with the left mouse button. For parameters with two windows (case no., height and weight), the setting can be changed by either scrolling to the desired setting using the arrows next to the window or by highlighting the window and typing in the desired setting. Height, weight, segment length, circumference 1, and circumference 2 must be in metric form (e.g. cm and kg).

1. Once the parameters to be measured and data input are complete, click on the BEGIN TESTING button and a save file window will appear.

2. Type in the name of the file or click on the name of the file if it already exist and click SAVE.. The raw data should be saved with the extension .DAT. The extension .DAT ensures raw data can be discerned from other types of data collected. If a file with the same name already exists, the program will ask you to replace it with the new data or cancel the save operation. If only raw data is collected, HYDRA will begin measuring immediately.

3. If MODELING data has been requested, the program automatically assumes the same file name but with the extension .MOD. If you wish to save it under a different name, type in the name of the file you wish the modeling data to be saved to and click SAVE. The extension .MOD ensures modeling data can be discerned from other types of data

collected. If a file with the same name already exists, the program will ask you to replace it with the new data or cancel the save operation.

4. If VOLUME data has been requested, the program automatically assumes the same name as the raw data file but with the extension .VOL.   If you wish to save it under a different name, type in the name of the file you wish to save the volume data and click SAVE. The extension .VOL ensures the volume data can be discerned from other types of data collected. If a file with the same name already exists, the program will ask you to replace it with the new data or cancel the save operation.

Approximate Time Required To Collect Data

Raw ECF:	3 seconds
Raw ECF-ICF:	5 seconds
Raw ECF and modeling:	15 seconds
Raw ECF-ICF and modeling:	45 seconds
Raw ECF, modeling and volume:	15 seconds
Raw ECF-ICF, modeling and volume:	45 seconds

Note: The above periods for data acquisition which includes modeling are assuming quality measurement data. Difficulty in solving for the Cole Model can increase the time required. Continuously measured data will be updated in the Data Results Screen at approximately the speeds listed above.   The run number indicates how many spectrums have been measured and modeled continuously. Be aware that continuous data collection can fill up your hard disk quite fast.

Data Results Screen

Once the measurement has been requested from HYDRA, the program will display a Data Results Screen.   When the HYDRA device has completed performing its measurements and computation of the data, depending upon what was requested, the data will appear in one, two or all three windows.

- Note -
The Continuous Measurement Mode and Data Plotting Utility were primarily developed for the hemodialysis field. Weight is used along with body density as a measure of total body volume and expressed in cube root form - thus a 10% error in weight is a 3% error in volume. If 3 liters were to be removed by ultrafiltration, this would represent an approximate 4% change in weight for a 70kg person, and a 1.3% error (0.195 L) in volume for a person with 15 L ECF.   The program automatically subtracts the weight lost according to the input ultrafiltration volume. The user is responsible for the accurate input of UF rate. None hemodialysis applications should make periodic single measurements, accounting for change in weight manually at each time point.

```
┌─────────────────────────────────────────────────────────────────────────────┐
│ ▶ Aquire data.vi                                          _ □ ✕               │
│ File  Edit  Operate  Windows  Help                              ┌──────┐      │
│  ⇛        [ ❚❚ ]                                          ·.  ·  │aquire│      │
│                                                           ·  ·   │data  │      │
│ ┌──────────────────────────────────┬─┐ ┌─mod out─────────────────────────┐   │
│ │Case 1 3/26/97 3:54:56 PM Run 1   │▲│ │ ┌─────────────────────────────┐ │   │
│ │5 668.77 47.74 670.47 4.08        ├─┤ │ │Case 1 3/26/97 3:54:56 PM    │ │   │
│ │6 664.95 56.37 667.34 4.85        │ │ │ │Run # Re(Ohm) Ri(Ohm) Cm(nF) Td(nS) alpha Fc(KHz)│
│ │7 661.72 64.59 664.87 5.57        │ │ │ │R 1 677.98 903.32 3.31 -0.17 1.00 31.00│ │   │
│ │8 657.69 72.11 661.64 6.26        │ │ │ └─────────────────────────────┘ │   │
│ │9 653.36 79.65 658.19 6.95        │ │ └─────────────────────────────────┘   │
│ │10 648.62 86.51 654.36 7.60       │ │                                        │
│ │11 642.93 93.14 649.65 8.24       │ │ ┌─vol out─────────────────────────┐   │
│ │12 638.05 99.35 645.74 8.85       │ │ │ ┌─────────────────────────────┐ │   │
│ │13 632.21 104.95 640.86 9.43      │ │ │ │Case 1 3/26/97 3:54:56 PM    │ │   │
│ │14 626.15 110.20 635.78 9.98      │ │ │ │Run # ECF(liters) ICF(liters) FFM(Kg) mark│ │
│ │15 619.99 115.12 630.59 10.52     │ │ │ │R 1 15.43 29.04 60.41 0      │ │   │
│ │16 613.89 119.34 625.38 11.00     │ │ │ └─────────────────────────────┘ │   │
│ │18 601.69 126.88 614.92 11.91     │ │ └─────────────────────────────────┘   │
│ │20 589.37 132.93 604.17 12.71     │ │                                        │
│ │23 571.72 138.94 588.36 13.66     │ │    ┌─────────────────────────┐         │
│ │25 560.31 141.66 577.94 14.19     │ │    │                         │         │
│ │28 544.33 144.01 563.06 14.82     │ │    │                         │         │
│ │31 529.82 144.35 549.13 15.24     │ │    │        EXIT             │         │
│ │35 512.57 143.08 532.17 15.60     │ │    │                         │         │
│ │39 497.67 140.22 517.05 15.74     │ │    │                         │         │
│ │43 484.64 136.29 503.44 15.71     │ │    └─────────────────────────┘         │
│ │50 466.44 128.41 483.79 15.39     │ │                                        │
│ │54 457.91 123.81 474.35 15.13     │ │                                        │
│ │60 447.32 116.78 462.31 14.63     │ │                                        │
│ │67 437.60 109.13 451.00 14.00     │ │                                        │
│ │75 429.13 100.99 440.86 13.24     │ │                                        │
│ │83 422.52 93.71 432.79 12.51      │ │                                        │
│ │93 416.18 85.77 424.92 11.64      │ │                                        │
│ │100 412.71 80.85 420.56 11.08     │▼│                                        │
│ └──────────────────────────────────┴─┘                                        │
└─────────────────────────────────────────────────────────────────────────────┘
```

Raw Data Window

In large screen on the left the raw frequency data is shown. No headings are provided so the data can be modeled by the Hydra Data Modeling Utility. On the first line is case number, date, time and run number (number of spectrum measured). The headings for the data from left to right are as follows:

Frequency (KHz), Resistance (ohms), Reactance (ohms), Impedance (ohms), Phase (degrees)

Mod Out Window

In small top right screen, the modeling data will be shown. On the first line is case number, date and time. The headings for the data from left to right are as follows:

Run Number, Re (ohms), Ri (ohms), Cm (nF), Td (nS), alpha, Fc (KHz)

Vol Out Window

In small middle right screen, the volume data will be shown. On the first line is Case number, date and time. The headings for the data from left to right are as follows:

Run Number, ECF (liters), ICF (liters) FFM (Kg), Mark (1 or 0)

Note: Windows for unrequested data will contain zeros, or nothing and should be ignored.

Although second order and prone to error, FFM %Fat, can be calculated by the equation shown in **Appendix B**.

Retrieving Saved Data

The frequency, (.DAT), modeled (.MOD) and volume (.VOL) data are saved as TAB delimited text files and can be read by most common spreadsheet programs, as well as the Windows 95® Notepad and Wordpad programs.

Data Output File Format

Raw Data Window

No heading is provided so the data can be modeled by the Data Modeling Utility.   On the first line is case number, date, time and run number (number of spectrum measured). The headings for the data from left to right are as follows:

Frequency (KHz), Resistance (ohms), Reactance (ohms), Impedance (ohms), Phase (degrees)

Mod Out Window

On the first line is case number, date and time. The headings for the data from left to right are as follows:

Run Number, Re (ohms), Ri (ohms), Cm (nF), Td (nS), alpha, Fc (KHz)

Vol Out Window

On the first line is case number, date and time. The headings for the data from left to right are as follows:

Run Number, ECF (liters), ICF (liters) FFM (Kg), Mark

Hydra Data Plotting Utility

Program Description and Use

The Hydra Data Plotting Utility is designed to allow the user to plot and view "continuously" measured real time data on a host computer. This utility is very easy to use with self-explained menu items.

Running The Program

The Hydra Data Plotting Utility can be ran by either clicking on the icon created "Hydra Plotting" or by opening the Windows 95 Explorer® program and Hydra subdirectory, and double clicking on the icon for Hydra Plotting.

Main Screen

Once the program has been opened, the following Main Menu will appear.
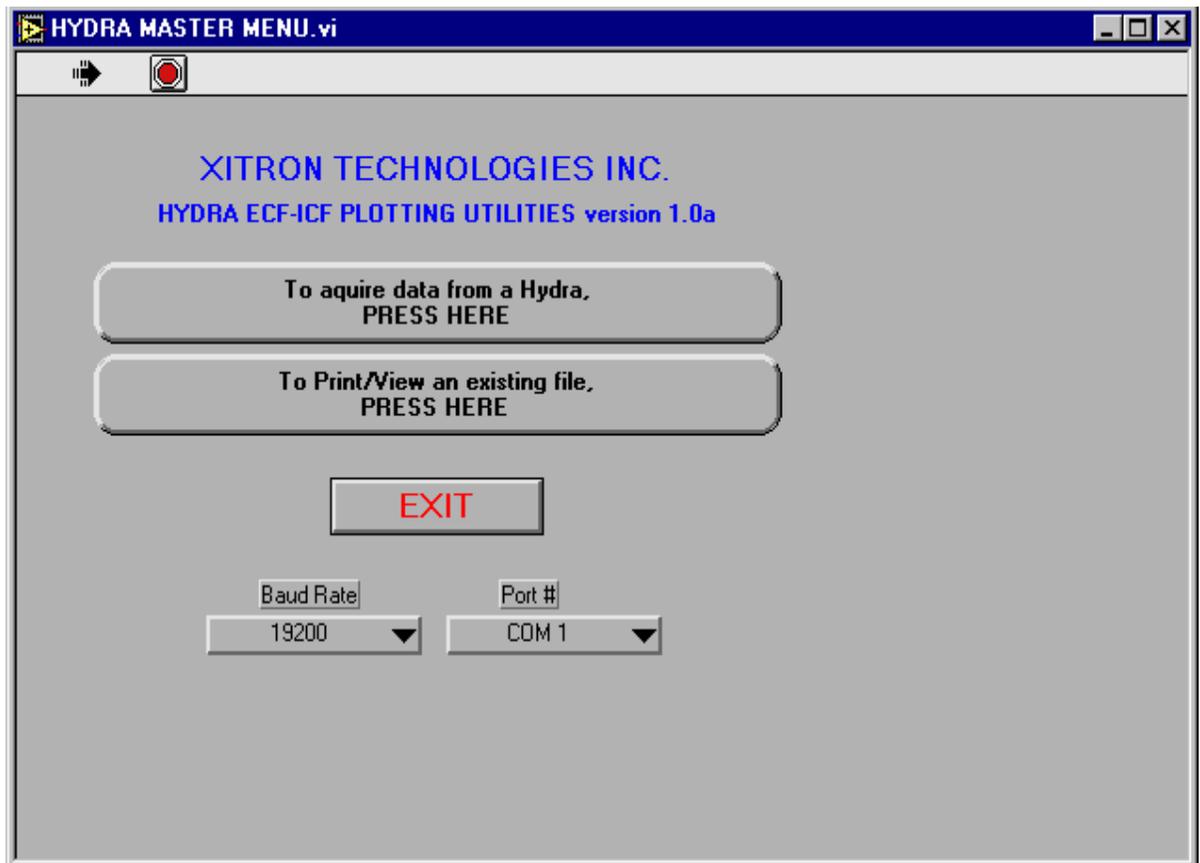
Communication Setup

Baud Rate

The baud rate can be set by clicking on the down-up arrows shown next to the baud rate window with the left mouse button until the desired baud rate is found. The baud rate can also be selected by simply clicking in the baud rate window using the left mouse button and then clicking the desired baud rate with the left mouse button. Be sure the HYDRA ECF/ICF device is set at the same baud rate.

Port Number (#)

The COM port number can be set by clicking on the down-up arrows shown next to the COM port number window with the left mouse button until the desired COM port number is found. The COM port number can also be selected by simply clicking in the COM port number window using the left mouse button and then clicking the desired COM port number with the left mouse button.

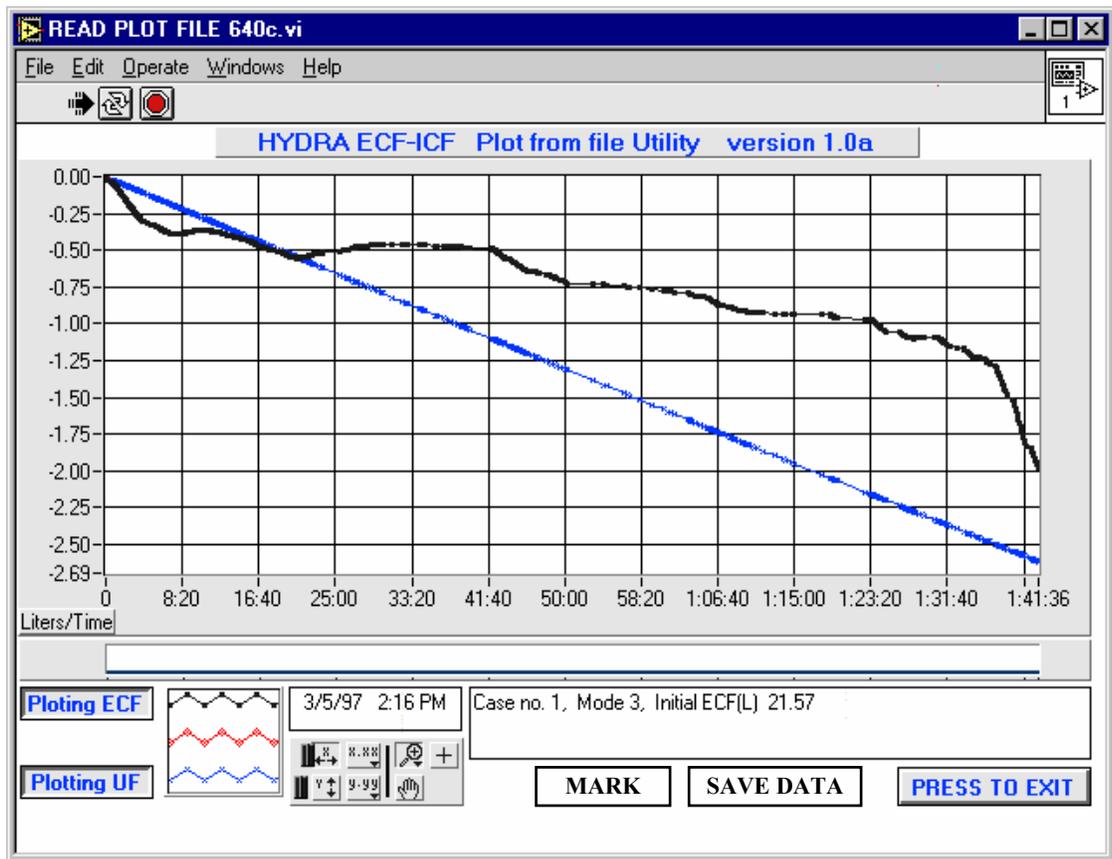## To Acquire Data From A Hydra

The Acquire Data button in the Main Menu allows the program to receive data from the HYDRA device. First setup the HYDRA device with the desired OBJECT, MODE and METHOD of measurement and input all required subject input data.

Second, press Start on the HYDRA ECF/ICF device and begin to collect data. For best results, allow the HYDRA device to complete its first measurement and then 3-4 additional measurements. HYDRA uses advanced (but common) adaptive filtering to reduce noise, thus, after 3-4 measurements, the calculated change becomes much more stable.

1. At the Main Menu , click on the Acquire Data button with the left mouse button. The following screen will appear.

- Note -

The Continuous Measurement Mode and Data Plotting Utility were primarily developed for the hemodialysis field. Weight is used along with body density as a measure of total body volume and expressed in cube root form - thus a 10% error in weight is a 3% error in volume. If 3 liters were to be removed by ultrafiltration, this would represent an approximate 4% change in weight for a 70kg person, and a 1.3% error (0.195 L) in volume for a person with 15 L ECF. The program automatically subtracts the weight lost according to the input ultrafiltration volume. The user is responsible for the accurate input of UF rate. None hemodialysis applications should make periodic single measurements, accounting for change in weight manually at each time point.

---

2. When the first measurement is completed, the date and start time of the measurement, case number, mode, and initial ECF and ICF volume values will be displayed in the window at the bottom of the screen. The first measurement will appear as zero on the plot. All following measurement will be <u>subtracted</u> from the first initial measurement and plotted as change.

3. During the procedure if your wish to save the data, click on the SAVE DATA button with the left mouse button. A Save File Window will appear. Type in the name of the file you wish to save the data in and click on the SAVE button. To ensure the data is not lost, repeat the save process periodically. During the period that data is being saved, no data will be recorded by the program.

4. If during the measurement an event is observed that the user wishes to make note of on the plot, simply click the MARK button. This will mark the plot with the time of the event.

5. The user can PRINT the screen shown at any time. During the period that data is being printed, no data will be recorded by the program.

6. When the user wishes to exit the program, SAVE the data one last time and click on the EXIT button. The program will ask you if you wish to exit or go back and save your data. Clicking on EXIT will stop data collection and return you to the Main Menu.

Mode Numbers Listed in Plots

Continuous Measurements

ECF-ICF, WB Wrist-Ankle, Continuous:	8
ECF, WB Wrist-Ankle, Continuous:	3
ECF-ICF, Segment, Continuous:	11
ECF, Segment, Continuous:	6
ECF-ICF, WB-Segment, Continuous:	9
ECF, WB-Segment, Continuous:	4

Single Measurements

ECF, WB Wrist-Ankle, Single	2
ECF-ICF, WB Wrist-Ankle, Single	7
ECF, Segment, Single	5
ECF-ICF, Segment, Single	10

Notes

- The desired way of exiting the program is through the EXIT buttons. However, if the program ever gets locked up, click on the RED hexagon button in the top left corner. Then select File, Close using the top left pull down window..

- The user is strongly advised to not to explore the various buttons and features during important data collection. The user is advised to play with the program and get a familiar with how to use it and its various functions before deviating from the default settings. This program was developed using the powerful LabView® program language that offers features that cannot be disabled but are inapplicable to the function of this program.

- As discussed in the HYDRA manual, an ultrafiltration volume is allowed to be included in the plot for those investigators studying hemodialysis. If the UF function has not been enabled in the HYDRA device, it will not appear in the plot.

Advanced Features

If the user explores the various buttons during the data collection and cannot get the settings back as originally shown, the program will continue to collect data. Simply save the data and when retrieved, the original settings will appear. However, this is not the case if "Reinitialize All To Default" is pressed in the top left Operate pull down menu or if the user gets the program lost using "Preferences" in the top left Edit pull down menu. DO NOT use these parameters during data collection.

Remove Data From Screen

If the user wishes to remove from view one or all of the data parameters being plotted, simply click on the Plotting ECF, Plotting ICF or Plotting UF buttons (if enabled) on the lower left side of the screen. The program will continue to collect and save un-plotted data.

Panning and Zooming

The Graph palette below is included with any graph created. This palette has controls for panning (scrolling the display area of a graph) and for zooming in and out of sections of the graph. The Graph Palette is shown as follows.
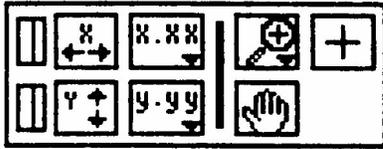
       If you press the x autoscale button, shown below, the program will autoscale the X data of the graph. If you press the y autoscale button, the program autoscales the Y data of the graph. IF you want the graph to autoscale either of the sacles continuously, click on the lock switch, shown below to lock autoscaling on. If auto scaling will not unlock, it is because a minimum change in the data of 0.05 liters must occur before auto scaling can be turned off.

The scale format buttons below give you run-time control over the format of the X and Y scale markers, respectively

Use the remaining buttons to control the operation mode for the graph.

If you press the Panning tool below, you switch to a mode in which you can scroll the visible data by clicking and dragging sections of the graph.

If you press the Zoom tool below, you can zoom in on a section of the graph by dragging a selection rectangle around that section.

If you click on the Zoom tool, you get a pop-up menu you can use to choose some other methods of zooming. This menu is shown in the following illustrations below:
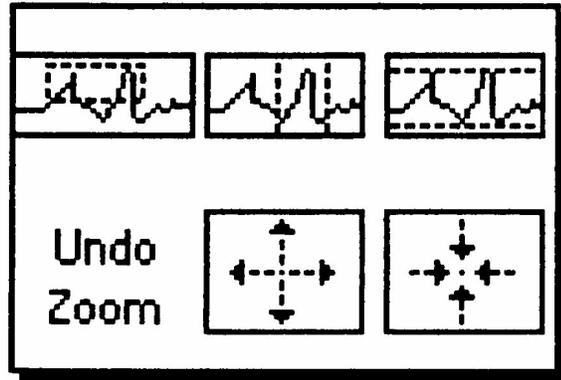
A description of each of these options from top to bottom is as follows:

First is the Zoom by rectangle. Next is the Zoom by rectangle, with zooming restricted to x data (the y scale remains unchanged). At the bottom is the Zoom by rectangle, with zooming restricted to y data (the z scale remains unchanged)
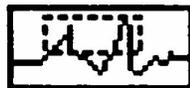
Undo last zoom below resets the graph to its previous setting.
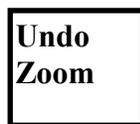
To use the Zoom IN or OUT about a point below, hold down the mouse on a specific point, the graph continuously zooms in or out until you release the mouse button.
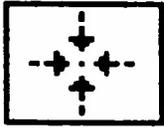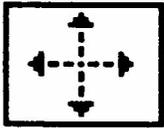
Change Plot Style. To change the plot style during the data collection, the user can click on the left or right mouse button while the mouse point is on one of the plot styles shown in the second from the left window. The options available will appear. Select the desired options by simply clicking the right mouse button.

To Print/View An Existing File

The Print/View Existing File button in the Main Menu allows the user to reconstruct a plot from previously collected data. Once the plot data file has been saved and recalled, it will always open with the original default settings.

1. Click on the Print/View Existing File button to retrieve an existing plot file and an Open File Window will appear. Type in the name of the file to retrieve or click on the file to retrieve and click on Open.

2. The user can use any of the above advances features above to modify or print the window but when the file is closed, the format will return to the original default file. Print out any changes the user wishes to save before closing the file.

3. When the user is finished viewing or formatting the retrieved plot file, press the Exit button. A window will appear asking the user "Would you like a copy of the plot data converted to a text file." If the user selects No, the binary plot file will be closed and the program will return to the Main Menu. If Yes is selected, a "Choose File To Write' screen will appear. Type in the name of the file you wish to save the text file in and click SAVE.

Text File Conversion

As discussed above (No. 3), the program converts the binary plot data into a TAB delimited text file so the actual data can be compared with other physiological measurements. The text file can be read by most common spreadsheet programs, as well as other programs designed to read text files.

Data Model-Vol Utility

Program Description and Use

This program allows the user to model the raw frequency data collected by the device using the Data Acquisition Utility. This enables the user to externally judge the fit of the data to the Cole model, thus, providing a cross check of data that is in question or cannot be modeled by the device. When only ECF has been measured, the program will only fit for resistance ECF using a 5KHz to 200KHz spectrum. When both ECF and ICF have been measured, the Modeling Utility will compute all the parameters of the Cole Model using a 5KHz to 1MHz spectrum. This program also allows the user to externally compute volume once the raw data has been modeled and ECW and ICW resistance's are obtained.

Running The Program

The Data Model-Vol Utility can be opened by either clicking on the icon created "Data Model-Vol.exe" or by opening the Windows 95 Explorer® program, the Hydra subdirectory, then double clicking on the icon for Data Model-Vol.exe.

Main Screen

After clicking on the icon established for the Data Model-Vol Utility, the following Main Menu will appear:
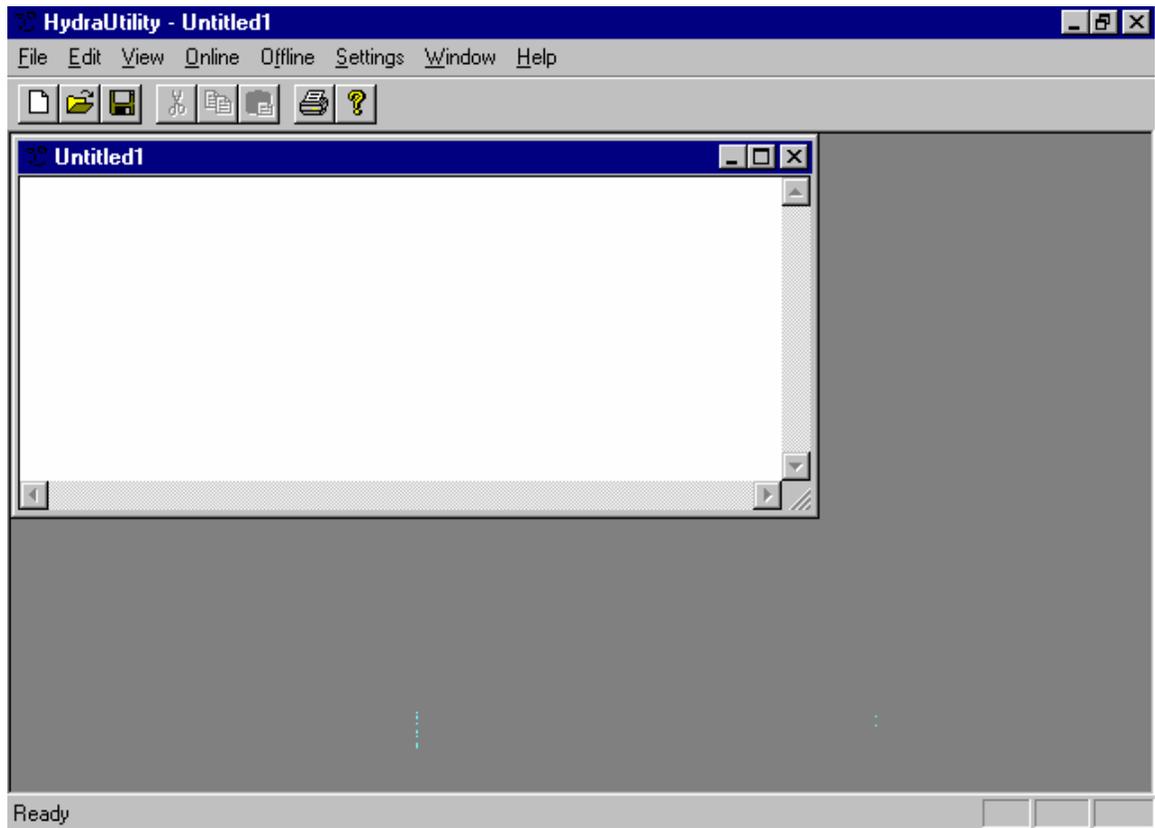
Device Model Setup

Using the pull down window "Settings", click on "Instrument." Setup the program for the device you used to collect the data. The Hydra model 4200 is the base product and the 4200S is a low impedance-high resolution model designed for segmental work. When you turn "On" the device, the display will show you the device model number.

Modeling Saved Frequency Data

1. Once raw frequency data (.DAT) has been collected from the device with the Data Acquisition Utility and saved to a file, open the desired file by clicking on the top menu named File or click on the folder icon. An open window will appear. Type in the name of the .DAT file to be modeled or double click on. The following Screen will appear:

HydraUtility - George0.dat				
File Edit View Online Offline Settings Window Help				

George0.dat

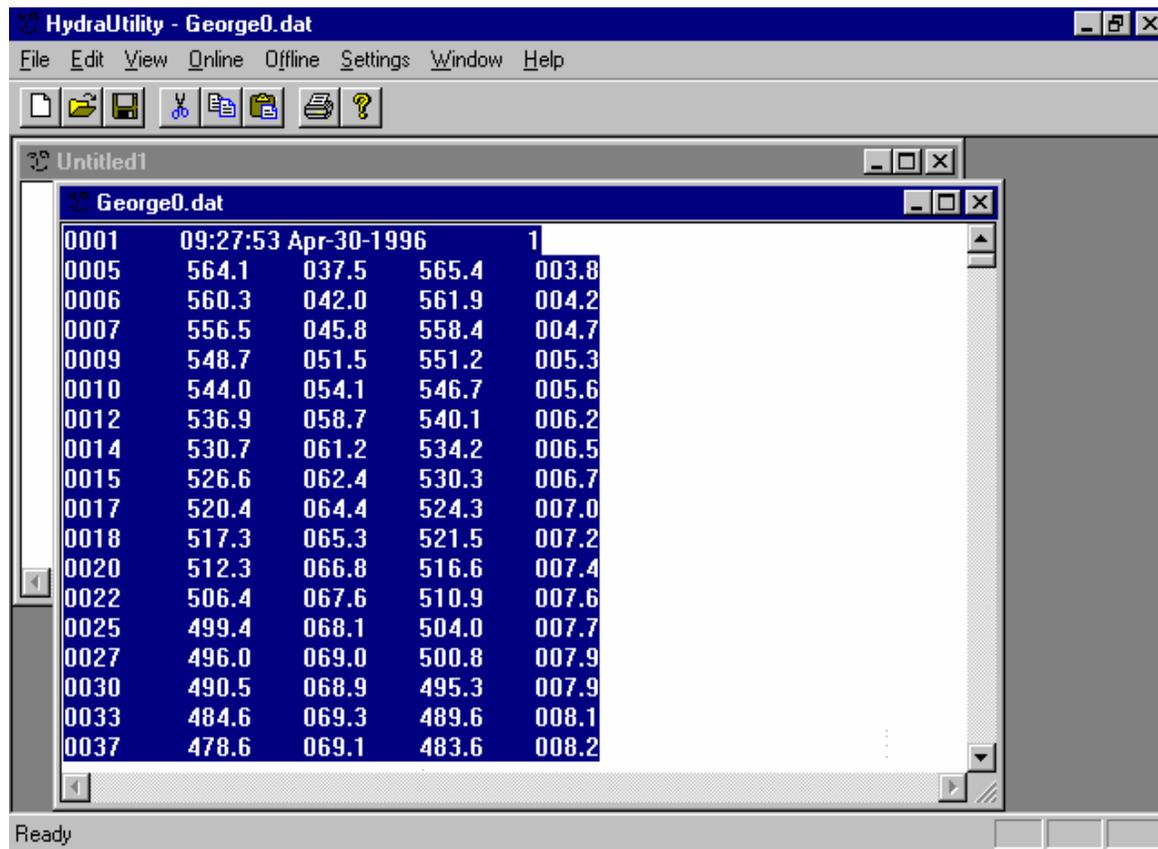| 0001	09:27:53 Apr-30-1996		1	
0005	564.1	037.5	565.4	003.8
0006	560.3	042.0	561.9	004.2
0007	556.5	045.8	558.4	004.7
0009	548.7	051.5	551.2	005.3
0010	544.0	054.1	546.7	005.6
0012	536.9	058.7	540.1	006.2
0014	530.7	061.2	534.2	006.5
0015	526.6	062.4	530.3	006.7
0017	520.4	064.4	524.3	007.0
0018	517.3	065.3	521.5	007.2
0020	512.3	066.8	516.6	007.4
0022	506.4	067.6	510.9	007.6
0025	499.4	068.1	504.0	007.7
0027	496.0	069.0	500.8	007.9
0030	490.5	068.9	495.3	007.9
0033	484.6	069.3	489.6	008.1
0037	478.6	069.1	483.6	008.2

Ready

2. If only a single measurement has been performed, a single raw data spectrum will appear. If a continuous measurement has been performed, multiple spectrums may appear. Highlight the data set to be modeled first line with case, time and date through 5KHz-200KHz for ECW and 5KHz-1MHz for ECW and ICW.

3. Once the data is highlighted, click on the top menu named Off-line, then click on Model Fitting. The program will model the data and create three files .MDL (full modeling report), .MOD (final result) and .PLO (plotting file). If any of these files exists, the program will ask you to Append, Overwrite or Cancel to quit function. When no other files exist, the program will begin modeling. When the mouse pointer goes from an arrow to a cursor, the modeling is complete.

4. Exit the file open by clicking on the X at the top right hand corner of the sub-window. Open the directory where the .DAT file is located and click on "All Files" in the files of type window. As shown below, displayed will be .DAT, .MDL, .MOD and .PLO files.
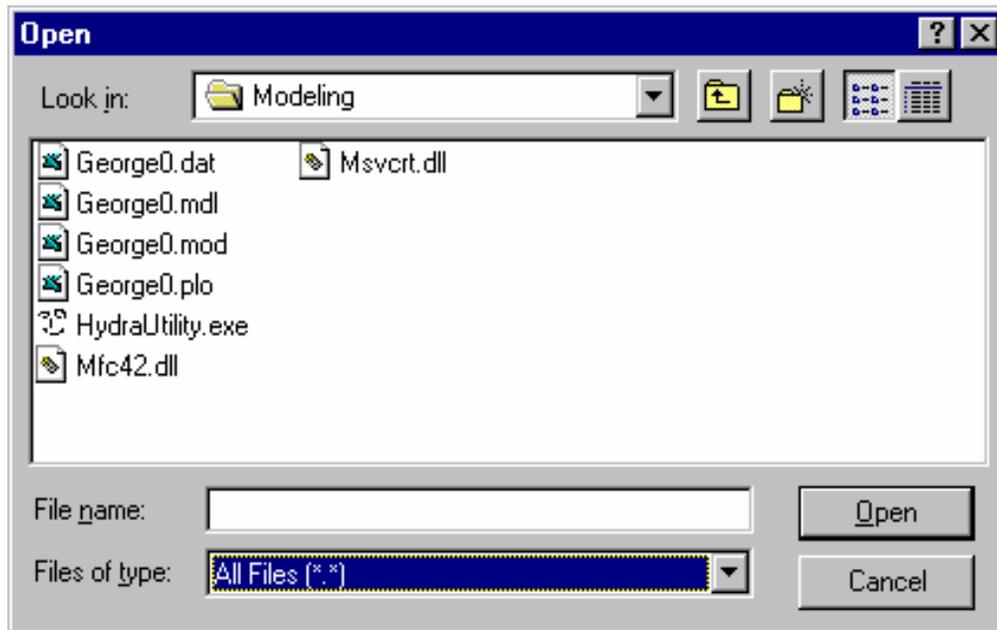
5. Open the desired file by double clicking on it. You can also cope it to another file by using the right mouse button.

6. As shown below, the .MDL file display the frequencies deleted, correlation of fit, resistance ECF (Recf) and resistance ICF (Ricf), cell membrane capacitance (Cm), time delay (Td), exponent alpha, and characteristic frequency (Fc). The final line shown is the final result of fitting. When only ECW has been measured, only case no., fit status, and Re will appear.

7. The .MOD file is the final model fit parameters (e.g., case number, fit status, Recf, Ricf, Cm, Td, alpha and Fc). When only ECW has been measured, only case no., fit status, and Re will appear.

A typical .MDL file is shown below:
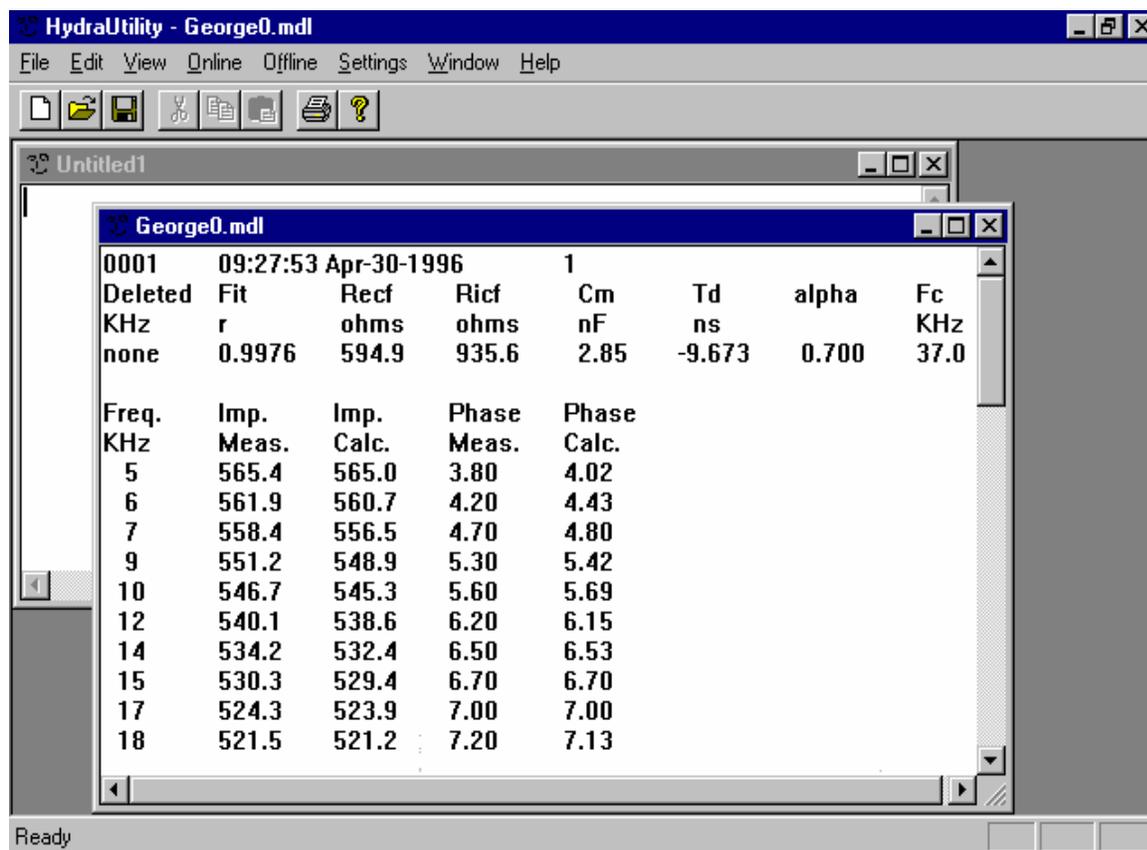
Plotting Spectral Data

1. When a raw frequency .DAT file is modeled with the Hydra Modeling Utility, a .PLO file will also be created. This file consists of raw resistance, reactance, impedance and phase data with the non-biological linear phase shift caused by time delay removed at each frequency (De Lorenzo, 1997). This file can be imported into a spreadsheet program for plotting. Before plotting, insert a row before 5KHz and 1MHz for the zero in infinite frequencies, respectively. Use 0.001Hz as the zero frequency and 100,000MHz as the infinite frequency. Always logarithmically space the frequency-X axis. Use the R for zero and infinite frequency found in the .MDL file. Use zero (0) for reactance and phase for the zero and infinite frequencies. For resistance versus reactance graphs, be sure the scaling (length) of the reactance-Y axis equals the same units on the resistance-X axis otherwise the data will not display the suppressed semicircle expected.

Evaluating The Quality Of Fit To The Cole Model

The accuracy of fit to the Cole model is extremely good for most subjects, thus, the fit to the model provides a quality control cross-check. If the data does not conform to the theoretical model, it is due to either an extreme biological deviation in the subject measured or poor measurement quality control. Judge the fit to the model by comparing the result to the following criteria normally observed:

1. Least mean squared error of fit <1.
2. Rating of fit good or excellent

3. R_E less than R_I by 1.5-2 to 1.
4. Alpha greater than 0.45
5. F_C less than 150KHz
6. Not to much movement in R_I once first few data points are removed
7. Not to many frequencies deleted and the solution found quite quickly (1 minute) on a 486 33MHz computer.

Computing Volume Following Modeling

1. After modeling, this function allows the user to compute volume using Xitron mixture equation. Open the .MDL or .MOD file.

2. At the top menu selection, click on "Off-line" with the mouse button. For example, click on segment volume and following screen will appear:

3. Change gender, segment length, circumference 1, circumference 2, Re and Ri by either highlighting the window to be changed with the mouse and typing in the new value or click in the far left corner and use the delete key. Do the same for height and weight when a wrist to ankle measurement is performed.

4. Re and Ri can be imported into the volume window in two ways. Before opening the volume window open the .MDL or .MOD file. Highlight both Re and Ri from modeling and Click on the the top Edit pull down menu. Click on copy. Then open Segment Volume through the Off-line pull down menu. Delete the value in the Re window. Copy the Re and Ri values from modeling through the right mouse key (copy). Both Re and Ri will now be in the Re window. A black cursor will separate the two values. Highlight the Ri value to the right with the left mouse button. Now click on the right mouse button and click on cut. Delete number shown in the Ri window and copy the new values through the right mouse key and clicking on paste.

5. Another way of doing it is to copy Re from modeling, go into volume and copy the new value in the Re window for volume. Exit volume and copy Ri from modeling. Go back into volume and copy the new value in the Ri window for volume.

6. When you are predicting volume for the first time, you must click on the Reflash Button in the top right hand corner.

7. At the present time, any change in Gender, height, weight, segment length, circumference 1, circumference 2, Re and Ri will only remain while the program is running. When the entire program is exited and reopened, the program will display the arbitrary default values.

Note: Although second order and prone to error, FFM %Fat, can be calculated by the equation shown in **Appendix B**.

Changing Resistivity Constants

1. To compute volume requires use of ECF and ICF resistivity constants. This feature allows the user to change the constants if research proves others more appropriate. At the present time, any change in resistivity made in the program will only remain while the program is running. When the program is exited and reopened, the program default display the default values. The default values can be found in the *Front Panel Controls, Menu Key-Set Resistivity Section* of this manual.

- IMPORTANT -

Resistivity does not affect the correlation or standard estimate of error. However, changing resistivity will dramatically alter the size of the predicted space. It is advised to not change resistivity. Refer to the *Accuracy Considerations, Scaling To Reference Methods Section* for information. The default values are based on the latest dilution research.

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2. First open the file you wish to compute volume for. Then Go to the top menu selection and click on Settings. Click on Resistivity and the following screen will appear:

3. To change resistivity highlight the number desired to be changed an type in the new number. You can also click with the mouse button in the far left side of the window of the number and use the delete key to erase the present number. To return to the default settings, simply click on the Default Button.

4. Once changed, exit by pressing the X button in the top right corner of the window. Go into volume calculation through the Off-line menu at the top.   Compute volume as described above.   The volume shown will reflect the new volume predicted by the modified resistivity constant.

5. At present this function has little use since closing the entire program returns the resistivity values to the default values. However, we have provided this function so users can compute volume with different constants if necessary.

Hydra Memory Utility

Description

This utility is provided to all users but is only applicable to those users who have purchased the MEM4200 Data Memory Storage Option. The third screen displayed when the device is turned on will inform the user if the device has been fitted with the MEM4200 Option. As discussed in the *Introduction and Front Panel Controls, Printing Stored Data*, the MEM4200 Option saves up to 250 single measurements according to date and time. Before 251 subjects are measured, the user may wish to download the stored results to a computer file. The *Hydra Data Memory Utility* has been created to allow the user to perform this function as well as erase data stored in memory.

WARNING

Be very careful to not click on the Erase The Memory Storage button if you do not wish to. Clicking this button will erase all stored data and it cannot be retrieved.

Running the Hydra Memory Utility

1. Double Click on the icon for this utility or go into the Windows 95® program Explorer and double click on the file named Hydra Memory.Exe. The following Screen will appear:
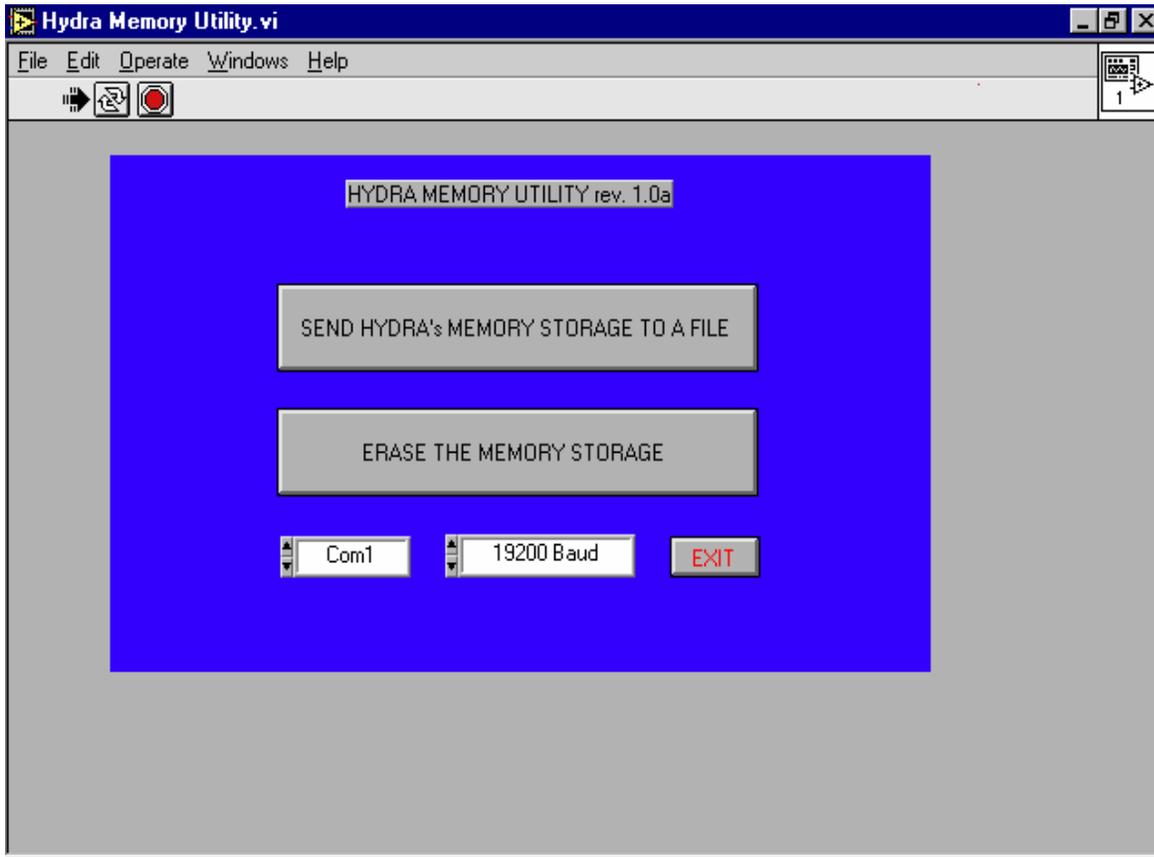
Send Data To a File

1. To send data to a file, click on the Send "Hydra's Memory Storage To A File" button. A Save File Window will appear. Type in the name of the file you wish to save the data to and press Enter. If the file already exists, the window will ask you to Replace or Cancel Save Option.

Output File Format

So as to allow the user to export the data file to other programs, the output data format has been formatted with a single row containing labels (headers) for each data parameter, followed by rows of data. Although this horizontal format is difficult to view on the computer screen, it allows the stored data to be easily copied and pasted to other files. The data will be displayed horizontally in the follow format:

Case No.	Date	Time	Fit Status	Meas. Mode	Gender
Height (cm)	Weight (cm)	Seg. Len. (cm)	Circum. 1 (cm)	Circum 2 (cm)	ρ ECF (Ω.cm)
ρ ICF (Ω.cm)	ECF (L)	ICF (L)	Re (ohms)	Ri (ohms)	Cm (nF)
Alpha	Td (ns)	Fc (KHz)	FFM (kg)		

Seg. Len. = Segment Length, Circum. 1 = Circumference 1, ρ ECF = resistivity ECF.

- IMPORTANT -

All data saved in the device at the time of measurement will be saved. For example, if the user performs a segment measurement which does not include height and weight, the last value for height and weight entered will appear when downloaded. The use can discern what parameters are relevant from the mode number. However, if segmental measurements are always going to be performed, set height to 5 cm/inch, and weight to 1 kg/lb. If wrist-ankle measurements will always be performed, set segment length to 1 cm/inch, circumference 1 and 2 to 1 cm/inch. These settings will remain in memory and will ensure that when the data is downloaded to a file, no confusion will occur as to which data was actually measured. However, again the measurement mode tells you what parameters we used to compute volume.

Measurement Mode Numbers

ECF, WB Wrist-Ankle, Single	2
ECF-ICF, WN Wrist-Ankle, Single	7
ECF, Segment, Single	5
ECF-ICF, Segment, Single	10
ECF-ICF Ratio	12

Erase Data From Memory Storage

1. To clear the Hydra ECF/ICF device memory, simply click on the Erase The Memory Storage button.

WARNING: By clicking on the Erase Memory Button you will lose all saved data if not saved first.

Hydra Update Utility

Introduction

The Update Utility was created to the user can update the Hydra device *Main Code* locally from a computer, without needing to send back the device, anytime an improvement or modification has been made to the device. Since device *Boot Code* would be rarely changed, we have not included instructions for updating *Boot Code* in these instructions. Any changes needed would be accompanied with instructions.

Confirm Code File Names With Device

Before attempting to use this utility or update your device, confirm that the appropriate *Main Code* File and Program Disks have been sent for your device model number. The Main Code file name and revision number of any accompanying program disks will be sent separately.

- Warning -

Once the Hydra Device has been setup to receive a file and a file has been sent, there is no means of stopping it's transfer to the Hydra. Confirm that you are in fact transferring the correct file to the Hydra. The transfer of an incorrect or corrupted file will disable the functioning of the device.

Running The Program

The Hydra_Update Utility can be opened by either clicking on the icon created "Hydra _Update" or by opening the Window 95 Explorer® program and Hydra_Update subdirectory, then double clicking on the icon for Hydra_Update.Exe.

Main Screen

When the utility has been opened, the following screen will appear:
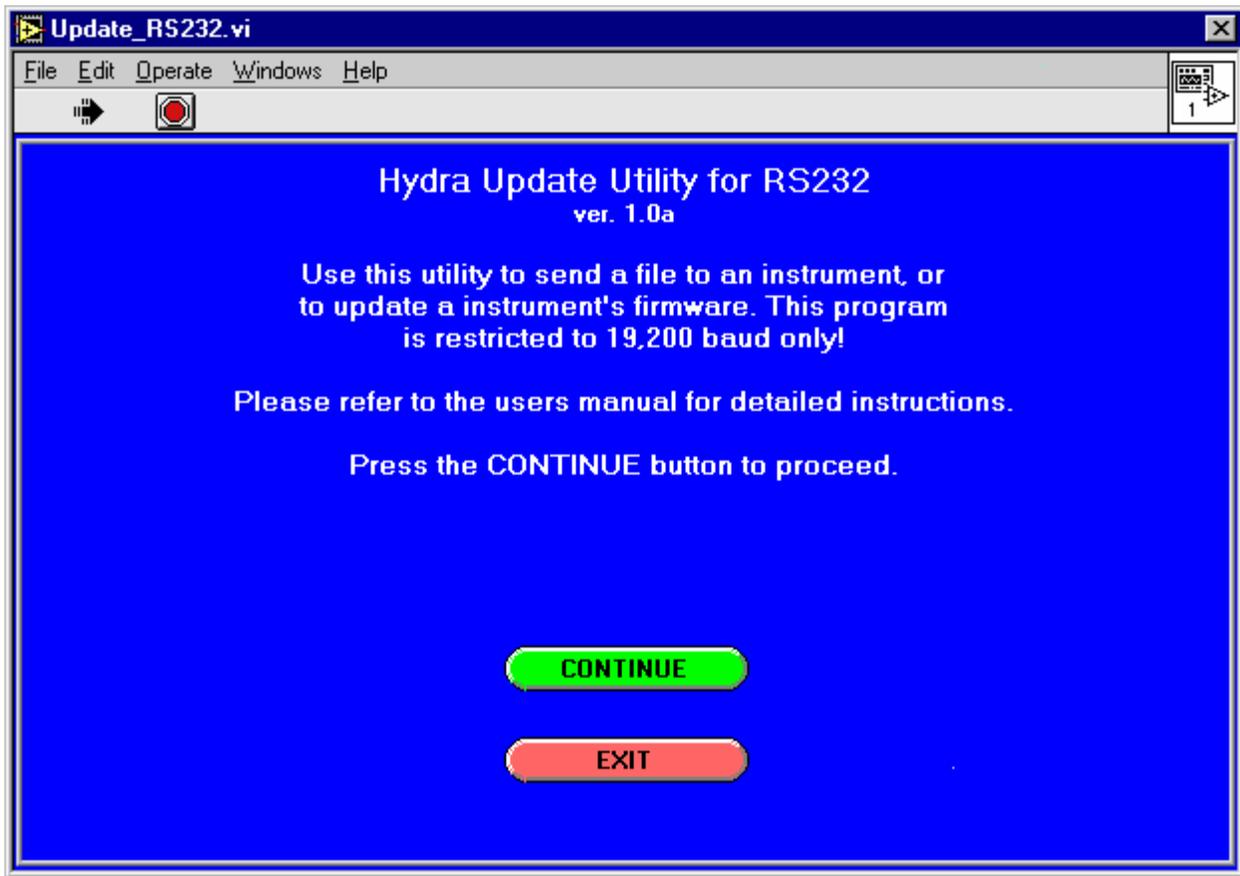
Figure 1

Communication Setup

When the continue button is clicked, the following screen will appear:
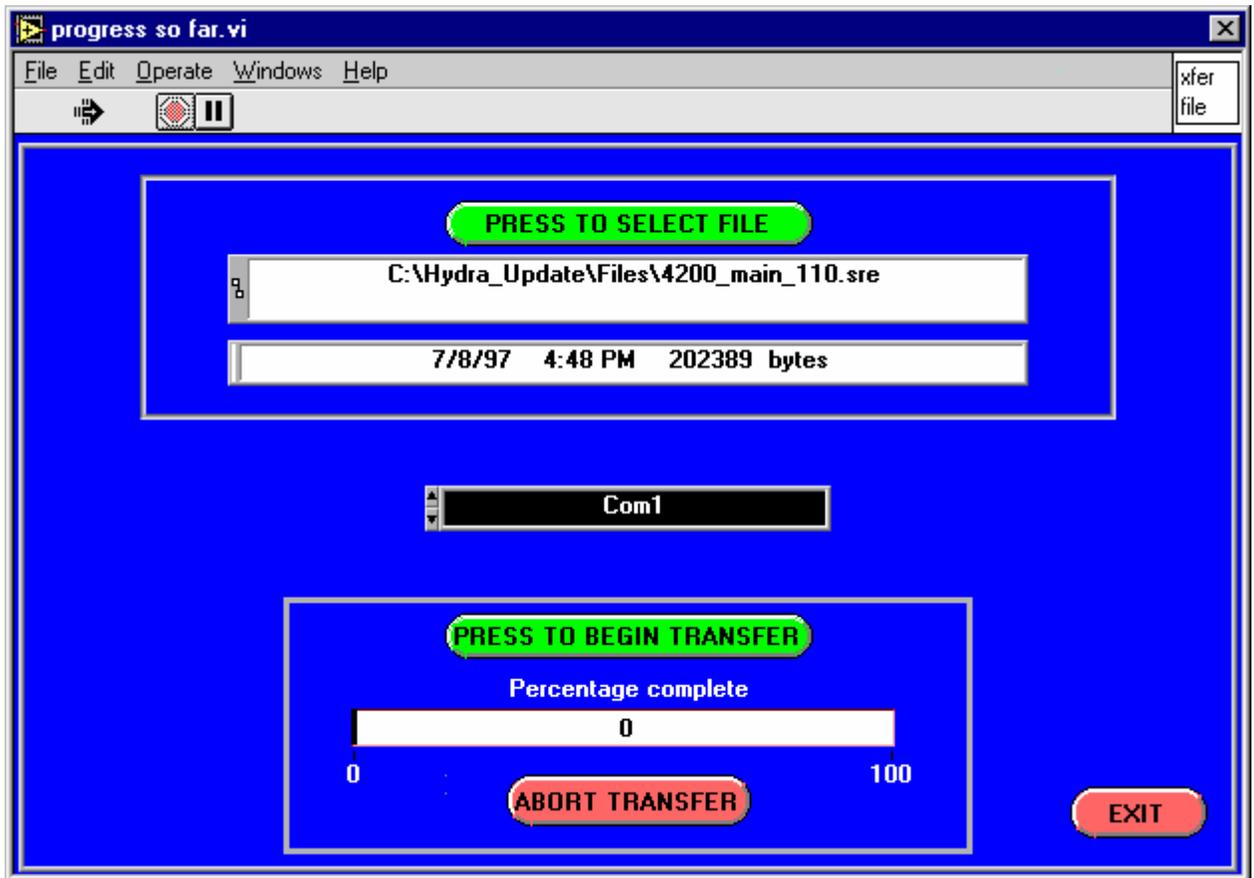
Figure 2

Baud Rate

The baud must be set at 19,200. The Hydra device was shipped with the baud rate set at 19,200. Confirm that the baud rate is set at 19,200. Instruction for doing this can be found in the Hydra ECF/ICF device Operating Manual listed as Changing Setup Parameters Chapter.

COM Port Number

The RS232 cable provided must be connected to the correct COM Port of the computer. The COM Port can be set clicking on the down-up arrows next to the COM Port number window with the left mouse button until the desired number is desired.

Update Main Code

Refer to the device Operating Manual in *Changing Setup Parameters Chapter* for the same following instructions:

1. Turn off the Hydra device and put the rear Panel "Mode" switch in the Maintenance position. Turn ON the device.

2. The display will read SET_UP MENU, Update Software. Press ENTER.

3. The display will ask the user if they wish to "Update Software" from a computer. Use the Arrow Keys to select Yes and press ENTER. The display will read WAITING MAIN CODE Baud Rate: 19.2k (Not "Waiting Boot Code!).

4. Now go back to the Progress Screen (**Figure 2**) and click on Press To Select File. A file screen will appear. Find the Main Code file named on the last page of this document and double click on it with the mouse button. The name of the file will appear in the File Window.

5. Click on the Press To Begin Transfer button. The Data Update Utility will immediately begin to transfer the new code to the Hydra device. When it is completed the program will display 'Transfer Complete."

6. Press Exit to return to the Main Screen (Figure 1).

7. Power OFF the device.

Device Performance Verification

After transfer of the "new" Main Code has been successfully completed, verify that the device is performing correctly. Instructions for verifying performance are found in the *Product Maintenance Chapter* in the device operating manual. Once measurement performance has been verified, perform measurements using different functions (ECF only, continuous versus single, etc.) on the Verification Module to confirm full functionality.

Appendix A. Modeling

The Z and θ spectra data is fit to the Cole-Cole model (Cole 1972), equation A1, using iterative non-linear curve fitting software (De Lorenzo 1997). The modeling program evaluates the weighted least square error of both Z and θ, where the weighting is established by the published accuracy specifications of the instrument and removes any frequency that would significantly decrease the total weighted least square error. The expected accuracy at each measured frequency is established as a pair of arrays (impedance and phase) at the start of the modeling function. The error ratio is then established at each modeling point by simply dividing the modeling error by the corresponding stored array error. In addition to the correlation of fit using scalar Z, the program established the accuracy of fit to the model as follows:

1. Mean offset to fit less than 1/2 the instrument specifications = excellent or 0.
2. Mean offset to fit less than the instrument specifications = good or 1.
3. Mean offset to fit less than 2x the instrument specifications = marginal or 2.
4. Mean offset to fit less than 6x the instrument specifications = questionable or 3.
5. Mean offset to fit greater than 6x the instrument measurement specifications = bad or 4.

In order to prevent the program from deleting frequencies solely to "force" a fit to the model, the following limitations are enforced in the software:

1. A maximum of 25% of the frequencies may be deleted.
2. Within any 3:1 range of frequencies, at least one frequency must remain.
3. Only frequencies whose Z and θ lay more than the instrument specification from the curve may be deleted.
4. Only one frequency is deleted per iteration of fitting.
5. A frequency is only deleted if it results in the maximum improvement in resultant fit, this is not necessarily the frequency whose Z and θ lay furthest from the fit.

The Cole model is extended to allow for the frequency invariant time delay (T_D), caused by the speed at which electrical information is transferred through a conductor. The error introduced by this fixed time delay is modeled as a phase error that increases linearly with frequency. This linear phase error is mathematically modeled by multiplying equation A1 by the factor e^{-jwT_D} (De Lorenzo 1997). Thus, the overall modeled equation is:

$$Z_{obs} = \left(\frac{R_E}{R_E + R_I} \right) \left(R_I + \frac{R_E}{1 + \left(j\omega C_M \left(R_E + R_I \right) \right)^{\alpha}} \right) \left(e^{-j\omega T_D} \right) \ldots\ldots\ldots\ldots \text{A1}$$

where
Z_{obs} is the observed complex impedance
R_E, R_I and C_M are the component values of this circuit
ω is frequency in radians/sec (= 2π x frequency)
j is $\sqrt{-1}$

F_C is computed after the model components (R_E, R_I, C_M, T_D and α) has been determined by solving the equation:

$$\frac{\partial X(F_C)}{\partial \omega} = 0 \quad \text{...} \text{A2}$$

where
X(F_C) is the imaginary part of equation A1 at frequency F_C.

Appendix B. Volume Equations

The extracellular water of fluid (ECW or ECF) and intracellular water or fluid (ICW or ICF) volumes are predicted from the modeled R_E and R_I, using equations formulated from Hanai mixture theory (Hanai 1968). The Hanai equation describes the effect that a concentration of non-conductive material has on the apparent resistivity of the surrounding conductive fluid, and is --

$$\rho = \frac{\rho_0}{(1-C)^{3/2}} \quad \text{...B1}$$

where
ρ is the apparent resistivity of a conductive material.
ρ_0 is the actual resistivity of a conductive material.
C is volumetric concentration of the non-conductive material contained in the mixture.

From equation B1, with the following assumptions, we derived a set of equations as follows:

$$V_{ECW} = k_{ECW} \left(\frac{L^2 \sqrt{W}}{R_E} \right)^{2/3} \quad \text{...B2}$$

where
V_{ECW} is the predicted total extracellular fluid volume (Liters).

$$k_{ECW} = \frac{1}{1000} \left(\frac{K_B^2 \rho_{ECW}^2}{D_B} \right)^{1/3} \quad \text{...B3}$$

W is body weight (Kg)
L is height (cm)
R_E is the value from the model fitting (Ω)
K_B is a factor, correcting for a whole body measurement between wrist and ankle, relating the relative proportions of the leg, arm, trunk and height (**Appendix C**).
ρ_{ECW} is the resistivity of extracellular fluid ($\Omega.cm$)
D_B is body density (Kg/L)

$$\left(1 + \frac{V_{ICW}}{V_{ECW}} \right)^{5/2} = \left(\frac{R_E + R_I}{R_I} \right) \left(1 + \frac{k_\rho V_{ICW}}{V_{ECW}} \right) \quad \text{..B4}$$

where

$$k_\rho = \frac{\rho_{ICW}}{\rho_{ECW}} \quad \text{...B5}$$

R_I is the value from the model fitting (Ω)

The following assumptions are made:

1. The volumetric concentration of non-conductive elements in the body at low frequencies is given by

$$\left(1 - \frac{V_{ECW}}{V_{TOT}} \right) \quad \text{where } V_{TOT} \text{ is the total body volume.}$$

2. The volumetric concentration of non-conductive elements in the body at high frequencies is given by

$$\left(1 - \frac{V_{ECW} + V_{ICW}}{V_{TOT}}\right)$$

3. Total Body Volume is Body Weight (W) / Body Density (D_B).

4. The total volume of a body fluid can be described by

$$V_F = K_B \rho_F \frac{L^2}{R} \quad\text{..B6}$$

where
V_F is the total volume of the fluid in the body.
K_B is a factor relating the relative proportions of the leg, arm, torso and height.
ρ_F is the resistivity of the fluid.
L is body height.
R is the measured resistance between wrist and ankle.
The factors D_B, K_B and ρ_F can be considered largely constant.
The Hanai equation is applicable at high and low frequencies to mixtures found in the human
    body.

Using equations B2 and B4, V_{ECW} and V_{ICW} are computed, from which total body water (TBW) and fat free mass or lean (FFM or L) are computed using the following equations:

$$TBW = V_{ECW} + V_{ICW} \quad\text{..B7}$$

FFM = ($d_{ECW}V_{ECW}$) + ($d_{ICW} V_{ICW}$) ……………………………………………………B8
where
   d_{ECW} (1.106) is the mean density of extracellular water and its associated materials.
   d_{ICW} (1.521) is the mean density of the intracellular water and its associated materials.

These constants are based on the assumption that 100% of the FFM is 6.8% bone, 73.8% water (with 44.3% ICW and 29.5% ECW), and 19% protein (with virtually all the protein in the cell and the cell is 30% protein and 70% water), and 0.4% protein in the ECW. It is assumed that the ICW-protein ratio remains constant. The effect of bone on density is spread equally over the ECW and ICW.

Fat and %Fat can be calculated by the following equation:

FAT = Wt-FFM
%FAT = FAT/WT*100

Less accurately, FFM can also be calculated from the predicted TBW as TBW/0.738

Computing The Wrist-Ankle Constants

   k_{ECW} is established as the mean value of $V_{ECW}\left/\left(\dfrac{L^2 \sqrt{W}}{R_E}\right)^{2/3}\right.$ using a standard

spreadsheet program. The method used to derive k_ρ is to repetitively predict V_{ICW}/V_{ECW} and

adjust k_ρ until a minimum mean error between the predicted and measured ratio was obtained (De Lorenzo 1997; Ho 1994).

Computing Segment Volume

From equation B1, with the following assumptions, we derived an equation for segment volume as follows:

$$V_{ECW} = \frac{\rho_{ECW}^{2/3}}{3 \cdot (4 \cdot \pi)^{1/3} \cdot 1000} \cdot L \cdot (C_1^2 + C_2^2 + C_1 C_2) \cdot (\frac{L}{C_1 C_2 R_E})^{2/3} \quad\ldots\ldots\ldots\ldots\ldots\ldots \text{B9}$$

where
V_{ECW} is the predicted total extracellular water volume (Liters).
ρ_{ECW} is the resistivity of extracellular fluid (Ω.cm)
L is segment length (cm)
C1 is segment circumference (cm)
C2 is segment circumference (cm)
R_E is the value from the model fitting (Ω)
ρ_{ECW} is the resistivity of extracellular fluid (Ω.cm)

$$\left(1 + \frac{V_{ICW}}{V_{ECW}}\right)^{5/2} = \left(\frac{R_E + R_I}{R_I}\right)\left(1 + \frac{k_\rho V_{ICW}}{V_{ECW}}\right) \quad\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\text{B10}$$

where
$$k_\rho = \frac{\rho_{ICW}}{\rho_{ECW}} \quad\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots\text{B11}$$
R_I is the value from the model fitting (Ω)

The following assumptions are made:

1. The volumetric concentration of non-conductive elements in the body at low frequencies is given by

$$\left(1 - \frac{V_{ECW}}{V_{TOT}}\right) \quad \text{where } V_{TOT} \text{ is the total segment volume.}$$

2. The volumetric concentration of non-conductive elements in the body at high frequencies is given by

$$\left(1 - \frac{V_{ECW} + V_{ICW}}{V_{TOT}}\right)$$

3. Total segment volume is determined by segment length and two circumferences, assuming the segment to be a cone.

4. The total volume of a uniform cylinder can be described by

$$V_F = \rho_F \frac{L^2}{R} \ \dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\text{B12}$$

where

    V_F is the total volume of the fluid in the segment.

    ρ_F is the resistivity of the fluid.

    L is cylinder length.

    R is the measured resistance of cylinder

    ρ_F can be considered largely constant.

    The Hanai equation is applicable at high and low frequencies to mixtures found in the human body.

Using equations B2 and B4, predicted V_{ECW} and V_{ICW} were computed, from which predicted TBW is computed using the following equation:

$$TBW = V_{ECW} + V_{ICW} \ \dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\text{B13}$$

Converting k_{ECW} into ρ_{ECW}

The ρ_{ECW} is established as the mean value of $\rho_{ECW} = (1000 \cdot V_{ECW})^{3/2} \cdot \dfrac{R_E \cdot \sqrt{D_B}}{K_B \cdot H^2 \cdot \sqrt{W}}$

where

    V_{ECW} is total body dilution ECW volume

    R_E is model term derived from wrist to ankle measurement

    D_B is body density

    K_B is a factor relating the relative proportions of the leg, arm, torso and height.

    H is height

    W is weight

The method used to derive k_ρ is to repetitively predict V_{ICW}/V_{ECW} and adjust k_ρ until a minimum mean error between the predicted and measured ratio was obtained (De Lorenzo 1997; Ho 1994).

Derivation Of K_B

It should be noted that the derivation for K_B shown here is only an approximation for the purposes of confirming if its' use results in a ρ_{ECW} value that is within the range measured by other investigators (De Lorenzo 1997).

The resistance of a cylinder, measured longitudinally, is given by --

$$R = \rho \frac{L}{A} \ \dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\dots\text{C1}$$

where

ρ is the resistivity of the material

L is the length of the cylinder

A is the cross-sectional area of the cylinder

Restating equation C1 in terms of the cylinder length and circumference --

$$R = \rho \frac{4\pi L}{C^2} \dotfill \text{C2}$$

where

C is the circumference of the cylinder

The volume of the cylinder is given by --

$$V = \frac{LC^2}{4\pi} \dotfill \text{C3}$$

If we consider the body to be formed by five cylinders, the legs, the arms, and the trunk, then the volume of the body is given by:

$$V = 2\left(\frac{L_A C_A^2}{4\pi}\right) + 2\left(\frac{L_L C_L^2}{4\pi}\right) + \left(\frac{L_T C_T^2}{4\pi}\right) \dotfill \text{C4}$$

where

L_A and C_A are the length & circumference, respectively, of an arm
L_L and C_L are the length & circumference, respectively, of a leg
L_T and C_T are the length & circumference, respectively, of the trunk

When we measure the impedance between the wrist and the ankle, the measured value will be:

$$R = \left(\rho \frac{4\pi L_L}{C_L^2}\right) + \left(\rho \frac{4\pi L_T}{C_T^2}\right) + \left(\rho \frac{4\pi L_A}{C_A^2}\right) \dotfill \text{C5}$$

But, in equation B6 we assumed that R was given by --

$$V = K_B \rho \frac{L^2}{R} \dotfill \text{C6}$$

where

L is the height

Combining equations C4, C5 and C6 yields --

$$K_B = \frac{1}{L^2}\left[\left(\frac{L_L}{C_L^2} + \frac{L_T}{C_T^2} + \frac{L_A}{C_A^2}\right)\left(2L_A C_A^2 + 2L_L C_L^2 + L_T C_T^2\right)\right] \dotfill \text{C7}$$

If we relate L_X and C_X to height by factors K_{XL} and K_{XC} respectively (i.e., $L_X = K_{XL}L$), equation C7 becomes:

$$K_B = \left[\left(\frac{K_{LL}}{K_{LC}^2} + \frac{K_{TL}}{K_{TC}^2} + \frac{K_{AL}}{K_{AC}^2}\right)\left(2K_{AL}K_{AC}^2 + 2K_{LL}K_{LC}^2 + K_{TL}K_{TC}^2\right)\right] \dotfill \text{C8}$$

Thus K_B can be set according to standard anthropometric ratios, and is independent of any electrical parameters of the body.

Appendix C. References

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Appendix D. RS232 Command Set

Command   **Description**

#A   Set measurement mode in HYDRA
#B   Set gender in HYDRA
#C   Set Height, Weight in HYDRA
#D   Set Ultrafiltration Rate in HYDRA
#E   Set segment length,circumference1,circumference2, whole body ECF, ICF value in HYDRA
#G   Set case number in HYDRA
#H   Set measure interval in HYDRA
#I   Let HYDRA send identification string to host
#J   Let HYDRA send status byte to host
#K   Let HYDRA send user entered data to host
#L   Flip send raw frequency data flag in HYDRA
#M   Flip send modeled data flag in HYDRA
#N   Flip send volumes flag in HYDRA
#P   Reset all three "send" flags
#O   Mark event in HYDRA
#R   Upload all stored data from HYDRA memory storage to host
#S   Clear memory storage in HYDRA (erase stored data)
#U   Let HYDRA start new measurement or stop measuring
#V   Let HYDRA continue previous measurement from STOP

Command Format and Description

#A   Set measurement mode in HYDRA
To HYDRA: '#', 'A', *measurement_mode*
From HYDRA: None
Description: Host send *measurement_mode* which is a byte to HYDRA. The following are all *measurement_modes* available to both keyboard and RS232 serial port:

Meas._Mode	Object	Method	Operation Mode
2	ECF	WB by WRIST-ANKLE	SINGLE MEAS.
3	ECF	WB by WRIST-ANKLE	CONTINUOUS MEAS.
4	ECF	WB by SEGMENT	CONTINUOUS MEAS.
5	ECF	SEGMENT	SINGLE MEAS.
6	ECF	SEGMENT	CONTINUOUS MEAS.
7	ECF and ICF	WB by WRIST-ANKLE	SINGLE MEAS.
8	ECF and ICF	WB by WRIST-ANKLE	CONTINUOUS MEAS.
9	ECF and ICF	WB by SEGMENT	CONTINUOUS MEAS.
10	ECF and ICF	SEGMENT	SINGLE MEAS.
11	ECF and ICF	SEGMENT	CONTINUOUS MEAS.
12	ECF:ICF Ratio		SINGLE MEAS.
13	ECF:ICF Ratio		CONTINUOUS MEAS.

In mode 2 through 6, 20 frequencies in range 5KHz to 200KHz will be used to make measurement, in mode 7 through 13, 50 frequencies in range 5KHz to 1MHz will be

used.   The other two *measurement_modes*, 0 and 1, are only available to RS232 serial port.   In these modes, HYDRA will make frequency measurements and, if "send modeled data" flag is on, will model the frequency data.   The difference for mode 0 and 1 is frequency range: in mode 0, HYDRA will make measurements at 20 frequencies in the range 5KHz to 200KHz; while in mode 1, HYDRA will make measurements at 50 frequencies in the range of 5KHz to 1MHz (see Specifications section for details).

#B	Set gender in HYDRA

To HYDRA: '#', 'B', *Gender*.
From HYDRA: None.
Description: Host send *Gender* which is a byte to HYDRA. The value of the *Gender* should be 0, represent male, or 1, represent female.

#C	Set Height, Weight in HYDRA

To HYDRA: '#', 'C', *Height*, *Weight*.
From HYDRA: None.
Description: Host send *Heigh*t, *Weight* (centimeters) to HYDRA.   Both *Height* and *Weight* should be in 4 bytes *IEEE Standard for Binary Floating-Point Arithmetic* format, and be sent MSB first.

#D	Set Ultrafiltration Rate in HYDRA

To HYDRA: '#', 'D', *Ultrafiltration_Rate*.
From HYDRA: None.
Description: Host send *Ultrafiltration_Rate* (Liter per Hour) to HYDRA. *Ultrafiltration_Rate* should be in 4 bytes *IEEE Standard for Binary Floating-Point Arithmetic* format, and
be sent MSB first.

#E	Set segment length,circumference1,circumference2, whole body ECF,ICF value in HYDRA

To HYDRA: '#', 'E', *Segment_length*, *Circumference1*, *Circumference2*, *WB_ECF*, *WB_ICF*.
From HYDRA: None.
Description: Host send *Segment_length, Circumference1, Circumference2* (centimeters*), and WB_ECF, WB_ICF* (Liters) to HYDRA.   They all should be in 4 bytes *IEEE Standard for Binary Floating-Point Arithmetic* format, and be sent MSB first.

#G	Set case number in HYDRA

To HYDRA: '#', 'F', *Case_Number*.
From HYDRA: None.
Description: Host send *Case_number* to HYDRA. *Case_Number* should be in 4 bytes unsigned long int format, and be sent MSB first.

#H	Set measure interval in HYDRA

To HYDRA: '#', 'H', *measure_interval*.
From HYDRA: None.
Description: Host send *measure_interval* to HYDRA. *Measure_interval* should be in 2 bytes unsigned int, and be sent MSB first.

#I	Let HYDRA send identification string to host

To HYDRA: '#', 'I'.

From HYDRA: "HYDRA" + "," + *Product_ID* + "," + *Boot_Version* "+" + *Main_Version* + "," +
MEM_Option.

Description : Let HYDRA send back an ASCII characteristic string which include information of product identification, boot code version number , main code version number, memory storage option separated by comma sign.

Product_ID : "ECF" or "ECF/ICF"

Boot_Version : version for boot codes in the form of floating number string.

Main_Version: version for main codes in the form of floating number string.

MEM_Option: Option for memory storage. "MEM" means the option is selected, and "NOMEM" means the option is not selected.

Example of Identification String: "HYDRA,ECF/ICF,1.00,1.02,MEM"

#J   Let HYDRA send status byte to host

To HYDRA: '#', 'J'.

From HYDRA: *status_byte*.

Description : Let HYDRA send back a byte represent current status. The following is format of status_byte:

Bit 7-4:   not used.

Bit 3:   flag in HYDRA for sending raw frequency data to host. RESET(0) means "do not send", and SET(1) means "send".

Bit 2:   flag in HYDRA for sending modeled data to host. RESET(0) means "do not send", and SET(1) means "send".

Bit 1:   flag in HYDRA for sending volume data to host. RESET(0) means "do not send", and SET(1) means "send".

Bit 0:   HYDRA running status. 1 means HYDRA is measuring, and 0 means HYDRA is in data entry mode.

#K   Let HYDRA send user entered data to host

To HYDRA: '#', 'K'.

From HYDRA: *case_number*, *measurement_mode, gender, height, weight, segment_length, circumference1, circumference2, ecf_resistivity, icf_resistivity*.

Description : HYDRA will send above user entered or selected parameters back to host. Where, *case_number* is in 4 byte unsigned long int format, *Measurement_mode* is a byte (see description of command #A for details), *gender* is a byte (see description of command #B for details), *height*(cm), *weight*(Kg), *segment_length*(cm), *circumference1*(cm), *circumference2*(cm), *ecf_resistivity*(Ohm.cm), and *icf_resistivity*(Ohm.cm) are 4 bytes *IEEE Standard for Binary Floating-Point Arithmetic* format. All will be sent back in MSB first.

#L   Flip send raw frequency data flag in HYDRA

To HYDRA: '#', 'L'.

From HYDRA: None.

Description: This command will change the status of the send raw frequency data flag from SET to RESET, or from RESET to SET. When the flag is SET, HYDRA will send raw frequency data consist of all frequencies(KHz) and their corresponding impedance(Ohm), phases(Degree) just been measured to host every time HYDRA completed a measurement (In mode 2 through 6, 20 sets of raw frequency data will be sent to host and in mode 7 through 13, 50 sets will be sent, see SPECIFICATION for detail of measurement). Impedance, and phases are in 4 bytes *IEEE Standard for Binary Floating-Point Arithmetic* format. Frequencies are in 2 byte unsigned int format. They all will be sent back MSB first.

Note: If it is single measurement(not continuous), all send data flags will be set to RESET automatically after HYDRA completed the measurement and sent data.

Note: If any of the three flags: send raw frequency data flag, send modeled data flag, and send volume data flag, are SET, then HYDRA will send back measurement time first (seconds past since midnight of the day), preceding al other measurement data. The measurement time is in 4 bytes IEEE Standard for Binary Floating-point Arithmetic format, accurate to hundredth second, and will be sent back MSB first..

#M   Flip send modeled data flag in HYDRA
To HYDRA: '#', 'M'.
From HYDRA: None.
Description :   This command will change the status of the send modeled data flag from SET to RESET, or from RESET to SET. When the flag is SET, HYDRA will send modeled data just been measured to host every time HYDRA completed a measurement. The modeled data been send back are measurement mode dependent. If measurement mode is 2, 3, 4, 5, or 6, then modeled data will consists of Re(Ohm) only. If measurement mode is 7, 8 , 9, 10, 11, 12, or 13, then modeled data will consists of Re(Ohm), Ri(Ohm), Cm(nF), alpha, Td(nS), Fc(KHz). (see appendix Modeling for detail about these modeled data). All modeled data are in 4 bytes *IEEE Standard for Binary Floating-Point Arithmetic* format, and will be sent back MSB first.

Note: If it is single measurement(not continuous), all send data flags will be set to RESET automatically after HYDRA completed the measurement and sent data.

Note: If any of the three flags: send raw frequency data flag, send modeled data flag, and send volume data flag, are SET, then HYDRA will send back measurement time first (seconds past since midnight of the day), preceding al other measurement data. The measurement time is in 4 bytes IEEE Standard for Binary Floating-point Arithmetic format, accurate to hundredth second, and will be sent back MSB first..

#N   Flip send volumes flag in HYDRA
To HYDRA: '#', 'N'.
From HYDRA: None.
Description: This command will change the status of the send volume data flag from SET to RESET, or from RESET to SET. When the flag is SET, HYDRA will send volume data just been measured followed by a byte contain information about event mark if in continuous mode to host every time HYDRA completed a measurement. The volume data been send back are measurement mode dependent. The following are volume data will be send back corresponding to measurement mode(see description of command #A for details about measurement mode).

Measurement Mode	Volume data will be send back
2, 5, 6	ECF (Liter)
3, 4	ECF, UF (Liters)
7	ECF (Liter), ICF (Liter), FFM (Kg)
8, 9	ECF, ICF, UF (Liters)
10, 11	ECF, ICF (Liters)
12, 13	ECF_ICF_Ratio

All volume data are in 4 bytes *IEEE Standard for Binary Floating-Point Arithmetic* format, and will be sent back MSB first. If measurement is continuous, HYDRA will send a byte to host after all volume data been sent. The byte will be 1 If the measurement just completed was marked. Otherwise it will be 0.

Note: If it is single measurement(not continuous), all send data flags will be set to RESET automatically after HYDRA completed the measurement and sent data.

Note: If any of the three flags: send raw frequency data flag, send modeled data flag, and send volume data flag, are SET, then HYDRA will send back measurement time first (seconds past since midnight of the day), preceding al other measurement data. The measurement time is in 4 bytes IEEE Standard for Binary Floating-point Arithmetic format, accurate to hundredth second, and will be sent back MSB first..

#P   Reset all three "send" flags
To HYDRA: '#' , 'P'.
From HYDRA: None.
Description: Reset all three flags: send raw frequency data flag, send modeled data flag, and send volume data flag to RESET status.

#O   Mark event in HYDRA
To HYDRA: '#', 'O'.
From HYDRA: None.
Description: Mark current measurement if in continuous mode. The mark will be reflect in print out and will be send to host if the send volume data flag is SET.

#R   Upload all stored data from HYDRA memory storage to host
To HYDRA: '#', 'R'.
From HYDRA: *number of records*, all *data records*.
Description: If the device does not have memory storage option or there is no data record in memory storage, HYDRA will send back a byte: 0. If the device does have memory storage option and there are data stored in memory storage, then HYDRA will send back a byte: total number of data records stored in memory and will be transfer to host, followed by all data stored in memory storage. A data record stored in memory storage has 92 bytes data in it and has the following format:

Case number	4 bytes unsigned long int
Date	9 bytes characteristic string
Time	8 bytes characteristic string
Model Fit Status	1 byte
Measurement Mode	1 byte
Gender	1 byte
Height (cm)	4 bytes Floating-Point Arithmetic format
Weight (cm)	4 bytes Floating-Point Arithmetic format
Segment Length (cm)	4 bytes Floating-Point Arithmetic format
Circumference 1 (cm)	4 bytes Floating-Point Arithmetic format
Circumference 2 (cm)	4 bytes Floating-Point Arithmetic format
ECF Resistivity (ohm.cm)	4 bytes Floating-Point Arithmetic format
ICF Resistivity (ohm.cm)	4 bytes Floating-Point Arithmetic format
ECF (Liter)	4 bytes Floating-Point Arithmetic format
ICF (Liter)	4 bytes Floating-Point Arithmetic format

Re (Ohm)	4 bytes Floating-Point Arithmetic format
Ri (Ohm)	4 bytes Floating-Point Arithmetic format
Cm (nF)	4 bytes Floating-Point Arithmetic format
Alpha	4 bytes Floating-Point Arithmetic format
Td (nS)	4 bytes Floating-Point Arithmetic format
Fc (KHz)	4 bytes Floating-Point Arithmetic format
FFM (Kg)	4 bytes Floating-Point Arithmetic format
Check Sum	4 bytes unsigned long int

Where, Check Sum is result of adding up of all bytes in data record except itself, and used to check the data record's integrity. 0 for Gender means male, and 1 means female. 0 for Model Fit Status means "Excellent Fit", 1 means "Good Fit", 2 means "Marginal Fit", 3 means "Questionable fit - USE WITH CAUTION", and 4 means "COULD NOT OBTAIN A VALID FIT - DO NOT USE RESULTS." All float data are in 4 bytes IEEE Standard for Binary Floating-Point Arithmetic format and all data will be sent to PC MSB first.

#S	Clear memory storage in HYDRA (erase stored data)
To HYDRA:	'#', 'S'.
From HYDRA:	None.
Description :	This command is effective only if the device has memory storage option. It will erase all data stored in memory storage memory

#U	Let HYDRA start new measurement or stop measuring
To HYDRA:	'#', 'U'.
From HYDRA:	None.
Description:	If HYDRA is in measuring, the command will stop it. Otherwise the command will let HYDRA start a new measurement.

#V	Let HYDRA continue previous measurement from STOP
To HYDRA:	'#', 'V'.
From HYDRA:	None.
Description :	This command is effective only when HYDRA is in "Data Entry" mode and patient data have not been changed. It will let HYDRA to continue previous measurement if the measurement mode is continuous, or start another single measurement.