AVOXimeter 1000E

Operator's & Service Manual

*Whole-Blood Oximeter**

* U.S. Patent No. 6,262,798; 6,519,025; 5,430,542; and other U.S. and foreign patents pending

Table of Contents

List of Specific Precautions

1. This instrument is intended for use by persons trained in health care delivery and should be used only by authorized personnel.

2. Operator should be thoroughly familiar with the information in this manual before using the instrument for diagnostic purposes.

3. This instrument should not be used in the presence of flammable agents or anesthetics.

4. For continued protection against fire, replace wall transformer only with the model provided by A-VOX Systems.

5. Do not allow blood, water, or other liquids to enter the instrument itself.

6. Cuvettes are not sterile. Blood exposed to the cuvette should not be returned to the patient.

7. Do not re-use the cuvettes; discard after each use.

8. **Always keep cuvettes in sealed bag with desiccant.**

9. For proper calibration and calibration verification, use only the controls recommended in this manual. Controls from other sources yield erroneous results.

10. Operator should take appropriate precautions when handling potentially infectious blood samples.

11. To minimize the hazard of electrical shock, connect the wall transformer only to a properly grounded outlet.

12. Do not leave a cuvette in the oximeter. Remove the cuvette as soon as the sample has been analyzed.

13. **When filling cuvette, do not use excessive pressure or cause the vent patch to bulge outward.**

Introduction

The *AVOXimeter 1000E* quickly measures the oxyhemoglobin fraction, the total hemoglobin concentration, and the oxygen content in a sample of whole blood in a disposable cuvette. This advanced, microcomputer-based oximeter was designed to outperform earlier whole-blood oximeters and to overcome their limitations. The AVOXimeter has few moving parts, requires almost no maintenance, and has other features to enhance its use in the cardiac catheterization laboratory.

Traditional oximeters determine the optical absorbance of blood to obtain a measure of the percentage of hemoglobin saturated with oxygen. Invasive cardiologists use such measurements chiefly for two purposes: 1) to detect intracardiac and great-vessel shunts, and 2) to compute cardiac output by the Fick Principle. Unlike earlier whole-blood oximeters, the AVOXimeter measures both total hemoglobin concentration and oxyhemoglobin fraction. From these measured quantities, it then automatically computes the oxygen concentration ($[O_2]$).

No sample preparation is required. Analysis is quickly accomplished by injecting the sample into a disposable cuvette and inserting the cuvette into the instrument. The AVOXimeter then illuminates the sample with multiple wavelengths, records the optical density of the sample at each of the wavelengths, and computes the results. In less than 10 seconds, the oxyhemoglobin fraction, the total hemoglobin concentration, and the oxygen content of the sample are shown in appropriate units on the liquid-crystal display on the front panel.

The total hemoglobin concentration measured by the *AVOXimeter 1000E* includes oxy-, deoxy-, met-, and carboxyhemoglobin: $[THb] = [HbO_2] + [Hb] + [MetHb] + [HbCO]$. Similarly, the percentage of oxyhemoglobin reported by the AVOXimeter is the so-called fractional saturation:

$$\%HbO_2 = \frac{[HbO_2] \cdot 100}{[HbO_2] + [Hb] + [MetHb] + [HbCO]}$$

The oxygen content of the sample is $[O_2] = 1.39 \bullet THb \bullet \%HbO_2 / 100$, if dissolved oxygen is ignored, THb is expressed in g/dl, and $[O_2]$ is expressed in ml/dl.

In addition to measuring the total hemoglobin concentration and automatically computing the oxygen content of the sample, the *AVOXimeter 1000E* has the following advantages over conventional whole-blood oximeters: 1) high sample through-put, 2) accuracy unaffected by carboxy- or methemoglobin, 3) small sample volume (50 µl) for low blood loss, and 4) commercially available material for quality control and proficiency testing. A calculator feature enables the operator to perform many common hemodynamic computations that are done routinely during cardiac catheterization. Examples are body surface area, cardiac output, saturation "step-ups", etc. The AVOXimeter's data management features help maintain regulatory compliance.

Getting Started

Chief Features

Each AVOXimeter is calibrated at the factory and ready for immediate use. To put your AVOXimeter to use as soon as possible, follow the brief directions on "Routine Analysis of Blood Samples" (page 8). Before using the instrument for clinical purposes, consult the section in this manual on "Calibration and Quality Control" (page 31) and see the "List of Specific Precautions" (page 3). The rear panel (not shown) has sockets for connecting the wall transformer and an external printer.

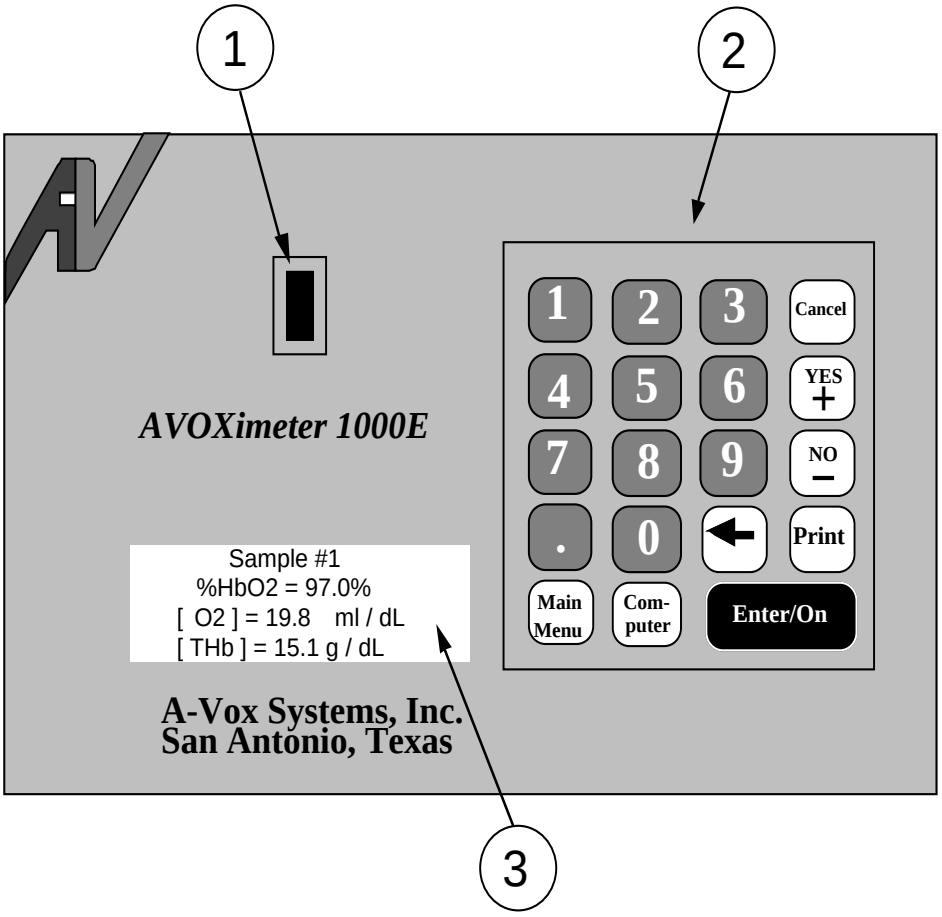
Front Panel

(1) Slot for cuvette insertion.

(2) Keypad for data entry.

(3) Liquid-crystal display or LCD.

The display has four lines, each with 20 characters.



GETTING STARTED (CONTINUED)

Installation

1. Place the *AVOXimeter 1000E* on a laboratory bench away from drafts and bright lights.

2. Plug the wall transformer (battery charger) into an appropriate electrical outlet (domestic model: 110 VAC, 50-60 Hz; export model: 220 VAC, 50-60 Hz).

3. Place the box of disposable cuvettes next to the instrument and keep it there at all times.

4. Turn on the instrument by holding down the **Enter/On** key.

5. Observe the liquid-crystal display (LCD) on the front panel.

6. Upon power-up, the *AVOXimeter 1000E* executes a self-test to confirm the proper operation of its light sources. If the self-test fails, the *AVOXimeter* will assist you in diagnosing the problem. For additional help, consult the "Troubleshooting" section of this manual or call the factory.

7. If you wish to set the correct time and date, press the **Computer** key and select choice "3. Time, Date, Battery". Then select choices 1 & 2 as shown on the flowchart on page 12.

8. If the *AVOXimeter 1000E* passes the self-test and the daily quality-control check (page 31), it is ready to analyze blood samples.

9. You may turn the AVOXimeter off by selecting "4. Turn Off" under the Main Menu. The AVOXimeter may also be turned off by pressing the **Cancel** and **Main Menu** keys simultaneously.

Sample Collection

1. The National Committee for Clinical Laboratory Standards (NCCLS) states that blood samples for blood gas measurements can be collected and kept in plastic syringes for up to 30 minutes at room temperature. If longer storage times are necessary, the NCCLS recommends glass syringes on ice (page 10 of C46-A; also see H18-A2). The AVOXimeter can analyze 6 samples per minute, so there is usually no need to store the samples before analyzing them.

2. Sodium or lithium heparinate and EDTA are the anticoagulants of choice. Citrate is known to change the pH of the blood and cause errors in spectrophotometric measurements. Similarly, fluoride/oxalate should be avoided. Anticoagulants are not necessary if the sample is analyzed immediately after it is drawn and in less than one minute after the cuvette is filled (Bailey, et al., *J Clin Monit Comput* 1997;13: 191-8.). If an anticoagulant is placed into the collection syringe, be aware that excessive volumes of anticoagulant can cause dilution errors.

3. When drawing blood samples from a saline-filled catheter, withdraw the saline first and make sure that only whole blood is sampled. Allowing the sample to be diluted with saline could possibly oxygenate the sample and will definitely induce dilution errors in the measurement of total hemoglobin concentration.

4. Keep each syringe containing a blood sample tightly sealed, and roll the syringe between your palms to keep the red blood cells and plasma well mixed.

5. To fill a cuvette, attach a disposable cuvette to the luer tip of the syringe. Point the cuvette downward at a 45° angle and observe the sample chamber in the cuvette. Press the plunger gently and fill the cuvette. Stop injecting the sample as soon as blood reaches the vent patch. **CAUTION**: Never insert a bloody or dirty cuvette into the instrument. If a cuvette does not fill easily, discard that cuvette and use another one.

6. Leave the syringe attached to the cuvette, and insert the cuvette into the instrument.

7. Remove the cuvette from the instrument as soon as the analysis is complete. Do not leave the cuvette in the oximeter. Although the results disappear from the display when the cuvette is withdrawn, the AVOXimeter stores the results of 100 analyses*. The data are saved permanently, until the 100th sample; then the stored data are replaced beginning with the oldest sample. Stored data can be erased from memory by pressing the **Main Menu** key, selecting choice "3. Stored Data" , then choice "3. Purge All Data". See "Screens under Main Menu Key", page 11.

***Newer circuit boards store readings from 500 samples in memory.**

Routine Analysis of Blood Samples

1. Turn on the AVOXimeter by pressing the **Enter/On** key and confirm that the self-test was successful. The instrument indicates that it is ready to analyze samples by displaying the following message:

READY SCREEN

```
    - - -  R E A D Y  - - -
  I n s e r t   C u v e t t e
P t.    I D :          N o n e
U s e r  I D :         N o n e
```

2. Using appropriate precautions for handling possibly infectious blood, draw a fresh blood sample into a heparinized, plastic syringe.

3. NEVER INJECT BLOOD INTO THE INSTRUMENT ITSELF. Attach a disposable cuvette to the luer tip of the syringe, and inject the blood into the cuvette following the directions on page 9.

4. Observing the cuvette closely, make sure that the light path at the widest portion of the sample chamber is completely filled with blood and that blood reaches the air vent at the opposite end of the cuvette. Proper technique for filling cuvettes is shown on page 9.

5. If any blood is on the exterior surface of the cuvette, wipe it off with gauze.

6. Leaving the syringe attached to the cuvette, and holding the cuvette firmly by its black cap, insert the cuvette into the slot in the front panel of the instrument.

7. Observe the LCD display. Do not disturb the AVOXimeter while it is busy. Within 10 seconds the results will be shown like this:

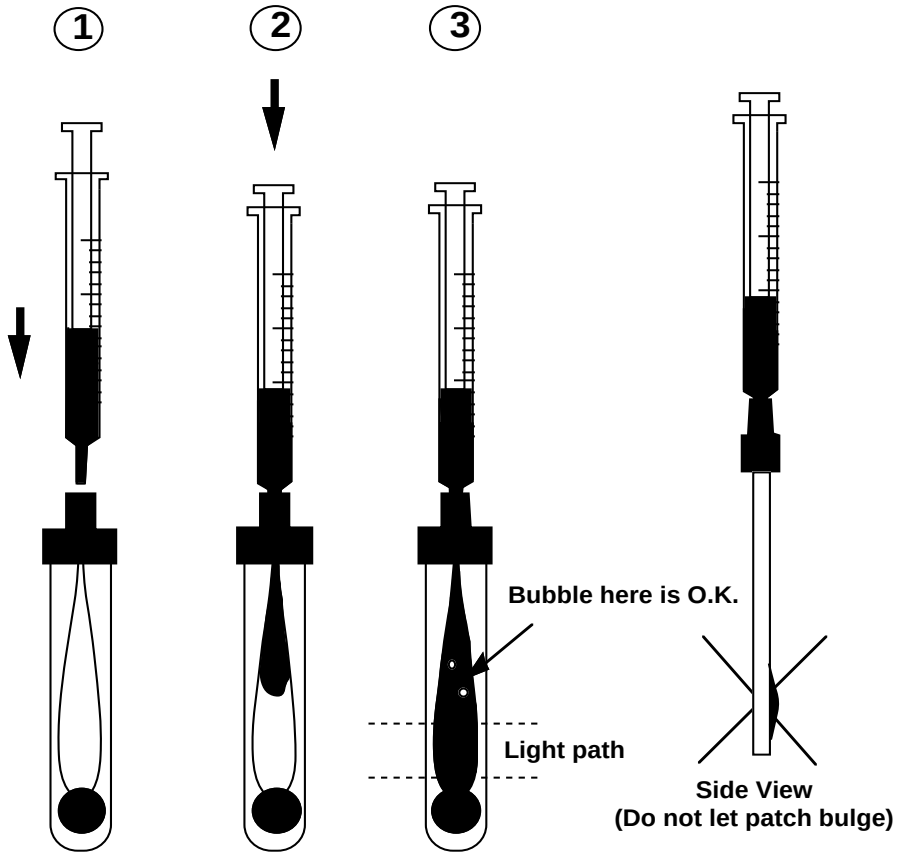
RESULTS SCREEN

```
      S a m p l e   #   1
%H b O 2    =   9 7 . 0 %
[ O 2 ]     =   1 9 . 8 m l / d l
[ T H b ]   =   1 5 . 1 g / d l
```

Withdraw the cuvette as soon as the sample has been analyzed. Data will stay on the display until the cuvette is removed. Data will also stay in non-volatile memory.

8. To analyze the next sample, discard the previously used cuvette, obtain a fresh cuvette from the box next to the instrument, and repeat the previous seven steps.

Correct Cuvette Technique



1. Connect blood-filled, plastic syringe to a new disposable cuvette.

2. Hold cuvette downward at a 45° angle and express blood into cuvette until sample fills cuvette up to the vent patch at the opposite end. **CAUTION: Never force blood into cuvette.** If cuvette does not fill easily, discard it and use another one.

3. Confirm that the light path at the widest portion of the sample chamber is free of debris or air bubbles. Ignore bubbles outside of the light path.

4. Remove any blood on cuvette's exterior surface before inserting cuvette into the AVOXimeter. Do not overpressure the cuvette or cause the vent patch to bulge outward.

5. Using the black cap as a convenient handle, insert cuvette into front panel slot on the instrument. Do not depress plunger while syringe is in the instrument.

6. After the AVOXimeter reports the results of the sample, withdraw cuvette and dispose of it.

7. Do not leave the cuvette in the instrument.

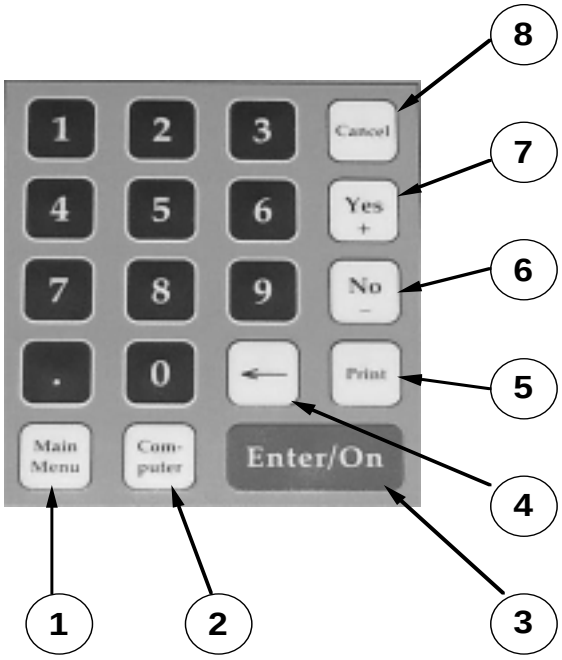
8. **Always keep cuvettes in sealed bag with desiccant.**

Using the keypad, menus and other functions

Data Entry

The routine analysis of blood samples does not require the operator to use the numeric keypad. However, the keypad enables the operator to take advantage of many useful features. To select choices from a menu, press the appropriate number key and then the **Enter** key **(3)**. To give the AVOXimeter data for calibration, press the appropriate number keys: each time a number key is pressed, that number appears on the display. If you make a mistake when entering a number, simply press the **backspace (<-)** key **(4)** to erase the erroneous digit, and enter the correct one. When the complete number has been entered, press **Enter**. If you reach a menu and then decide that you do not want to make a selection from it, the **Cancel** key **(8)** returns to the previous menu or to the normal mode for analyzing samples. To answer a query, use the **Yes/+** key **(7)** or the **No/-** key **(6)**.

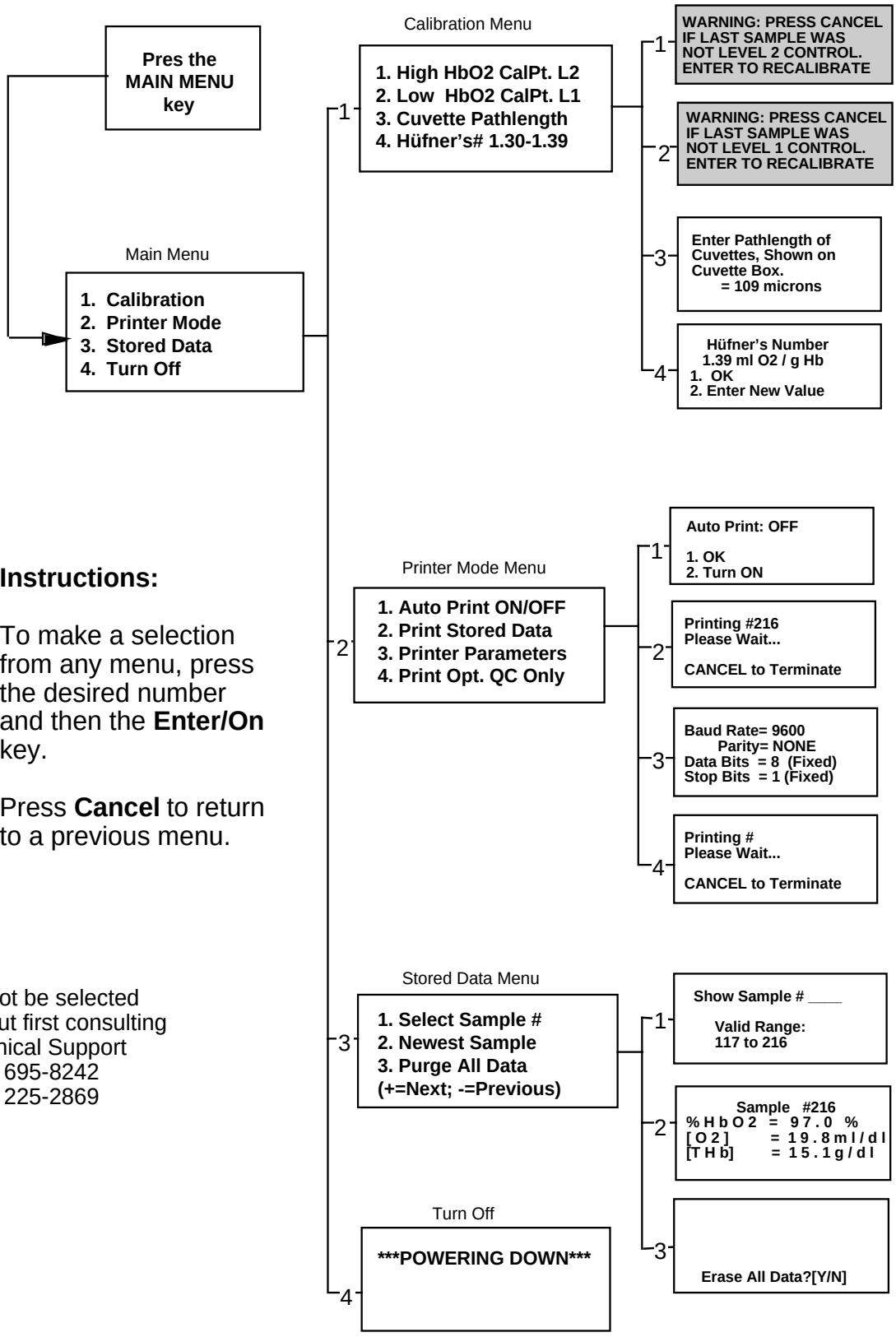
Keypad



Special Function Keys

Three keys have special functions. The **Main Menu (1)** and **Computer (2)** keys interrupt the normal sample analysis mode and display menus for access to other functions. These functions are outlined on pages 11-15. The **Print (5)** key sends sample results to an external printer. Pressing the **Print** key while viewing the READY screen sends the results of the last sample analyzed. For more on printing, see p. 18.

Screens under MAIN MENU key



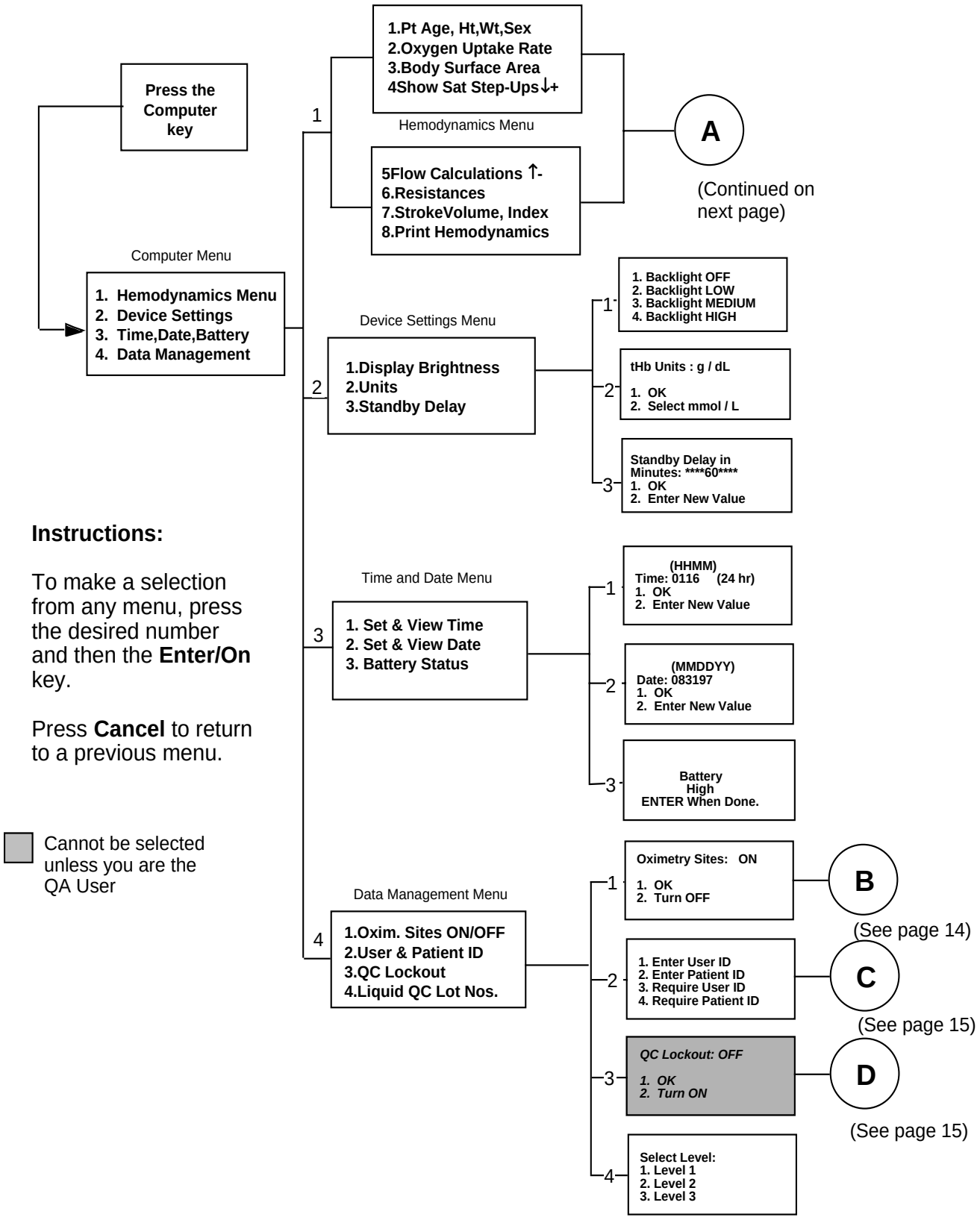
Instructions:

To make a selection from any menu, press the desired number and then the **Enter/On** key.

Press **Cancel** to return to a previous menu.

Cannot be selected without first consulting Technical Support
(210) 695-8242
(800) 225-2869

Screens under COMPUTER key



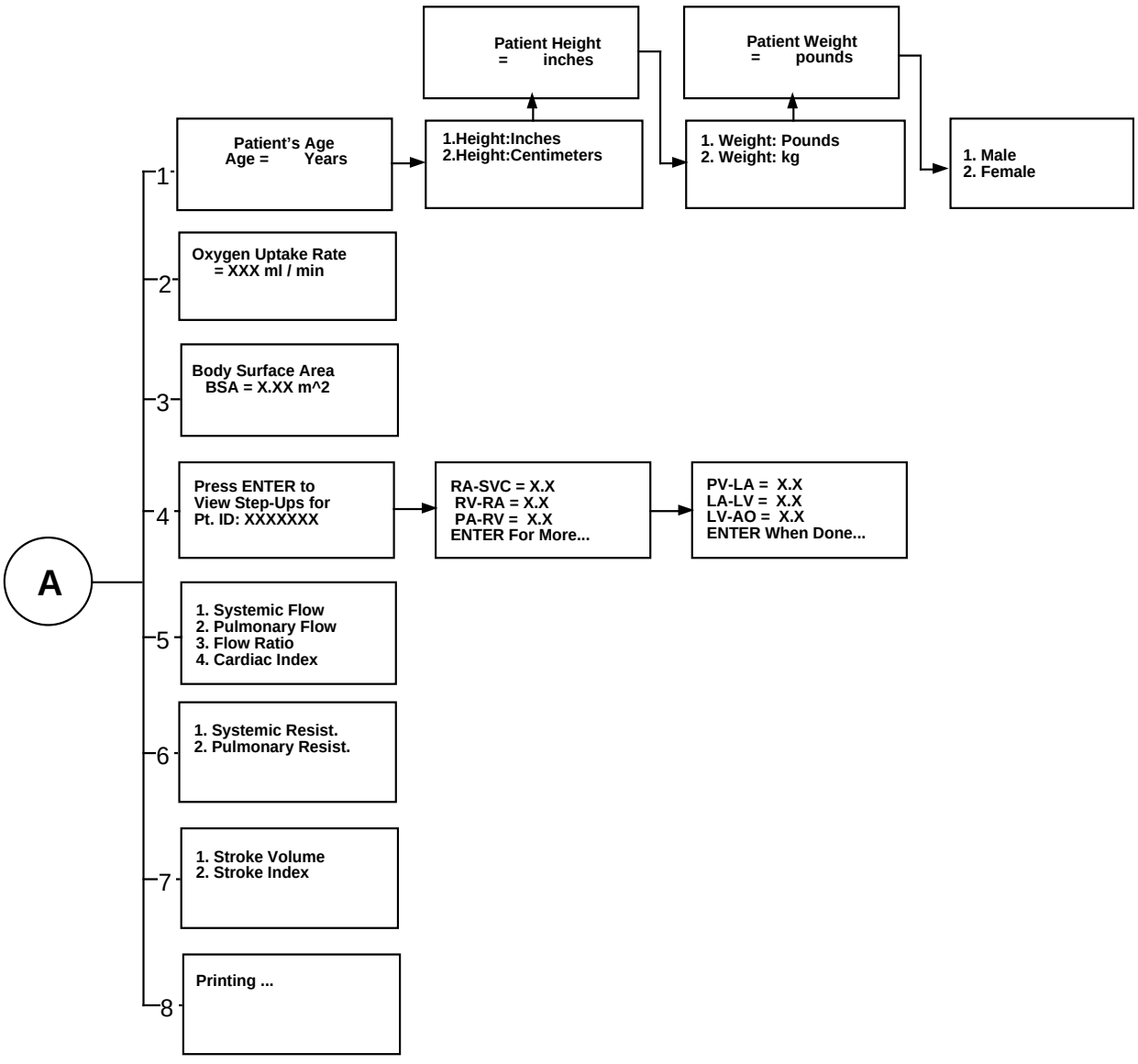
Instructions:

To make a selection from any menu, press the desired number and then the **Enter/On** key.

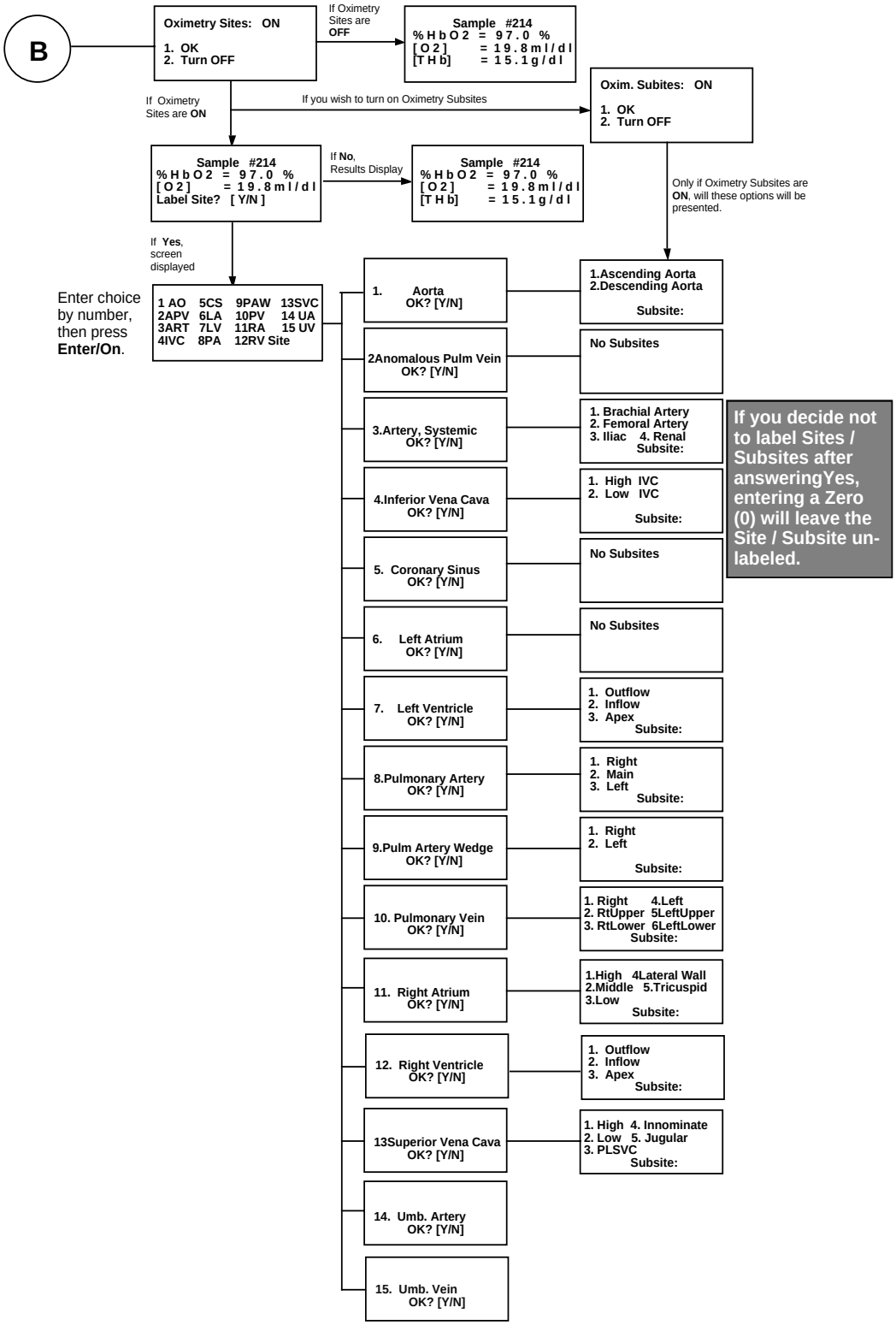
Press **Cancel** to return to a previous menu.

Cannot be selected unless you are the QA User

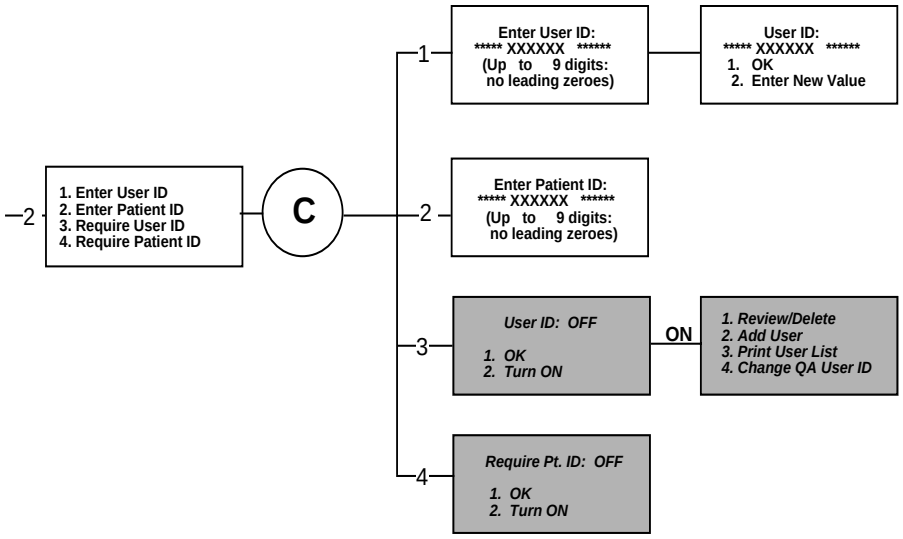
SCREENS UNDER COMPUTER KEY (CONT'D)



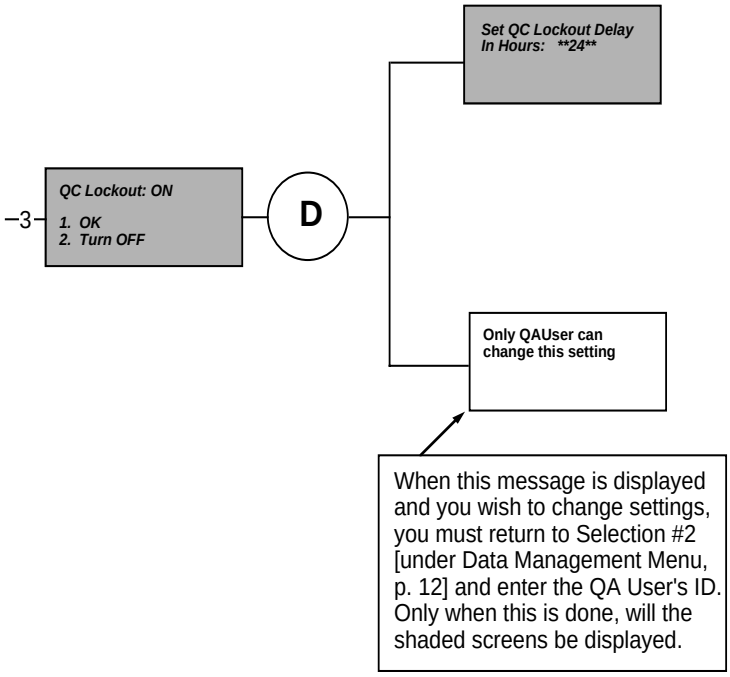
SCREENS UNDER COMPUTER KEY (CONT'D)



SCREENS UNDER COMPUTER KEY (CONT'D)



Cannot be selected unless you are the QA User



When this message is displayed and you wish to change settings, you must return to Selection #2 [under Data Management Menu, p. 12] and enter the QA User's ID. Only when this is done, will the shaded screens be displayed.

Battery Power

Tips on Battery Power

The AVOXimeter can be powered either from its internal batteries or from the wall transformer that serves as a battery charger or AC adapter. Furthermore, it can analyze blood samples and perform all of its other functions using either power source. You can even charge the batteries and analyze blood samples at the same time.

Standby Mode

To maximize the operating time from a battery charge, the AVOXimeter has several modes of operation. When the AVOXimeter is displaying its READY screen, it is in the Sample Analysis Mode. This is the usual mode of operation in which you analyze blood samples, use various menus, print stored data, and so forth. However, if you do not analyze any blood samples or press a key within a specified time, the AVOXimeter will go into Standby Mode to conserve its battery charge.

Standby Mode draws very little power and thus extends the operating time from a battery charge. This mode allows you to minimize the drain on the batteries yet "wake up" the AVOXimeter so that it can quickly resume analyzing samples. You can adjust the Standby Delay from 10 to 180 minutes as follows: press the **Computer** key, select Device Settings, and finally select Standby Delay (see Screens under **Computer** key on page 12). The factory default value for the Standby Delay is 60 minutes (1 hour). Ordinarily, the AVOXimeter will not go into Standby Mode when you are analyzing samples or making menu selections or if the charger is connected. However, if the battery voltage is critically low, the AVOXimeter will immediately go into Standby Mode and will prompt you to plug in the charger. To come out of Standby Mode, hold down any key for approximately one full second.

Automatic Power Down

The AVOXimeter will shut itself off completely if it has been in Standby Mode for 240 minutes (4 hours). You cannot adjust this Power Down Delay.

Getting the Most Use from a Battery Charge

If the batteries are fresh and fully charged, the AVOXimeter can analyze blood samples continuously for up to 8 hours when the display backlighting is set at medium brightness. However, the operating time per battery charge depends on a number of user-selectable factors. The following tips will help you maximize the number of samples that you can analyze from a single battery charge.

1) Turning the display backlighting off will conserve battery energy and thus increase the operating time per battery charge. If the backlight is needed, the LOW backlight setting is the next best choice. Press the **Computer** key and select Device Settings to set the level of backlighting (see Screens under **Computer** key on page 12).

BATTERY POWER (CONT'D)

Getting the Most Use from a Battery Charge (Cont'd)

2) Ni-Cad batteries suffer from a "memory effect" if they are charged before being completely discharged. To get the best use of the batteries, let them discharge completely before charging them. If a screen message says "Battery Critical — Connect Charger", connect the charger and leave it connected for a minimum of 4 hours.

Battery Status and Voltage

You can check the status of the battery by pressing the **Computer** key, then choice "3. Time, Date, Battery", followed by choice "3. Battery Status" (see **Computer** key flowchart starting on page 12). The second and third lines of the display show a battery status message such as High, OK, Low, or Critical. These messages will help you to gauge when the batteries need to be charged. When the battery status becomes critical, the AVOXimeter will immediately go into Standby Mode and will prompt you to plug in the battery charger. Connect the charger and leave it connected for a minimum of 4 hours.

Data Management

Setting Time & Date

If you wish to set the correct time and date, press the **Computer** key and select choice "3. Time, Date, Battery". Then select choices 1 & 2 as shown in the flowchart on page 12 . If QC Lockout is turned on, only the Quality Assurance user (QA User) can change the time and date setting, but other users can view the current time and date.

Printing & Stored Data

Selecting the Printer Mode option from the Main Menu displays the following menu:

1.Auto Print ON/OFF
2.Print Stored Data
3.Printer Parameters
4.Print Opt. QC Only

Auto Print

The AVOXimeter includes a feature to print results automatically following the analysis of each blood sample. Selecting the Auto Print ON/OFF option from the Printer Mode menu displays the current status. Press **Cancel** or select "OK" to leave the status as currently displayed, or change the status to the alternate value.

ON

When Auto Print is ON, the AVOXimeter automatically prints results to an external printer upon completion of sample analysis.

OFF

When Auto Print is OFF, the AVOXimeter prints results only when the **Print** key is pressed.

Print Stored Data

This function prints all results stored in memory, beginning with the most recent sample. Upon selection of the function, the display shows "Printing # XXXXXX", where XXXXXX is the sample number currently printing.

Press the **Cancel** key to stop printing. When **Cancel** is pressed before all samples have been printed, a message will be displayed stating that not all results have been printed.

Printer Parameters

This function configures the serial port for compatibility with an external printer. Both the baud rate and parity can be adjusted. However, the data bits are fixed at 8 and the stop bit(s) are fixed at 1.

When "3.Printer Parameters" is selected from the Printer Mode menu, the currently defined baud rate and parity are displayed. Pressing **Cancel** leaves the values as currently displayed; changes can be made as described below.

DATA MANAGEMENT (CONTINUED)

Baud Rate The default baud rate is 9600 bps. The available baud rates are 110, 300, 600, 1200, 4800, 9600, and 19200 bps

Enter/On • leaves the baud rate as displayed and moves the cursor to the parity value.
Yes/+ • displays the next available baud rate.
No/- • displays the previous available baud rate.

Parity The default parity is NONE. The available parity options are NONE, EVEN, ODD.

Enter/On • leaves the parity as displayed and presents a confirmation screen for both baud rate and parity values.
Yes/+ • displays the next available parity value.
No/- • displays the previous available parity value.

Print Opt. QC Only This function allows you to ignore the patient data stored in memory and to print out only the optical QC readings.

Stored Data

The Stored Data function displays and prints results stored in memory. AVOXimeters can store 100 or 500 readings depending on the amount of memory installed on the circuit board. Upon selection of the Stored Data option from the Main Menu, the following menu is displayed:

1. Select Sample #
2. Newest Sample
3. Purge All Data

(+= Next; -=Previous)

Select Sample # This function allows reviewing and printing selected results by specifying the sample number. The AVOXimeter automatically increments the sample number by one for each new successful sample analysis. The sample number will increment to 999999 before it must be reset. Upon selection of this function, the AVOXimeter displays the currently available range of sample numbers.

Newest Sample This function automatically displays results for the most recent successful sample analysis.

Yes/+ • displays results for the first (oldest) sample stored in the AVOXimeter.
No/- • displays results for the last (newest) sample stored in the AVOXimeter.
Print • prints the results of the currently displayed sample to an external printer.

DATA MANAGEMENT (CONTINUED)

Scrolling Through Data

Once a sample has been selected for viewing, the **Yes/+ (No/-)** key will scroll through the stored data, incrementing (decrementing) the sample number by 1. Pressing **Yes/+ (No/-)** while viewing the newest (oldest) sample will display the oldest (newest) sample.

Result Display

The result display is the same as the display following sample analysis. However, because the result display does not provide information about the sample other than the results of the analysis, the **Enter/On** key toggles between two display modes: results and sample information. If the record is the reading on a blood sample, the display shows the following information:

Line 1:	Sample number and User number.
Line 2:	Patient identification number.
Line 3:	Abbreviated oximetry site, e.g. RA.
Line 4:	Numerical codes for the oximetry site and subsite.

If the record is an optical or liquid QC reading, other appropriate information is shown.

If a sample has the wrong site or subsite label, make certain that 'Oximetry Sites' are enabled (see p. 25); then press the **Backspace** key, while viewing the above sample information screen, to edit the site label for the presently displayed sample.

Printing From Stored Data Menu

To print the results of a previously analyzed sample, first call up the sample results from one of the selections described on p. 19 (e.g. "1. Select Sample #"). Then press the **Print** key. You may press the **Print** key when viewing either the results display *or* the sample information display.

User and Patient ID

To enter a user or patient identification number, press the **Computer** key (e.g. 4. Data Management, → 2. User & PatientID → 1.Enter User ID) [see p. 12.] The User ID may have as many as nine digits, and the Patient ID may have as many as twelve digits. When either ID has been entered, it will be displayed on the READY screen. All samples analyzed will be assigned the currently displayed User and Patient IDs; this includes the case when an ID is displayed as "None". To delete an existing ID and return to the "None" condition, press **Enter** when prompted for the ID.

DATA MANAGEMENT (CONTINUED)

Mandatory User and Patient IDs

To make entry of the User or Patient ID mandatory, the Quality Assurance User, having entered the QA User ID (see below), may turn either feature on as follows: **Computer** key → 4. Data Management → 2.User & Patient ID → 3.Require User ID or 4.Require Patient ID. If 3.Require User ID is turned on, the QA User is immediately admitted to a menu in which secure User IDs may be entered, reviewed, deleted, or printed. This menu may be viewed on p. 15.

Note The User and Patient IDs are reset to "None" each time the instrument is turned on. If Require User ID has been turned on, User ID numbers expire after the instrument has not been used for 15 minutes.

Quality Assurance User and QC Lockout

The AVOXimeter automatically gives a sample number and a time-date stamp to the results of each blood sample before storing the data in memory. To take advantage of the QC Lockout feature or other features controlled by the Quality Assurance User (e.g., making the entry of Patient or User IDs mandatory), one must first enter the QA User ID.

When the unit is shipped to you, the default QA User ID is 123456. In order to register as the QA User, first use the default ID 123456. To enter the default QA User ID, press the **Computer** key, select "4. Data Management", then select "2.User & Patient ID", and finally "1. Enter User ID".

To change the QA User ID, first enter the presently valid QA User ID as just described, and then navigate the menus as follows: **Computer** key → 4. Data Management → 2.User & Patient ID → 3.Require User ID(turn ON) → 4. Change QA User ID.

Note Feature 3. Require User ID must either be on, or it must be turned on, in order to change the QA User ID. If the feature is already turned on, then simply select 1. OK at the screen which displays User ID: ON. If you do not wish to require secure User IDs, go back to 3. Require User ID following the path shown above, and turn this feature off.

Features that can be accessed only by the QA User are indicated by gray boxes in the menus on pages 12 and 15. Additionally, only the QA User may change time or date if QC Lockout is ON.

DATA MANAGEMENT (CONTINUED)

Enabling QC Lockout

The QA User, having entered the QA User ID, may turn QC Lockout on as follows (see p. 12 and p. 15): **Computer** key → 4. Data Management → 3.QC Lockout → 2. Turn ON.

After turning QC Lockout on, or accepting the "on" setting if it is on already, the QA User may then specify the lockout time interval, which prevents users from analyzing samples unless the optical quality-control check is performed within that interval (so-called QC Lockout). Note: Any user may activate the feature for labeling each blood sample with the anatomical site from which it was taken (see page 25).

If you are unable to operate the oximeter because you do not have or cannot remember your User ID, only your QA User can re-authorize your use of the oximeter. If the QA User cannot remember the QA User ID, A-VOX can provide assistance only if the chief of your clinical service, e.g. director of cardiology, faxes a signed, written request to (210) 696-5263.

Hemodynamic Computations

Hemodynamics Menu

The Hemodynamics Menu allows you to use the AVOXimeter for several different purposes. First, if you give the AVOXimeter certain information, it can compute 10 different hemodynamic variables such as body surface area, estimated oxygen consumption rate, and cardiac output. Second, the AVOXimeter can calculate and display the differences in oxygen saturation between adjacent anatomical sites from which blood samples were taken. For example, it can calculate the "step-up" in saturation between the right ventricle and pulmonary artery (see p. 13). Third, if a printer is connected, the AVOXimeter can print out a report of the hemodynamic values that you have calculated.

To reach the Hemodynamics Menu, first press the **Computer** key. Then select Choice 1 on the Computer Menu. The Hemodynamics Menu is actually a double menu with a total of eight selections. The first four lines look like this:

```
1. Pt Age, Ht, Wt, Sex
2. Oxygen Uptake Rate
3. Body Surface Area
4 Show Sat Step-Ups ↓+
```

The next four lines look like this:

```
5 Flow Calculations ↑–
6. Resistances
7. StrokeVolume, Index
8. Print Hemodynamics
```

To switch back and forth between these two screens, press the **Yes/+** or **No/-** key. To return to the normal sample analysis mode, press **Cancel** repeatedly until you reach the READY screen.

HEMODYNAMIC COMPUTATIONS (CONTINUED)

Option 1 in the Hemodynamics Menu allows you to inform the oximeter of your patient's age, height, weight, and sex. These data are used to compute your patient's body surface area and an estimated rate of oxygen consumption. Options 2 and 3 allow you to see these results and accept them or replace them with other values such as a measured oxygen consumption rate. Note that previously calculated values are retained for use in subsequent calculations. The use of Option "4Show Sat Step-Ups" is described below (see Saturation Step-Ups). To calculate cardiac output and other blood flow values, select Option 5. Option 8 will print out all the hemodynamic values that you have calculated for your patient. The following equations define the hemodynamic variables that the AVOXimeter can compute.

Variable		**Reference**
1. Body surface area (BSA) =	$0.007185 \cdot \text{Weight}^{0.425} \cdot \text{Height}^{0.725}$	DuBois & DuBois
2. Estimated oxygen uptake =	157.3 • BSA + 10 •Sex – 10.5 • ln (Age) + 4.8 (Sex = 1 for males; sex = 0 for females)	Bergstra et al.
3. Cardiac output or Systemic blood flow =	$\frac{\text{O2 Uptake}}{\text{CaO2-CvO2}}$	Kern, p. 132
4. Cardiac index =	$\frac{\text{Cardiac Output}}{\text{Body Surface Area}}$	Kern, p. 109
5. Stroke volume =	$\frac{\text{Cardiac Output}}{\text{Heart Rate}}$	Kern, p. 109
6. Stroke index =	$\frac{\text{Stroke Volume}}{\text{Body Surface Area}}$	Kern, p. 109
7. Pulmonary blood flow =	$\frac{\text{O2 Uptake}}{\text{CpvO2-CpaO2}}$	Kern, p. 132
8. Total systemic resistance =	$\frac{\text{MSAP-MRAP}}{\text{Cardiac Output}}$	Kern, p. 109
9. Total pulmonary resistance =	$\frac{\text{MPAP-MLAP}}{\text{Cardiac Output}}$	Kern, p. 110
10a. Pulmonary-to-Systemic flow ratio = (from flows)	$\frac{\text{Pulmonary flow}}{\text{Systemic flow}}$	Kern, p. 132
10b. Pulmonary-to-Systemic flow ratio = (from saturations)	$\frac{\%Sat_a - \%Sat_v}{\%Sat_{pv} - \%Sat_{pa}}$	Kern, p. 134

HEMODYNAMIC COMPUTATIONS (CONTINUED)

Key

C_aO_2 = concentration of oxygen in arterial blood
C_vO_2 = concentration of oxygen in mixed venous blood
$C_{pv}O_2$ = concentration of oxygen in pulmonary venous blood
$C_{pa}O_2$ = concentration of oxygen in pulmonary arterial blood
MSAP = mean systemic arterial pressure
MRAP = mean right atrial pressure
MLAP = mean left atrial pressure
MPAP = mean pulmonary arterial pressure

Oximetry Site Labels

Each blood sample analyzed by the AVOXimeter is automatically given a sample number, stamped with time and date, and stored in memory. You can also label each sample with the anatomical site from which it was drawn. To use this feature, first press the **Main Menu** key, then select the Stored Data menu, and erase all data in memory by selecting "3. Purge All Data". Then press **Cancel** twice to return to the READY screen, press the **Computer** key, select "4. Data Management", and give the oximeter a patient number (Option 2). Finally, use Option "1.Oxim. Sites ON/OFF" under the "4. Data Management" menu to enable the labeling of oximetry sites.

As the table on the following page shows, there are 15 main oximetry sites, some of which are divided into optional subsites. If the site-labeling feature is turned on, the AVOXimeter will analyze each blood sample in the usual manner, but it will ask after each analysis: "Label Site? [Y/N]". If you press the **Yes/+** key, a menu appears with 15 choices. The site abbreviations and the numeric selections on the menu correspond to those in the table. To ignore a result such as a quality-control reading, press **No/-** in response to the query, or give the sample site label zero (0). If subsites are enabled, entering 0 for a subsite causes the AVOXimeter to ignore the subsite label for that sample.

There are at least two advantages to using the oximetry site labels. First, when the stored data are printed out or transferred to a computer, each blood sample will be labeled with the anatomical site from which it was drawn. Second, if the samples in memory have both a patient number and oximetry site labels, the AVOXimeter can compute and display the so-called saturation step-ups between adjacent sites.

Table 1. Anatomical Site Labels for Blood Samples Analyzed on AVOXimeter

Menu Choice	Abbr.	Main Sites	Optional Subsites					
			1	*2*	*3*	*4*	*5*	*6*
0	-	No site label						
1	AO	Aorta	Ascending	Descending				
2	APV	Anomalous pulm. vein						
3	ART	Artery, systemic	Brachial	Femoral	Iliac	Renal		
4	IVC	Inferior vena cava	High	Low				
5	CS	Coronary sinus						
6	LA	Left atrium						
7	LV	Left ventricle	Outflow	Inflow	Apex			
8	PA	Pulmonary artery	Right	Main	Left			
9	PAW	Pulmonary artery wedge	Right	Left				
10	PV	Pulmonary vein	Right	Right Upper	Right Lower	Left	Left Upper	Left Lower
11	RA	Right atrium	High	Mid	Low	LateralWall	Tricuspid	
12	RV	Right ventricle	Outflow	Inflow	Apex			
13	SVC	Superior vena cava	High	Low	PLSVC	Innominate	Jugular	
14	UA	Umbilical artery						
15	UV	Umbilical vein						

HEMODYNAMIC COMPUTATIONS (CONTINUED)

Saturation Step-Ups

If the blood samples from a given patient have been labeled both with a patient number and with the anatomical sites from which they were drawn, the AVOXimeter can compute and display the differences in oxygen saturation between adjacent sites ("sat step-ups"). This feature is Option 4 of the Hemodynamics Menu. If you select "4Show Sat Step-Ups", the AVOXimeter searches through the results stored in memory and uses all the blood samples that have the current patient number. It then averages all the saturation readings from each main oximetry site (ignoring subsite labels) and shows the differences between the average oxygen saturation readings in the following six pairs of main oximetry sites:

Right atrium – Superior vena cava	(RA –SVC)
Right ventricle – Right atrium	(RV – RA)
Pulmonary artery – Right ventricle	(PA – RV)
Pulmonary vein – Left atrium	(PV – LA)
Left atrium – Left ventricle	(LA – LV)
Left ventricle – Aorta	(LV – AO)

The results shown on the display look like this example:

```
RA-SVC=  7.1
  RV-RA=  2.1
  PA-RV= -0.9
ENTER For More...
```

The most common method for diagnosing intra-cardiac and great-vessel shunts with oximetry is to specify a saturation step-up of a predetermined magnitude as the diagnostic criterion. For example, Baim and Grossman's handbook states that a saturation step-up of 5% or greater between the right atrium and right ventricle indicates the presence of a significant shunt at the ventricular level. When you are using this method, the AVOXimeter can help you exploit the statistical benefits of multiple blood samples by averaging all of the readings from the same oximetry site.

HEMODYNAMIC COMPUTATIONS (CONTINUED)

Accuracy in Hemodynamic Computations

When systemic or pulmonary blood flow is computed in absolute units, e.g. ml/min, the Fick Principle requires oxygen content, not percent oxyhemoglobin saturation. As a convenience, the AVOXimeter automatically computes the oxygen content of each sample as soon as it is analyzed. If one neglects the normally small amount of dissolved oxygen, the oxygen concentration can be calculated from the total hemoglobin concentration (THb) and oxyhemoglobin saturation (%HbO2):

$$[O2] = 1.36 \bullet THb \bullet \%HbO2/100, \qquad \text{Eq. 1}$$

where THb is expressed in g/dl and [O2] is expressed in ml/dl.

Of course, any measurement has some error associated with it, and there are errors in both of the directly measured quantities: THb and %HbO2. Furthermore, these two quantities are multiplied together. Therefore, the computed oxygen content, [O2], contains greater error than either of the two directly measured quantities.

In a given patient, the total hemoglobin concentration is often constant during a cath-lab procedure if nothing is done that could alter THb. For example, if significant volumes of intravenous solutions are not administered and if blood loss is minimal, a series of blood samples taken during a "sat run" are likely to have the same total hemoglobin concentration. Under such conditions, the accuracy of Fick Principle calculations can be improved by averaging three or more of the AVOXimeter's measurements of THb and then using the average THb in Equation 1. This average THb value should then be used to compute oxygen content at each of the sampling sites of interest, e.g. pulmonary artery, pulmonary vein, inferior vena cava, etc.

The common oximetric technique for determining the magnitude of a right-to-left or left-to-right shunt is to calculate the ratio of pulmonary to systemic blood flow. The Fick Principle equation for systemic blood is

$$\text{Cardiac output or systemic flow} = Qs = \frac{O_2 \text{ Uptake}}{[O_2]a - [O_2]v} \qquad \text{Eq. 2}$$

where O2 uptake is measured from the patient's expired gases, and [O2]a and [O2]v stand for the oxygen content of arterial and mixed venous blood, respectively.

HEMODYNAMIC COMPUTATIONS (CONTINUED)

Accuracy in Hemodynamic Computations (Cont'd)

Similarly, the equation for pulmonary blood flow is

$$\text{Pulmonary flow} = Qp = \frac{O_2 \text{ Uptake}}{[O_2]pv - [O_2]pa} \qquad \text{Eq. 3}$$

where [O2]pv and [O2]pa stand for the oxygen content of blood from the pulmonary vein and pulmonary artery, respectively.

Dividing Eq. 3 by Eq. 2 yields the ratio of pulmonary to systemic blood flow.

$$\frac{Qp}{Qs} = \frac{O_2 \text{ Uptake}}{[O_2]pv - [O_2]pa} \times \frac{[O_2]a - [O_2]v}{O_2 \text{ Uptake}} = \frac{[O_2]a - [O_2]v}{[O_2]pv - [O_2]pa} \qquad \text{Eq. 4}$$

Substituting appropriate Eq. 1 expressions into Eq. 4 gives

$$\frac{Qp}{Qs} = \frac{1.36 \text{ THb } [\%HbO_2]a/100 - 1.36 \text{ THb } [\%HbO_2]v/100}{1.36 \text{ THb } [\%HbO_2]pv/100 - 1.36 \text{ THb } [\%HbO_2]pa/100} \qquad \text{Eq. 5}$$

Note that THb appears in all four terms on the right side of Eq. 5. Obviously, considerable error could be propagated into the computed Qp/Qs ratio even if four slightly different measured values for THb were substituted into Eq. 5. In other words, do not insert into Equation 4 the AVOXimeter's readings of the oxygen content of individual samples. Instead, use a common averaged value for THb in all calculations of oxygen content, as previously recommended. Alternatively, the Qp/Qs ratio can simply be calculated from oxyhemoglobin saturations alone since canceling the common terms in Eq. 5 yields

$$\frac{Qp}{Qs} = \frac{[\%HbO_2]a - [\%HbO_2]v}{[\%HbO_2]pv - [\%HbO_2]pa} \qquad \text{Eq. 6}$$

Many authors state that oximetry may fail to detect a small shunt that is less than 20% of the cardiac output. Nevertheless, the simple precautions recommended here can increase the probability of success.

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Calibration and Quality Control

General QC Principles

Because the AVOXimeter employs highly stable state-of-the-art light sources, it does not need to be re-calibrated frequently. In fact, factory tests and extensive clinical use indicate that the AVOXimeter easily maintains its calibration for two or more years. The most frequent cause of error messages or erroneous readings is not loss of calibration but contamination of the optical detector by spilled blood or other debris. Re-calibration cannot solve these problems. Therefore, the Quality Control Procedures are designed to determine quickly and conveniently whether the AVOXimeter's optics have been fouled by spilled blood and to verify that its calibration has not changed.

Quality Control Materials

Two types of materials are used in the Quality Control Program:

1. Cuvette-shaped yellow and orange optical filters and
2. Aqueous CO-Oximeter Controls.

Before your AVOXimeter was shipped to you, it was carefully calibrated at the factory. The yellow and orange optical filters supplied with the AVOXimeter give you a quick and easy way to show each day that the calibration has not changed. These filters also enable you to determine whether the AVOXimeter's optics have been obscured by spilled blood.

The aqueous CO-Oximeter Controls serve as a second method to confirm that the AVOXimeter is operating properly. In addition, they confirm that the cuvettes currently in use are functioning properly.

Quick Calibration Check and Test for Spilled Blood

Each AVOXimeter is equipped with cuvette-shaped yellow and orange optical filters that can be inserted into the instrument to simulate a blood sample of known composition. Each filter has a serial number that matches the serial number of the AVOXimeter with which it is used. A word of caution: if you have two or more AVOXimeters, their optical filters cannot be used interchangeably. Each set of yellow and orange filters can be used only with the AVOXimeter of the same serial number. These cuvette-shaped filters are used for the daily Quick Cal Check which also serves as a Test for Spilled Blood.

CALIBRATION AND QUALITY CONTROL (CONTINUED)

NOTE The quality-control program recommended by Avox consists of 1) daily readings on the yellow and orange optical filters, and 2) weekly readings on one level of liquid control material. For customers in the U.S., Avox can provide a copy of a letter from the College of American Pathologists stating that this QC program satisfies CLIA and CAP requirements.

On each day you plan to use the AVOXimeter for clinical purposes, you should quickly verify that it is properly calibrated. To do so, simply wipe off one of the cuvette-shaped yellow or orange optical filters, and observe that the AVOXimeter is displaying its READY message. Insert the filter into the AVOXimeter, and wait until the readings appear on the display. Then compare your readings with the following table.

	low THb	high THb	low %HbO2	high %HbO2
Yellow filter:	**7.7**	**8.3 g/dl**	**93.5**	**96.5%**
Orange filter:	**16.4**	**17.6 g/dl**	**37.2**	**40.8%**

Your readings should fall within the ranges shown in this table. For example, your THb reading with the yellow filter should be between 7.7 and 8.3 g/dl, and your %HbO2 reading should be between 93.5 and 96.5% with the yellow filter.

If all four readings fall within the ranges shown in the table, your AVOXimeter passes both the Quick Cal Check and the Test for Spilled Blood. However, if any one of the four readings falls outside the acceptable range, your AVOXimeter fails these tests and should not be used for clinical purposes until the problem has been remedied. The most likely cause of failure is blood or other debris obscuring the light detector. The Troubleshooting section contains instructions for cleaning the light detector (pp. 45-46).

CALIBRATION MENU

```
1. High HbO2 Cal Pt. L2
2. Low HbO2 Cal Pt. L1
3. Cuvette Pathlength
4. Hüfner's# 1.30 - 1.39
```

CALIBRATION AND QUALITY CONTROL (CONTINUED)

Cuvette Path-length (THb Calibration)

Each time you receive a new box of cuvettes, it is likely to contain cuvettes with a different optical pathlength from the last box. Therefore, to obtain correct measurements of total hemoglobin concentration (THb), you must inform the AVOXimeter of the pathlength of the cuvettes currently in use. To do so, press the **Main Menu** key, and select option 1 to reach the Calibration Menu. Then select choice "3.Cuvette Pathlength" on the Calibration Menu. When you are prompted to do so, give the AVOXimeter the pathlength value on the bag or box of cuvettes you are currently using, e.g. 98, 103, 110 μm, etc. After you confirm that the value you have entered is correct, the instrument will store a new calibration constant in non-volatile memory and use it in subsequent analyses. When you confirm that the new value for the cuvette pathlength is correct, the AVOXimeter will display a "calibration complete" message. Use the **Cancel** key to return to the sample analysis mode of operation.

Hüfner's Number (The Oxygen Constant)

If you wish to change the constant (k) that the AVOXimeter uses to compute the oxygen content ([O2]) of each sample, e.g. [O2] = k•THb•%HbO2 /100 (where THb is in g/dl and [O2] is in ml/dl), select choice 4 from the Calibration Menu. Values from 1.30 to 1.39 can be used to compute each sample's oxygen content. The default value set at the factory is 1.39. After you confirm the value that you wish to use, the AVOXimeter will return to the Calibration Menu. Use the Cancel key to return to the sample analysis mode of operation.

Sources of Aqueous Controls

The weekly Check with Aqueous Controls can be performed with controls made by RNA Medical and Instrumentation Laboratory. Do not use substitutes; verifying the calibration depends on these particular controls.

Description	Product #
RNA Medical CO-Oximeter Controls (Levels 1, 2, and 3)	RNA CC 527
RNA Medical CO-Oximeter Linearity Kit (Levels 1-5)	RNA CVC 223
IL Multi-4™ CO-Oximeter Control Level 2	IL33142-50
IL Multi-4™ CO-Oximeter Control Level 1	IL33152-50
IL Multi-4™ CO-Oximeter Control Multipak	IL33162-50

Any pool number will do, but ask for "best dating" to assure fresh controls.

To order from RNA Medical, call (508) 263-6162 or (800) 533-6162 or fax (508) 263-2860.

To order directly from Instrumentation Laboratory, call Business Administration at (800) 955-9525. For sources of Multi-4™ CO-Oximeter Controls in other countries, consult Instrumentation Laboratories' International Customer Service Department, 113 Hartwell Ave., Lexington, MA 02173-3190. Phone: (617) 861-4493 or Fax: (617) 862-8964.

Check with Aqueous Controls

The Level 2 Control is used for the weekly Check with Aqueous Controls and can be used to construct the Quality Control Log described later. Hospitals that wish to verify calibration at two different levels of oxyhemoglobin saturation can also use Level 1 Control.

To obtain readings on Aqueous Controls, simply break open a fresh ampule of Level 2 Control, fill a cuvette with this solution, and analyze it just as you would a blood sample (see page 8). Then compare the AVOXimeter's readings with the values shown on the insert sheet or value chart.

NOTE If the AVOXimeter is not listed on the insert sheet, fax the insert sheet for the lot of controls that you are currently using to A-VOX [fax (210) 696-5263]. A-VOX will fill in the values and fax it back to you.

If the AVOXimeter's values for the total hemoglobin concentration and the oxyhemoglobin saturation fall within the upper and lower limits specified on the insert sheet, the AVOXimeter is properly calibrated for both measurements.

Even if the AVOXimeter's readings with Aqueous Controls fall within the acceptable ranges specified on the data sheet, the AVOXimeter can still give spurious readings on whole blood if blood or other debris has gotten onto the light detector. To rule out this possibility, use the yellow and orange filters to perform the Test for Spilled Blood (see p. 31).

CALIBRATION AND QUALITY CONTROL (CONTINUED)

Quality Control Program

To determine with confidence whether an instrument is properly calibrated to accepted standards, you should establish a quality control program and execute it consistently over a period of weeks and months. Such a program makes it easy to spot long-term trends in an instrument's performance and to decide whether an out-of-range result is a cause for concern or just a single aberration. Moreover, accreditation agencies are placing increasing demands on hospital laboratories to establish and maintain quality control programs. The Avox Quality Control Program makes it easy to document your accuracy and satisfy regulatory requirements.

Quality Control Log

The liquid QC part of the Avox Quality Control Program consists of the simple protocol described under Check with Aqueous Controls, a quality control log, and the Level 2 RNA or Multi-4™ CO-Oximeter Controls. The blank quality control log in this manual (p. 38) has spaces for one year of weekly entries and provides spaces for recording the instrument's serial number, the lot number of the Level 2 Controls, and the optical pathlength of the cuvettes. Blank quality control logs can also be downloaded from the Avox website: avoxsystems.com.

Start your Quality Control Log by recording the information about your instrument, the CO-Oximeter controls, and the pathlength of cuvettes currently in use. Then break open a fresh ampule of Level 2 Control, fill a cuvette with it, and take a reading as described under Check with Aqueous Controls. In the data log, plot the AVOXimeter's readings of THb and %HbO2. See the example quality control log in this manual (p. 39).

To Re-Calibrate or Not?

If the AVOXimeter occasionally yields results that are out of range with either blood samples or Controls, the problem could be due to poor technique. For example, cuvettes with smudges, bubbles, fingerprints, or blood smears can cause erratic readings. Likewise, the total hemoglobin reading might be out of the specified range because the AVOXimeter is not informed of the correct optical pathlength from the box of cuvettes you are currently using (see Cuvette Pathlength, p. 33). Similarly, you should check the expiration date on the CO-Oximeter Controls and make sure there is no precipitate in the ampule. The Multi-4™ CO-Oximeter Controls must be kept refrigerated; do not use them if they have been left open to room air or have not been kept refrigerated.

CALIBRATION AND QUALITY CONTROL (CONTINUED)

If the AVOXimeter consistently yields results that are out of range, use the yellow and orange filters to perform the Test for Spilled Blood (see p. 31). If necessary, clean the light detector (see Troubleshooting, pp. 45-46). If the oximeter passes the Test for Spilled Blood, try to rule out all of the previously mentioned sources of error, e.g. bubbles, smudges, etc. If the out-of-range readings on Level 2 Control persist after the detector has been cleaned, make sure none of the previously mentioned sources of error is causing the problem. Then record your readings and what the proper readings should be, and call the factory or your distributor for assistance with re-calibration.

THb Readings Out of Range

If the AVOXimeter's measurements of the total hemoglobin concentration consistently fall outside the range specified for the AVOXimeter on the Level 2 insert sheet, the AVOXimeter is probably not using the correct value for the optical pathlength of the cuvettes. To re-calibrate the measurement of total hemoglobin concentration, follow the procedure Cuvette Pathlength (p. 33) and give the AVOXimeter the value of the optical pathlength shown on the bag or box of cuvettes currently in use. The next most likely cause of out-of-range THb readings is blood or debris on the detector. If giving the AVOXimeter the current cuvette pathlength fails to correct the problem, carry out the Test for Spilled Blood (p. 31), and if necessary, clean the detector (pp. 45-46). The AVOXimeter's measurements of oxyhemoglobin saturation may be correct even if the measurement of the total hemoglobin concentration is not.

%HbO2 Readings Out of Range

If the AVOXimeter's measurements of the oxyhemoglobin saturation consistently fall outside the range specified for the AVOXimeter on the Level 2 insert sheet, use the yellow and orange cuvette-shaped filters to carry out the Test for Spilled Blood (p. 31) and clean the light detector (if necessary). If these steps fail to identify the cause of the out-of-range %HbO2 readings, you may have to call the factory for assistance and re-calibrate the oximeter. The AVOXimeter's measurements of total hemoglobin concentration may be correct even if the measurement of the oxyhemoglobin saturation is not.

If you call the factory, obtain the necessary password, and change the calibration, the optical filters will need to be reset. Factory personnel will help you reset them at the time of re-calibration.

CALIBRATION AND QUALITY CONTROL (CONTINUED)

Choice 1 under the Main Menu Key takes you to the Calibration Menu. If you then select either 1 or 2 in the Calibration Menu, the instrument will request a special password. Thus, the re-calibration procedure is not accessible to the user without factory assistance. To conduct this procedure, call the factory or your distributor to obtain the necessary password and additional guidance. Do not attempt this procedure without first cleaning the light detector and inspecting the aperture that admits light to the cuvette holder. Instructions for doing so are given in the Troubleshooting Section (pp. 45-46).

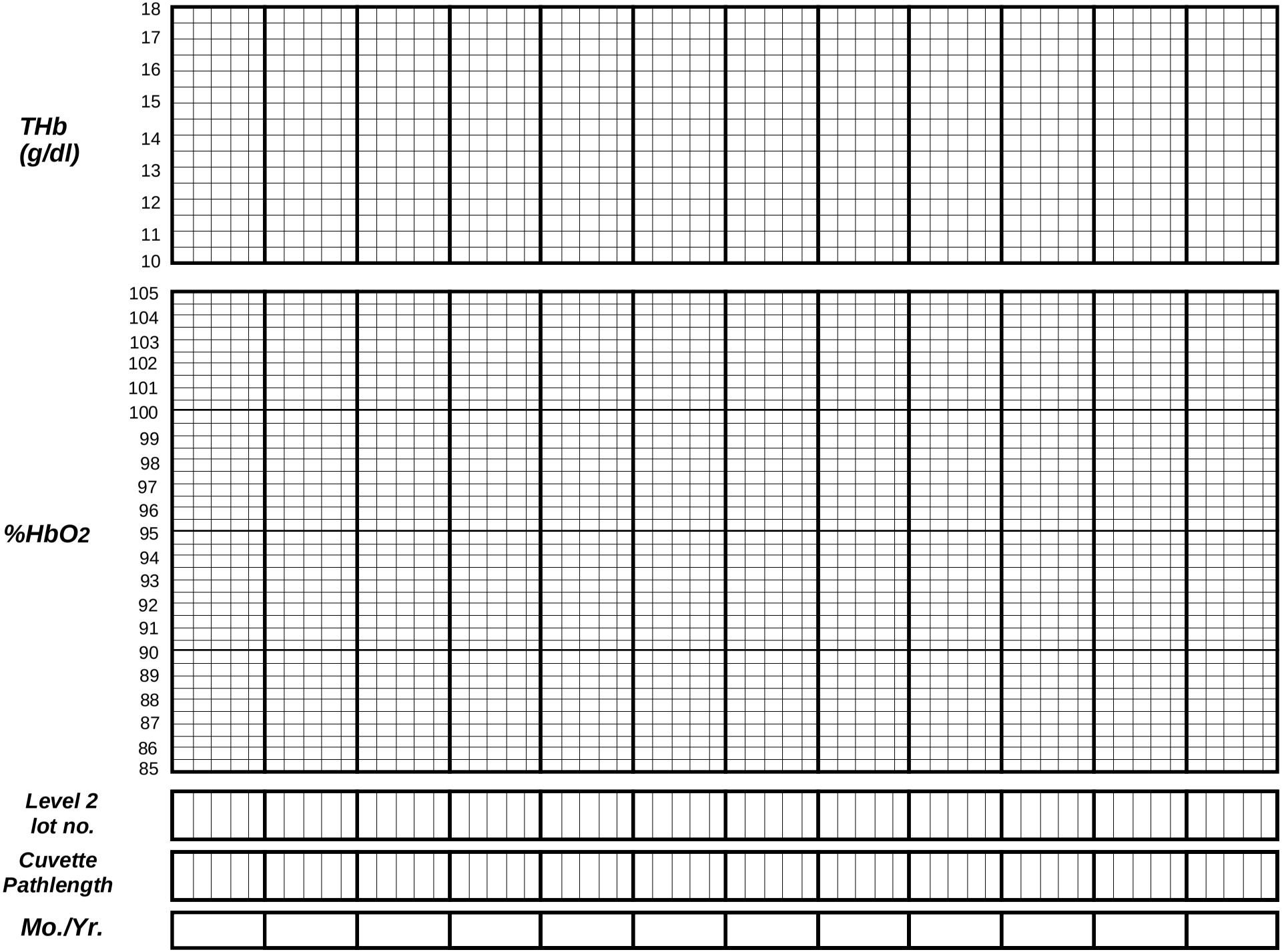
Proficiency Testing

In the United States, hospitals under the Clinical Laboratory Improvement Amendments of 1988 must periodically test the proficiency of the people operating analytical instruments to ensure that the operators can obtain accurate results. At least two organizations provide these materials for the AVOXimeter:

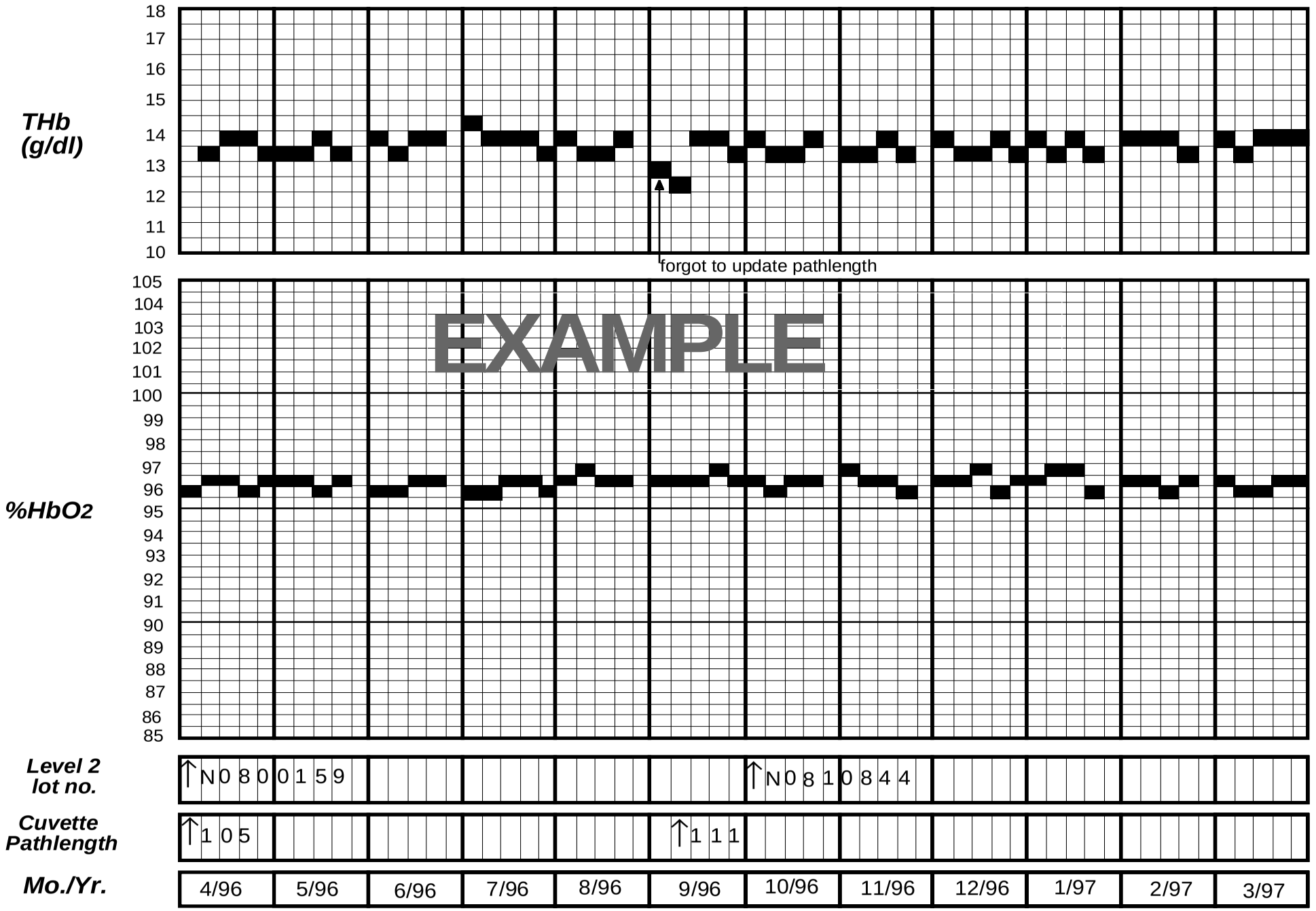
American Proficiency Institute (419 E. 8th St., Traverse City, MI, 49684, tel. 616-941-5887 and 800-333-0958, fax. 616-941-7287; ask for Blood Oximetry, catalog #114-94)

College of American Pathologists (325 Waukegan Road, Northfield, IL, 60093, tel. 708-446-8800 and 800-323-4040; ask for Blood Oximetry "Survey SO")

AVOXimeter 1000 Quality Control ***Serial number_____***



AVOXimeter 1000 Quality Control ***Serial number*** 1234



Theory of Measurement

According to Beer's Law, if several light-absorbing compounds are present in a solution, the concentration of each compound can be deduced if the compounds differ in their optical absorbances and if optical density is measured at as many wavelengths as there are compounds present. For example, if three compounds X,Y, and Z are present and if the optical density (OD) is measured at three different wavelengths (λ), the result is a set of simultaneous equations with as many equations as there are unknown concentrations (c). Thus, if the optical pathlength (ℓ) and the extinction coefficients (ε) are known, the concentrations, c_x, c_y, and c_z can be computed from this set of equations:

$$OD_{\lambda 1} = \varepsilon_{x,\lambda 1} c_x \ell + \varepsilon_{y,\lambda 1} c_y \ell + \varepsilon_{z,\lambda 1} c_z \ell \qquad \text{Equation 1}$$

$$OD_{\lambda 2} = \varepsilon_{x,\lambda 2} c_x \ell + \varepsilon_{y,\lambda 2} c_y \ell + \varepsilon_{z,\lambda 2} c_z \ell \qquad \text{Equation 2}$$

$$OD_{\lambda 3} = \varepsilon_{x,\lambda 3} c_x \ell + \varepsilon_{y,\lambda 3} c_y \ell + \varepsilon_{z,\lambda 3} c_z \ell \qquad \text{Equation 3}$$

Conventional whole-blood oximeters use only two wavelengths to measure the relative concentrations of two hemoglobin species: oxy- and deoxyhemoglobin. Thus, for a conventional whole-blood oximeter, the functional oxyhemglobin saturation is defined as:

$$\%HbO_2 = 100 \cdot \frac{HbO_2}{Hb + HbO_2} \qquad \text{Equation 4}$$

where the total hemoglobin concentration is assumed to consist entirely of oxy- and deoxyhemoglobin. Consequently, if other hemoglobin species such as met- or carboxyhemoglobin are present in substantial concentrations, the conventional two-wavelength oximeter's measurements of %HbO2 suffer from considerable error.

The AVOXimeter 1000E uses multiple wavelengths to obtain accurate measurements of %HbO2 even if bilirubin and four different hemoglobin species are present in the sample. Thus, for the AVOXimeter, the value reported on the display is the fractional saturation (%HbO2) and defined as:

$$\%HbO2 = \frac{[HbO_2]}{[HbO_2] + [Hb] + [MetHb] + [HbCO]} \qquad \text{Equation 5}$$

THEORY OF MEASUREMENT (CONTINUED)

Similarly, the *AVOXimeter 1000E* reports a value for the total hemoglobin concentration that is the sum of the concentrations of oxy-, deoxy-, met-, and carboxyhemoglobin:

$$[THb] = [HbO_2] + [Hb] + [MetHb] + [HbCO] \qquad \text{Equation 6}$$

Conventional whole-blood oximeters do not measure the total hemoglobin concentration because whole blood does not really obey Beer's Law. Whole blood does not simply absorb light; the red blood cells also scatter the light. Thus, conventional oximeters are unable to measure the total hemoglobin concentration accurately. The AVOXimeter makes an assessment of the amount of light scattering in each sample, employs proprietary optics and mathematical algorithms (US Patents 6,262,798 and 6,519,025) to correct its measurements, and thus obtains an accurate measurement of both oxyhemoglobin saturation and the total hemoglobin concentration.

In conventional whole-blood oximeters, the following can constitute major sources of error:

a. hemolysis (which changes the amount of light scattering in the sample),

b. light-absorbing compounds such as bilirubin,

c. other hemoglobin species including carboxyhemoglobin and methemoglobin.

By using additional wavelengths, the AVOXimeter avoids errors due to other hemoglobin species, and by making appropriate corrections for the light scattering in each sample, the AVOXimeter yields accurate measurements regardless of the extent of hemolysis. Thus, the AVOXimeter is capable of analyzing samples of whole blood, partially hemolyzed blood, and even hemoglobin solutions. Finally, at the wavelengths used by the AVOXimeter, bilirubin absorbs almost no light. Thus, bilirubin causes no appreciable error (see Specifications, p 47).

Troubleshooting

SYMPTOM	POSSIBLE CAUSE	REMEDY
AVOXimeter fails to turn on.	1. Battery is discharged and AC adapter is not plugged into AC outlet.	1. Plug wall transformer into AC outlet and into AVOXimeter.
	2. Wall transformer not plugged into back of instrument.	2. Connect power cord to power input jack.
AVOXimeter doesn't respond to cuvette insertion or keypresses.	Microprocessor is "locked up".	Try to turn AVOXimeter off by pressing MAIN MENU and CANCEL simultaneously. Turn the AVOXimeter on again. If this fails, open the case and disconnect the battery for 3 sec, then reconnect the battery and restart the instrument.
Self-Test fails on power-up. "Cuvette Inserted???" shows on LCD screen	1. Cuvette inserted in instrument. If no cuvette is in instrument:	1. Remove cuvette, turn unit off and restart.
	2. Intensities are out of range.	2. At "Cuvette Inserted???" screen, press ENTER, and then press ENTER again for Diagnostic Mode. Press any key and then press YES to re-adjust light sources. When program finishes, turn instrument off and then on.
	3. Cable from detector to circuit board is disconnected.	3. Open cabinet; connect co-axial cable to small circuit board (J1XX) and to optical unit (BNC connector).
	4. No power to LEDs. LED cable may be loose, disconnected or improperly placed on connector at one or both ends.	4. Open cabinet; check multi-colored LED cable. Plug in cable to circuit board (J203) and to optical unit, matching pins correctly.
	5. One or more LEDs is defective.	5. With the power off, use a 9 volt battery and a 200 ohm resistor in series to power the suspected LED directly. If defective, return instrument to factory for service.
External printer not printing.	1. No power to printer.	1. Connect printer to power and turn on.
(Continued on next page)	2. Printer not connected to AVOXimeter.	2. Connect cable both to printer and to AVOXimeter.

TROUBLESHOOTING (CONTINUED)

SYMPTOM	POSSIBLE CAUSE	REMEDY
External printer not printing (cont'd)	3. "Auto Print" mode not selected, or baud rate or parity is wrong.	3. Go to Main Menu, then Printer Mode menu to select printer mode and baud rate. Set baud rate and/or parity on AVOXimeter and on printer to same value (see pages 18-19).
	4. AVOXimeter is locked up, i.e. fails to respond to cuvette insertion or key presses.	4. Turn off printer and AVOXimeter. Turn on printer FIRST and then turn on AVOXimeter. If problem persists, reverse the order turning the AVOXimeter on first, then the printer.
	5. Printer does not respond or prints question marks.	5. See remedy #4 or #3 above.
%HbO2 measurements on blood or Level 2 control are inaccurate.	1. Dried blood or other foreign material may be obscuring part of detector surface (or the aperture through which the light enters the cuvette chamber).	1. & 2. Perform Test for Spilled Blood (p. 31) and clean detector if necessary following instructions at end of this section. If %HbO2 is still inaccurate, write down results obtained, and what results should be, and call factory for assistance in recalibration.
	2. %HbO2 calibration has changed.	
THb measurements on blood or Level 2 control are inaccurate.	1. New box of cuvettes is being used, but cuvette pathlength has not been updated.	1. Follow "Cuvette Pathlength" instructions (page 33).
	2. Incorrect pathlength for current box of cuvettes was entered.	2. Same as above.
	3. Dried blood or other foreign material may be obscuring part of detector surface (or the aperture through which the light enters the cuvette chamber).	3. & 4. Perform Test for Spilled Blood (p.30) and clean detector if necessary following instructions at end of this section. If THb is still inaccurate, write down results obtained, and what results should be. Then call factory for assistance with recalibration.
	4. THb calibration has changed.	
Pulmonary-to-Systemic Flow Ratio (from Computer Menu) is negative, large in magnitude, or otherwise unbelievable.	User has attempted to divide by zero (e.g. by entering equal values for Pulm. Venous and Pulm. Arterial %HbO2), or else has simply entered a wrong value for one of the entered quantities.	Make sure entered values are correct.

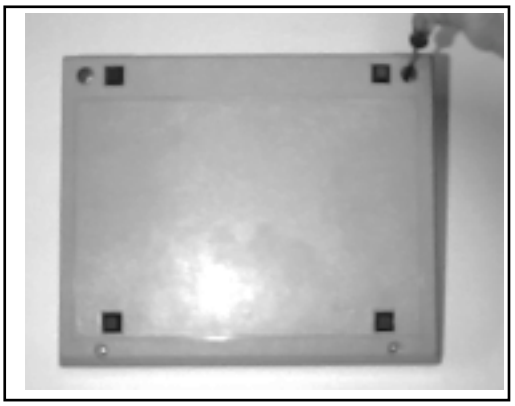
TROUBLESHOOTING (CONTINUED)

SYMPTOM	POSSIBLE CAUSE	REMEDY
Message on LCD Reads: ERROR: %HbO2 <> XX.X% or ERROR: %HbCO<> XX.X% or ERROR: %HbMet<> XX.X% or ERROR: %RHb<> XX.X% or	1. Cuvette inserted with no sample. 2. Cuvette not properly filled. 3. Blood spilled onto detector. 4. LED intensities too low.	1. Fill cuvette with sample. 2. Make sure sample reaches vent patch. 3. Use yellow and orange test filters in "Test for Spilled Blood" (p. 31). 4. Turn off/on to see if Self-Test fails.
ERROR: %Scat<> XX.X%	5. Lipemic Sample	5. No remedy.
ERROR: THb < 4.0 g/dl	THb may actually be low. In this case THb and %HbO2 values are not likely to be accurate.	Not Applicable
ERROR: THb > 25.0 g/dl	THb may actually be high. In this case THb and %HbO2 values are not likely to be accurate.	Not Applicable
THb reading for yellow or orange filter is out of range OR % HbO2 reading for yellow or orange filter is out of range.	1. Dried blood or other foreign material may be obscuring part of detector surface (or the aperture through which the light enters the cuvette chamber). 2. Calibration has slowly drifted over time.	1. Follow directions for opening the instrument and cleaning the detector (pp. 45-46). 2. Call factory for assistance in resetting values for yellow and orange filters.
Message on LCD Reads: "ERROR: Uninitialized Vector Service Required..."	Microprocessor error.	Turn off/on as necessary to restart. If problem is persistent, call factory. If unable to turn instrument off, open instrument case, disconnect battery cable and after 3 seconds, reconnect the cable and restart the instrument.

TROUBLESHOOTING (CONTINUED)

Disassembling the AVOXimeter and Cleaning the Detector

If you suspect that the optical unit has been contaminated with blood, you may clean the detector of the AVOXimeter by following these instructions.

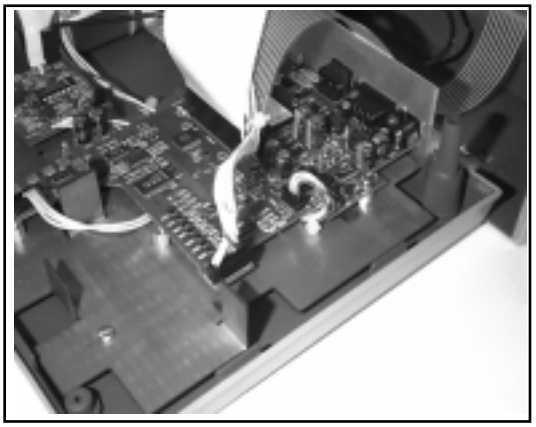


You need the following tools for this procedure:

a. #0 Phillips screwdriver
b. 5mm nutdriver
c. 1/4" nutdriver

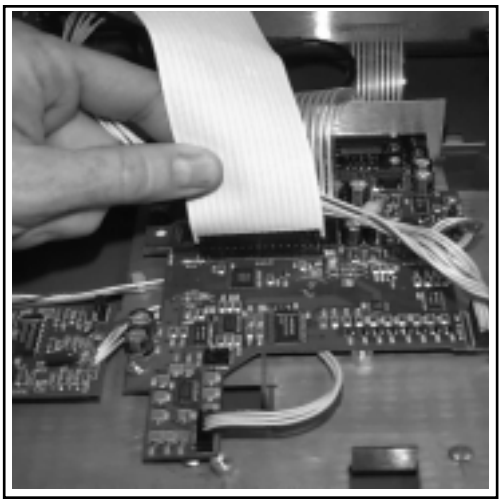
1. Disconnect the wall transformer from the AVOXimeter.

2. Turn the AVOXimeter upside down and remove the four screws using the #0 phillips screwdriver.



3. Hold the upper and lower parts of the case together, and turn the AVOXimeter right side up again with the keypad to your right.

4. Slowly and carefully lift the upper part of the case slightly, keeping it parallel with the lower part.



5. Find the battery cable that runs from the battery pack to the circuit board. Disconnect the battery cable at the circuit board (JP301).

6. Tilt the top half of the case backward to gain access to the front of the circuit board.

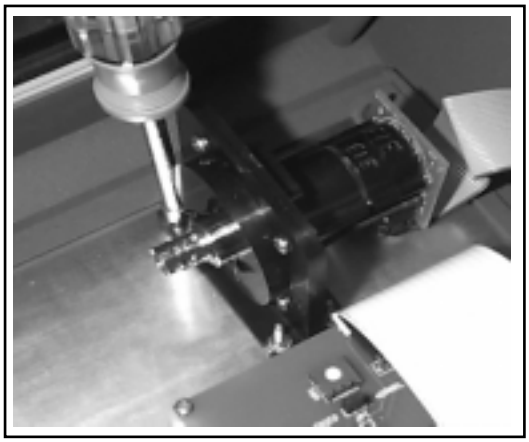
7. Find the flat keypad cable that runs from the keypad to the circuit board. Disconnect the keypad cable at the circuit board (J101).

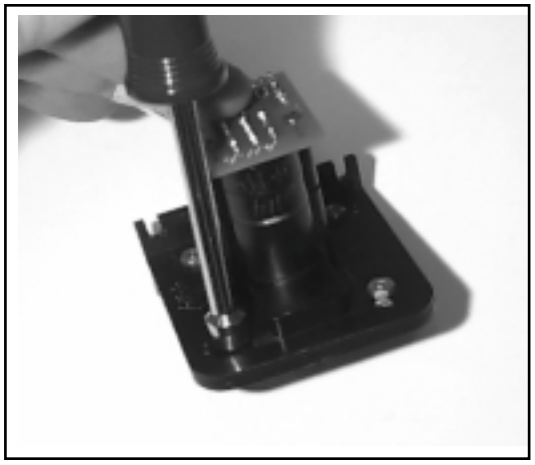
8. Find the flat LCD cable that runs from the LCD to the circuit board (connector J102). Disconnect the LCD cable at the circuit board. CAUTION: Grasp the connector only and gently rock in an upward direction.

9. Disconnect the LED cable that runs from the black optical unit to the circuit board (J203), unplugging it at the circuit board . Disconnect the coaxial detector cable that runs from the black optical unit to the small circuit board (J1XX), unhooking it at the circuit board end.

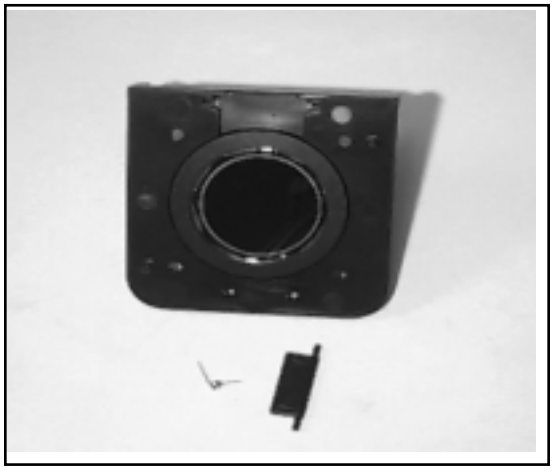
TROUBLESHOOTING (CONTINUED)

10. Now turn the top half of the AVOXimeter's case upside down so that you are looking directly at the black optical unit. Using the 5mm nutdriver, remove the four nuts (and washers, if applicable) that hold the optical unit to the front panel, and completely remove the optical unit from the instrument.

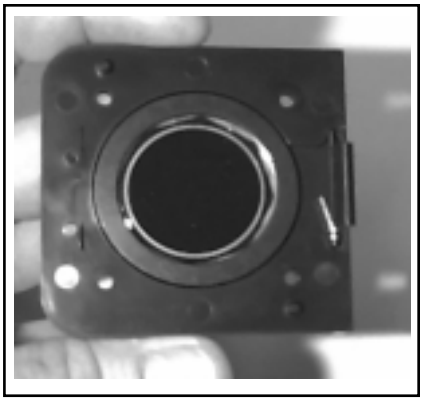




11. Using the 1/4" nutdriver, remove the four screws and four nuts. Take care when separating the two halves of the optical unit. Do not lose the small torsion spring or the shutter door. Set them aside in a safe place for reassembly.



12. Clean the exposed detector with gauze pads dampened with detergent. Do not use abrasives. Then dry off the detector surface, making sure that it is clean. Remove any other debris inside the optical unit.



13. Reassemble the two halves of the optical unit, making sure that the shutter door and torsion spring are installed correctly (the two door ribs will face outward). One leg of the spring fits into a hole in the door slot, the other leg rests behind the shutter door. Bolt the optical unit back together.

14. Reverse steps 1 through 10 to reassemble the AVOXimeter.

15. Turn on the instrument. The AVOXimeter should run its self-test and display its READY screen. **Reset time and date (see Time, Date menu, p.12).**

16. If the AVOXimeter fails its self-test or displays error messages, the most likely cause of the problem is improper re-assembly, particularly cables not connected to the correct pins on their sockets (see Troubleshooting, p 42).

Specifications

Measurements and Operating Ranges

	percent oxyhemoglobin (HbO2)		0 to 100 %
	total hemoglobin concentration (tHb)		4 to 25 g/dl
	oxygen content [O2]		0 to 35 ml O2/dl
Accuracy			
	percent oxyhemoglobin		1 %HbO2
	total hemoglobin concentration	(> 10 g/dl) (< 10 g/dl)	0.45 g/dl 0.35 g/dl
Precision	percent oxyhemoglobin		0.5 %HbO2
	total hemoglobin concentration		0.3 g/dl
Sample			
	type		whole blood
	volume		50 µl
Time per Sample			7 to 10 sec
Number of Wavelengths			5
Calibration			hemoglobin controls
Computed Hemodynamic Variables			10
Data Display			4 lines X 20 characters
Data Input			19-key keypad
Interference			
bilirubin			none
hemolysis			none
carboxyhemoglobin			none
methemoglobin (THb=16g/dl, MetHb<10%, 7.1< pH < 7.8)			<1% HbO2, < 0.2 g/dl THb
fetal hemoglobin (THb=13.5 g/dl, HbF £ 100%)			<1%HbO2, <0.45g/dl THb
Battery			Custom NiCad Pack
Dimensions			10 X 8 X 3.75 inches (25.4 X 20.4 X 9.5 cm)
Weight			4 lbs (1.8 kg)
Serial Port			RS232
Approvals			CE mark [IVD Directive]
			and UL 544

Appendix A

The AVOX Printer

The AVOX printer is a small, convenient thermal printer which attaches to the *AVOXimeter 1000E* via a custom DB9 to RJ11 (modular plug) cable. The printer and cable may be purchased directly from A-Vox Systems.

The AVOX printer is powered by an AC adapter. Do not operate the printer with any adapter other than the one provided by A-Vox Systems, Inc.

INSTALLATION

Connect the cable supplied with the AVOX printer to the printer using the RJ11 modular plug. Connect the DB9 connector to the serial port on the rear panel of the *AVOXimeter 1000E*. Secure the cable with the screws. The baud rates of both the AVOX printer and the *AVOXimeter 1000E* are preset at the factory to 9600 bps. To set baud rates for the *AVOXimeter 1000E*, use the Main Menu to reach the Printer Mode menu.

Pin-Out for the AVOXimeter 1000E Serial Port

The following diagram explains the pin-out for the rear connector (DB9, male) of the *AVOXimeter 1000E* Serial port. The connector is shown as viewed from the back of the instrument.

Pin 1: NC

Pin 2: RXD (Input)

Pin 3: TXD (Output)

Pin 4: DTR (Data Terminal Ready)

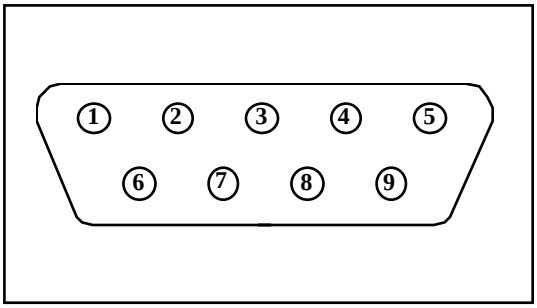
Pin 5: Signal ground

Pin 6: NC

Pin 7: RTS (Ready to Send)

Pin 8: CTS (Clear to Send)

Pin 9: NC



The AVOXimeter will not respond to any incoming signals on pins 1, 6, or 9.

Certification, Warranty and Service

A-VOX Systems, Inc., declares to the original purchaser that each instrument manufactured and sold byA-VOX, or sold by an authorizedA-VOX distributor, shall be free from defects in material and workmanship and, under normal and proper use conditions, warrants it for a period of one year from installation and no more than 13 months from the shipping date, except as otherwise provided in writing.

A-VOX's obligation is limited to repairing, replacing, or modifying (at A-VOX's undisputed judgment) at AVOX's factory, or elsewhere, the material whose defects have been verified, on condition that the purchaser has informed A-VOX of any defects found within 15 days from receipt. Damages caused by or connected to transport are excluded. Transport to and from A-VOX facility will be at purchaser's charge and risk, and shall also be prepaid for reshipment, except as otherwise provided in writing. These replacements, repairs, or alterations will in no case determine extension to the above specified warranty period.

The warranty does not cover those parts that deteriorate, or which are in any case considered consumables, or those parts or "items", which by their nature are normally required to be replaced periodically consistent with normal maintenance. It is also understood that, following the purchase and delivery of the instrument, the purchaser shall be deemed liable for any losses, damages, or complaints concerning persons or things incurred by the use, or misuse of the instrument, on behalf of the purchaser, its employees, co-operators, or others. A-VOX does not assume any obligation or warranty engagement concerning precision and/or accuracy of the measurements, as well as for any damage to the instrument, directly or indirectly resulting from the use of reagents and/or consumables different from those produced by A-VOX specifically for its own instruments, and for the same properly tested.

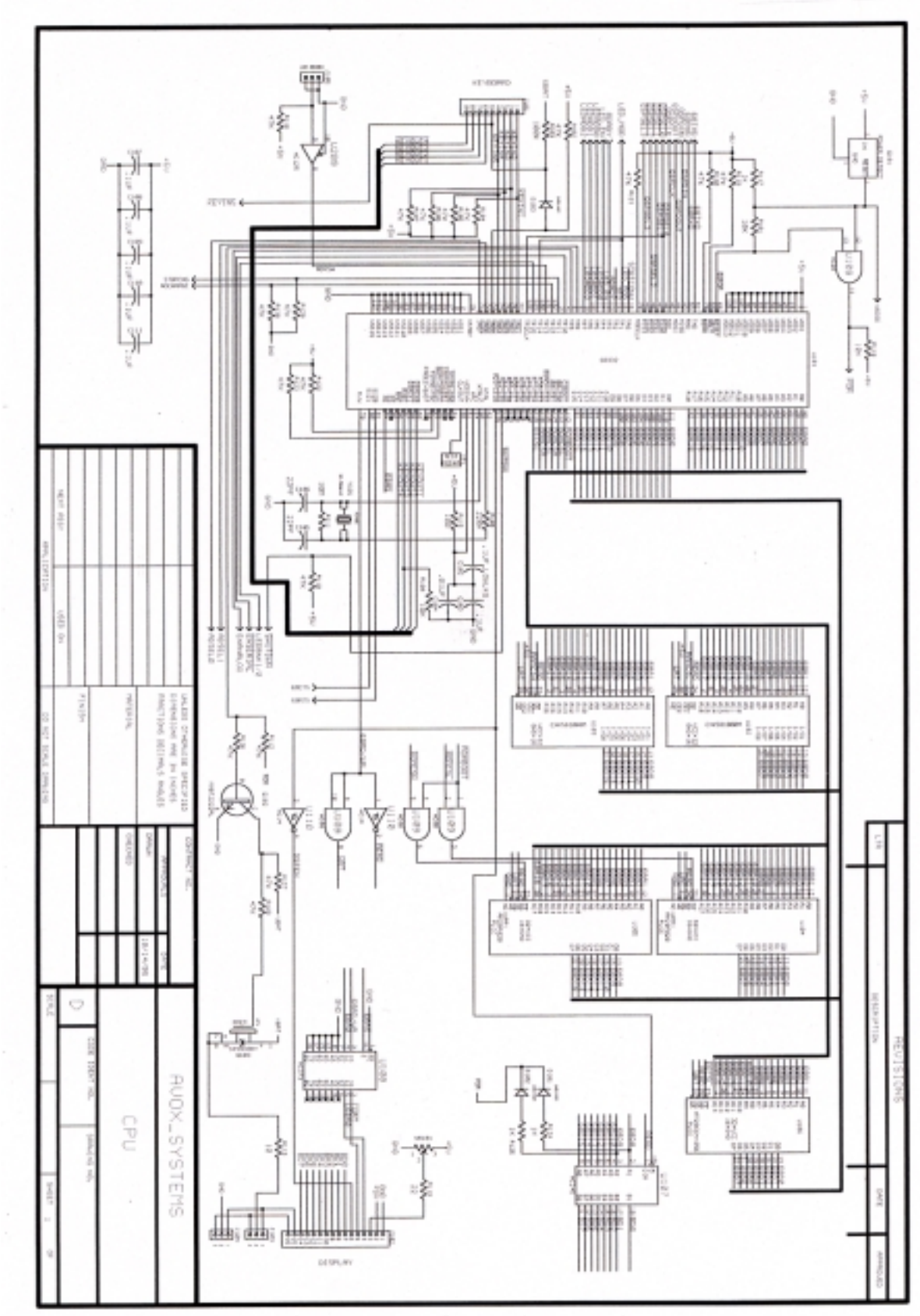
Warranty will not apply to those defective instruments or materials showing defects or damage arising from the following causes:

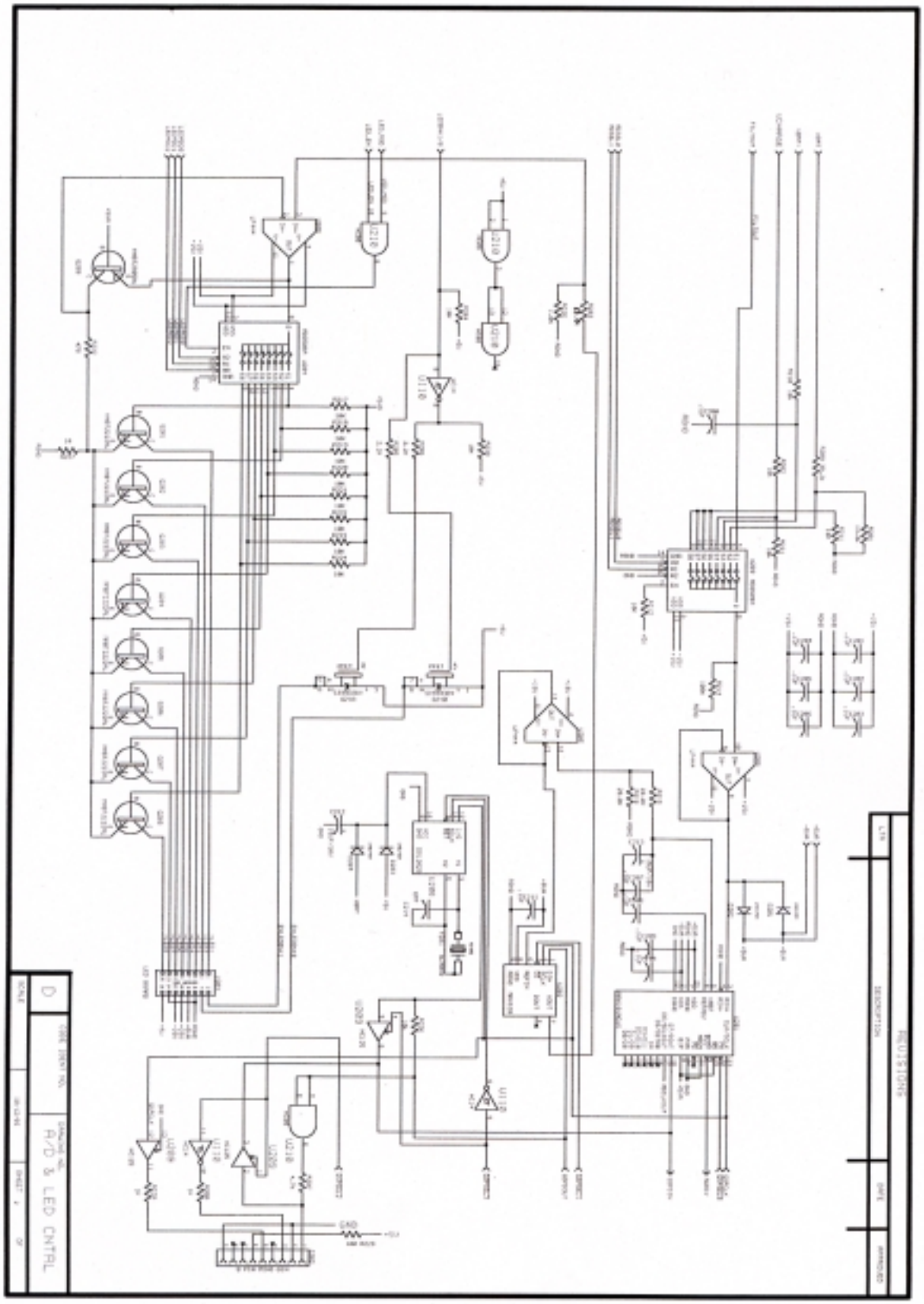
1. Insufficient or negligent care by the purchaser.
2. Insufficient or negligent maintenance by the purchaser in relation to the instructions contained in the manuals prepared by A-VOX for this purpose; tampering or alterations of the instruments, or in any case interventions or repairs made by any person not duly authorized by A-VOX.
3. Misuse due to carelessness, negligence, or inexperience.
4. Employment of materials under heavier conditions than those for which they have been designed and manufactured, and use of the same in combination with incompatible or dangerous products.
5. Non-observance of the regulations relevant to installation, power supply, and operation of the instruments (with particular regard to the regulations for accident prevention).

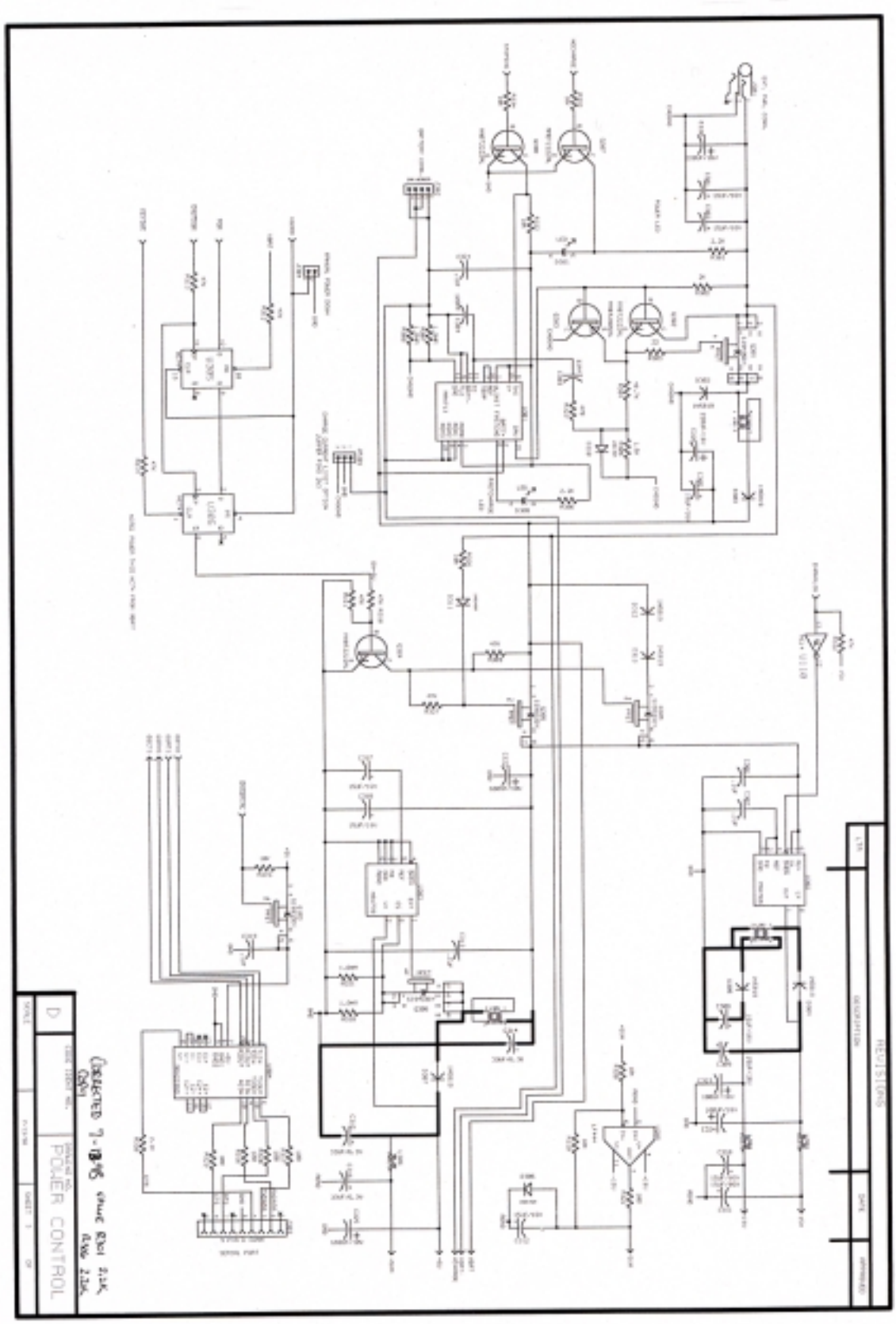
THIS WARRANTY IS GIVEN EXPRESSLY AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. PURCHASER AGREES THAT THERE IS NO WARRANTY OR MERCHANTABILITY AND THAT THERE ARE NO OTHER REMEDIES OR WARRANTIES, EXPRESS OR IMPLIED, WHICH EXTEND BEYOND THE CONTENTS OF THIS AGREEMENT.

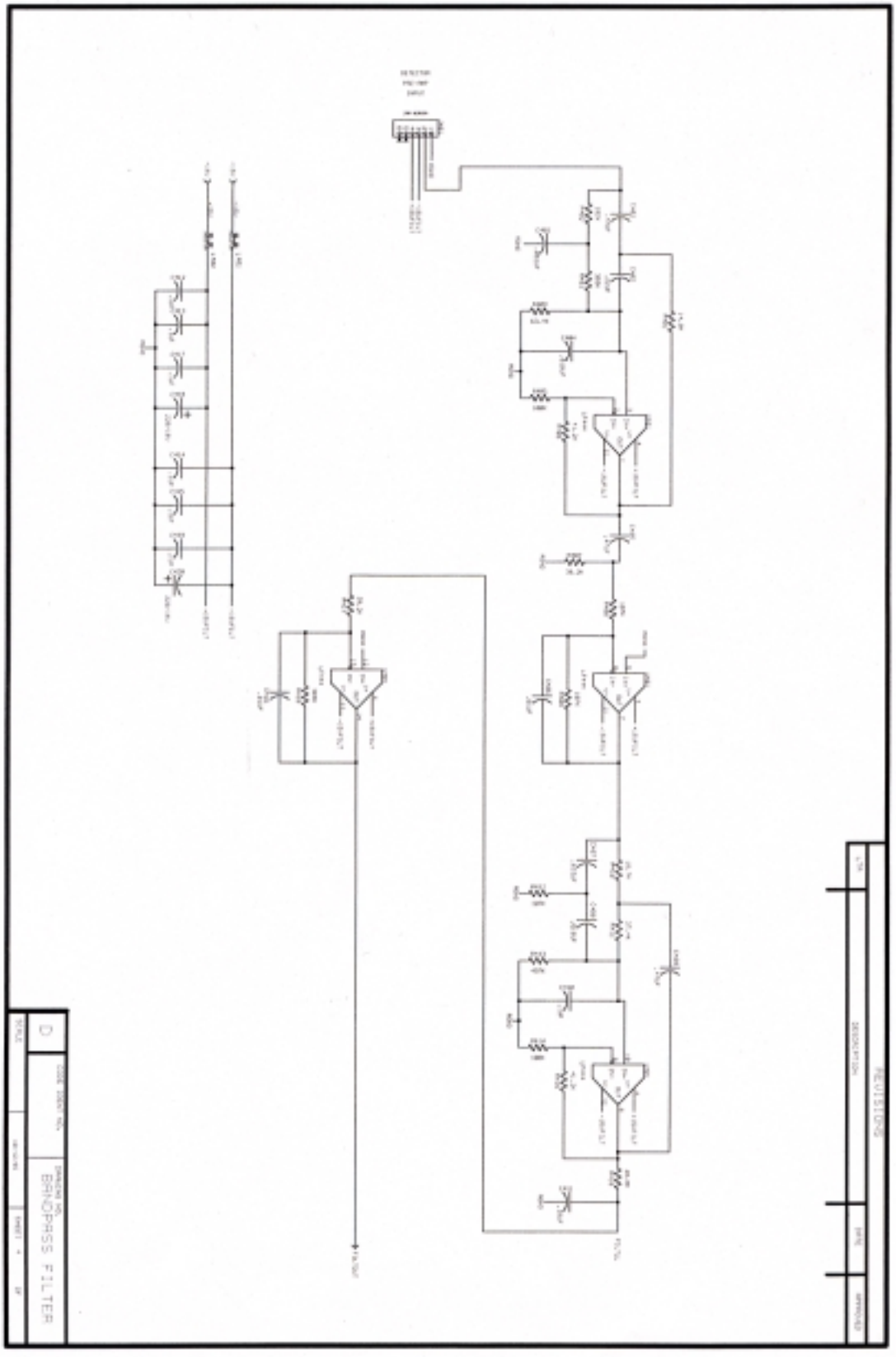
No agent or employee of A-VOX is authorized to extend any other warranty or to assume for A-VOX any liability except as above set forth.

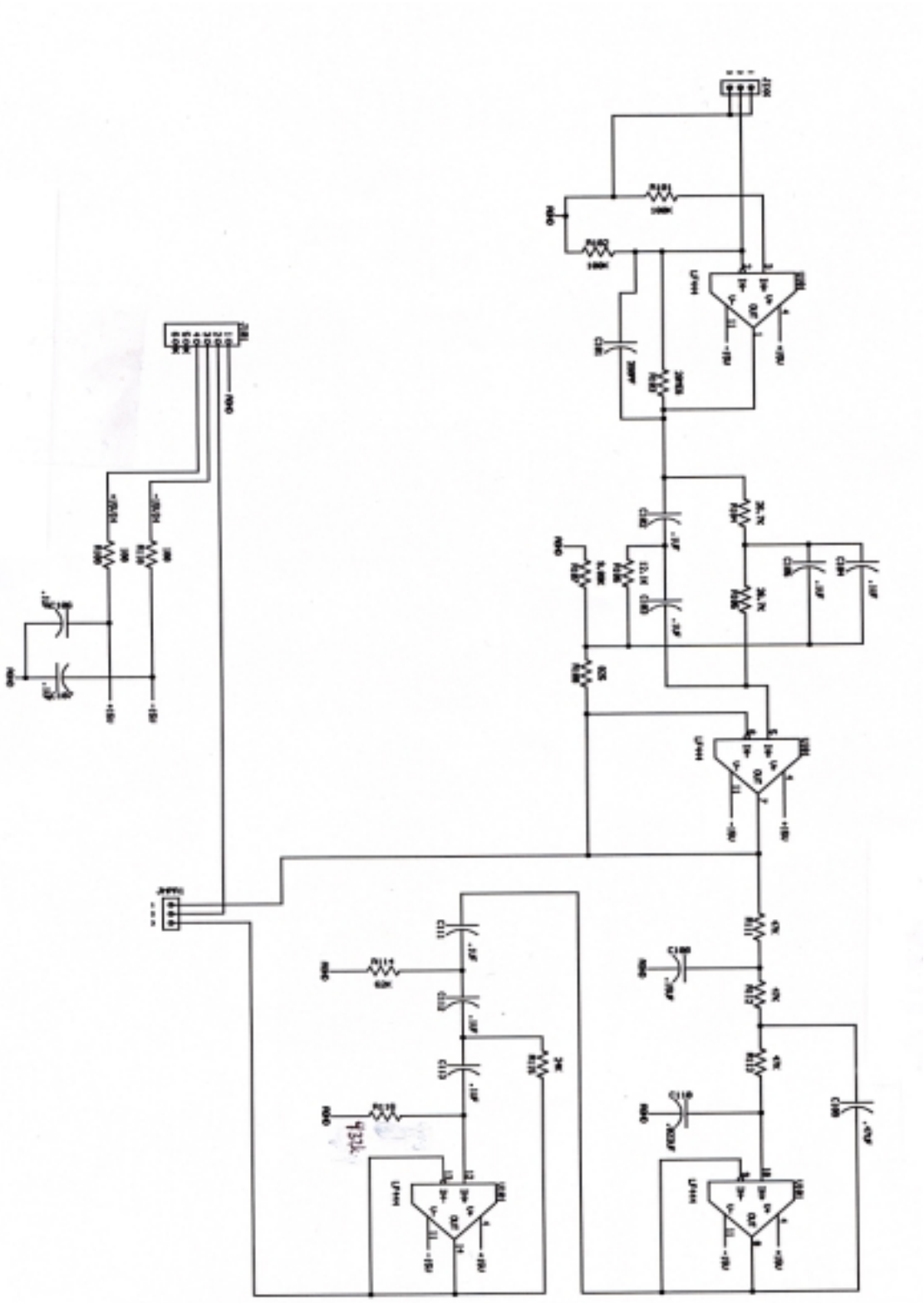
Please contact Technical Support, if any malfunction is discovered.


AUDIX-SYSTEMS
CPU


A/D & LED CNTRL


POWER CONTROL


D
BANDPASS FILTER



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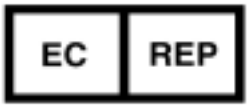

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