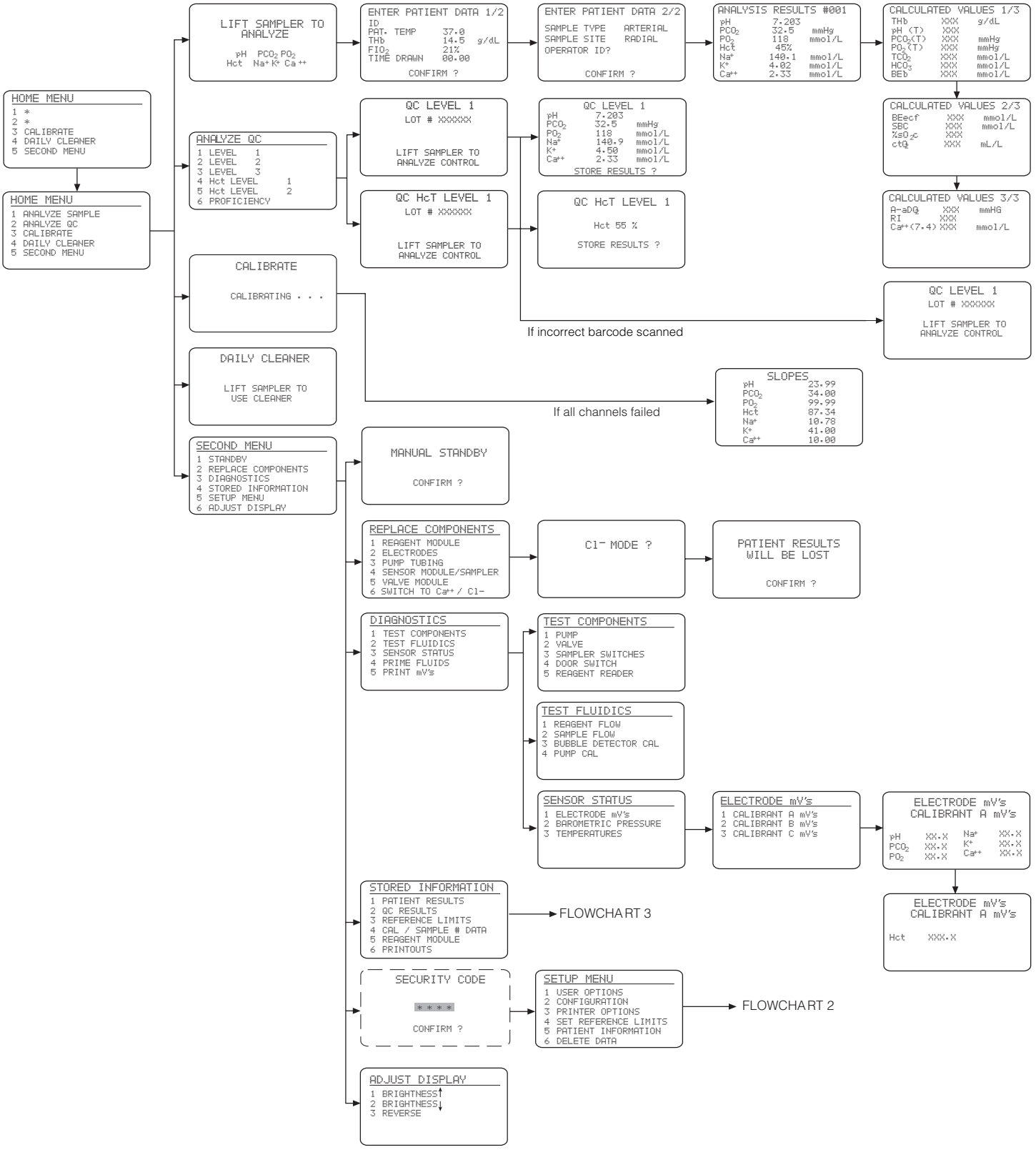
Operator's Manual

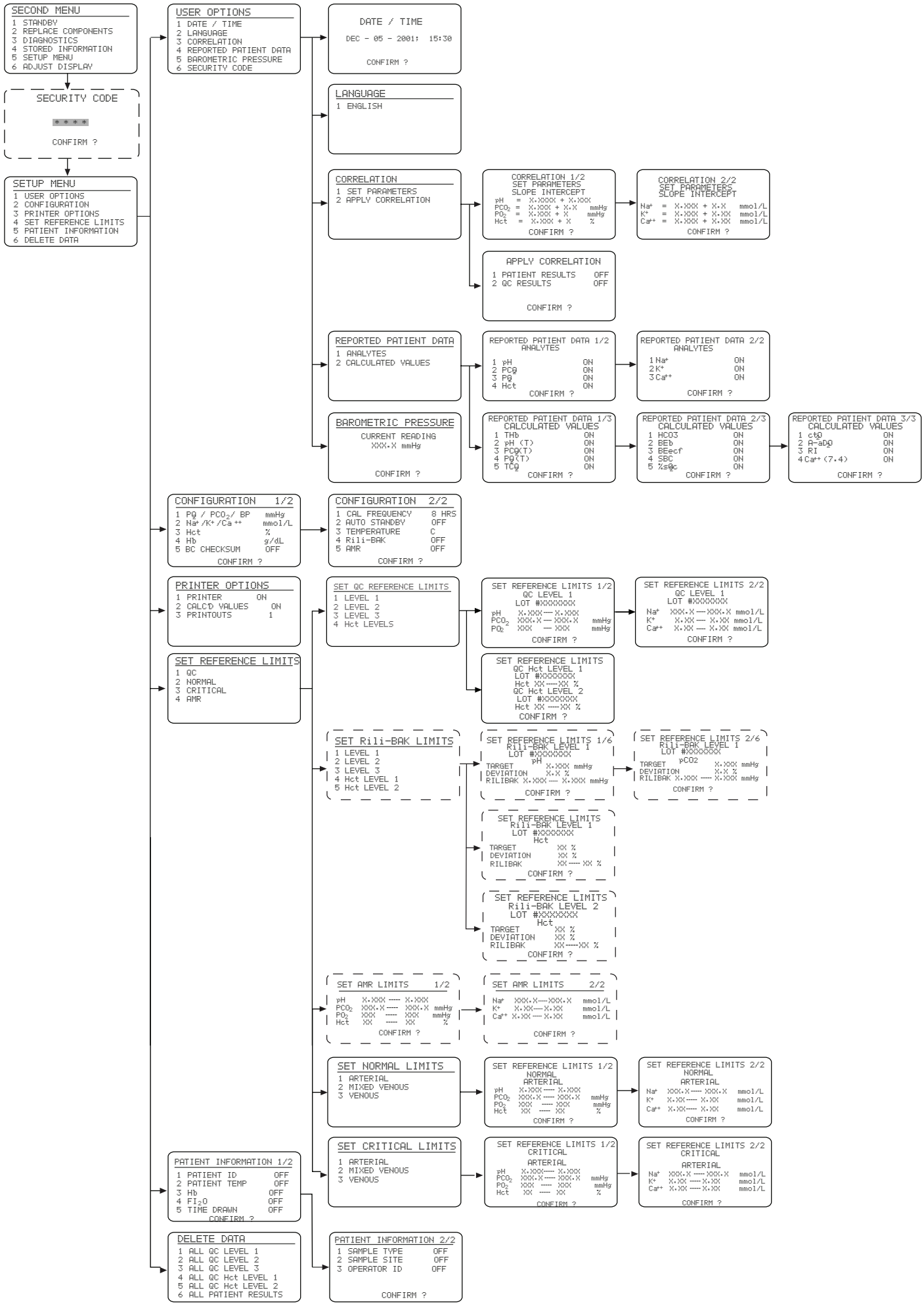
MEDICA EasyStat

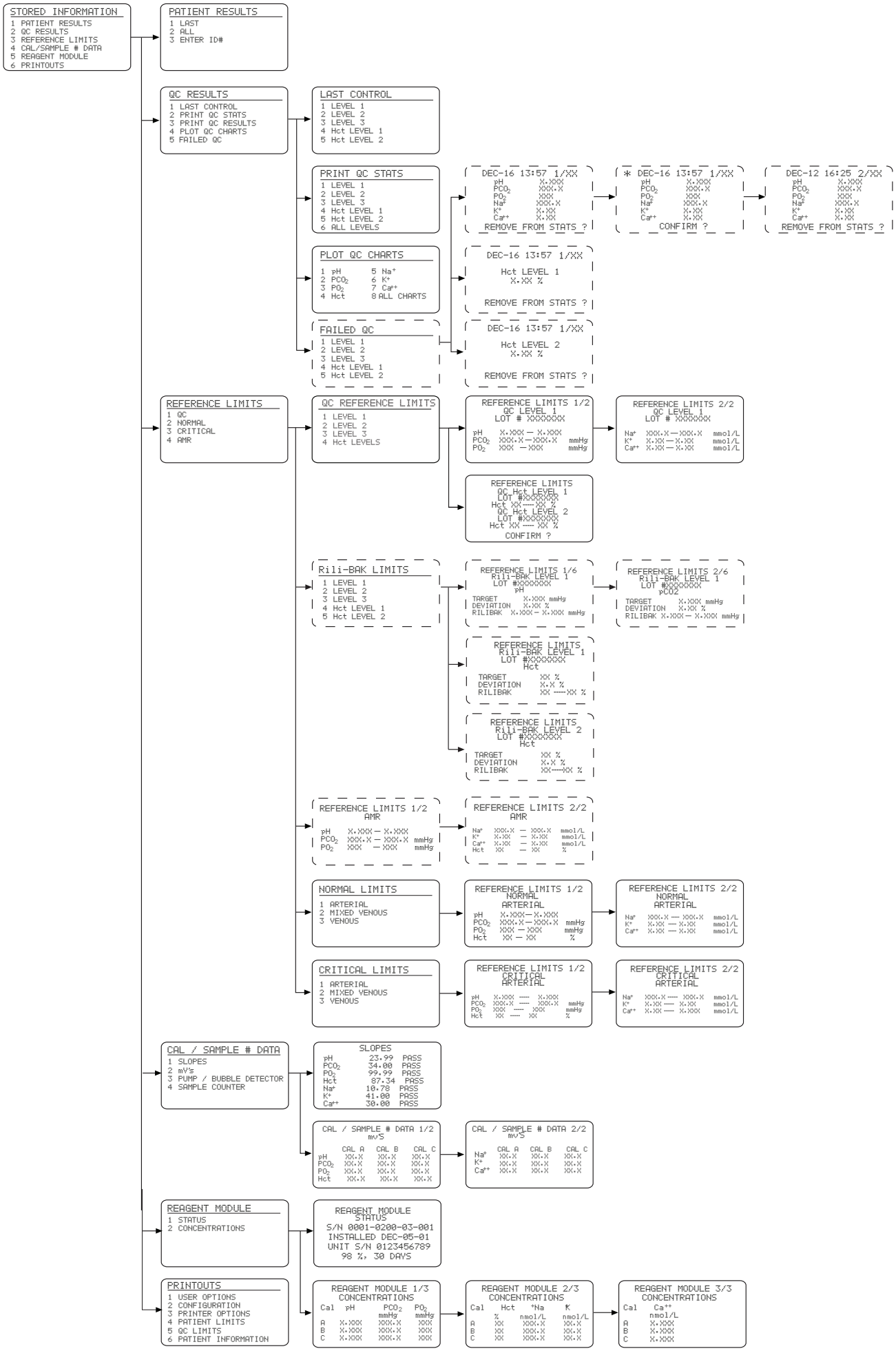


Flow Charts



Note: Ca++ will be replaced by Cl^- in Cl^- mode.
Ca++ (7.4) will be replaced by Anion Gap in Cl^- mode


SECOND MENU
1 STANDBY
2 REPLACE COMPONENTS
3 DIAGNOSTICS
4 STORED INFORMATION
5 SETUP MENU
6 ADJUST DISPLAY
SECURITY CODE
****
CONFIRM ?
SETUP MENU
1 USER OPTIONS
2 CONFIGURATION
3 PRINTER OPTIONS
4 SET REFERENCE LIMITS
5 PATIENT INFORMATION
6 DELETE DATA
USER OPTIONS
1 DATE / TIME
2 LANGUAGE
3 CORRELATION
4 REPORTED PATIENT DATA
5 BAROMETRIC PRESSURE
6 SECURITY CODE
DATE / TIME
DEC - 05 - 2001: 15:30
CONFIRM ?
LANGUAGE
1 ENGLISH
CORRELATION
1 SET PARAMETERS
2 APPLY CORRELATION
CORRELATION 1/2
SET PARAMETERS
SLOPE INTERCEPT
pH = X.XXXX + X.XXX
PCO2 = X.XXX + X.X mmHg
PO2 = X.XXX + X mmHg
Hct = X.XXX + X %
CONFIRM ?
CORRELATION 2/2
SET PARAMETERS
SLOPE INTERCEPT
Na+ = X.XXX + X.X mmol/L
K+ = X.XXX + X.XX mmol/L
Ca++ = X.XXX + X.XX mmol/L
CONFIRM ?
APPLY CORRELATION
1 PATIENT RESULTS OFF
2 QC RESULTS OFF
CONFIRM ?
REPORTED PATIENT DATA
1 ANALYTES
2 CALCULATED VALUES
REPORTED PATIENT DATA 1/2
ANALYTES
1 pH ON
2 PCO2 ON
3 PO2 ON
4 Hct ON
CONFIRM ?
REPORTED PATIENT DATA 2/2
ANALYTES
1 Na+ ON
2 K+ ON
3 Ca++ ON
CONFIRM ?
REPORTED PATIENT DATA 1/3
CALCULATED VALUES
1 THb ON
2 pH (T) ON
3 PCO2(T) ON
4 PO2(T) ON
5 TCO2 ON
CONFIRM ?
REPORTED PATIENT DATA 2/3
CALCULATED VALUES
1 HCO3 ON
2 BEb ON
3 BEecf ON
4 SBC ON
5 %sO2c ON
CONFIRM ?
REPORTED PATIENT DATA 3/3
CALCULATED VALUES
1 ctO2 ON
2 A-aDO2 ON
3 RI ON
4 Ca++(7.4) ON
CONFIRM ?
BAROMETRIC PRESSURE
CURRENT READING
XXX.X mmHg
CONFIRM ?
CONFIGURATION 1/2
1 PO2 / PCO2 / BP mmHg
2 Na+ /K+ /Ca++ mmol/L
3 Hct %
4 Hb g/dL
5 BC CHECKSUM OFF
CONFIRM ?
CONFIGURATION 2/2
1 CAL FREQUENCY 8 HRS
2 AUTO STANDBY OFF
3 TEMPERATURE C
4 Rili-BAK OFF
5 AMR OFF
CONFIRM ?
PRINTER OPTIONS
1 PRINTER ON
2 CALC'D VALUES ON
3 PRINTOUTS 1
SET REFERENCE LIMITS
1 QC
2 NORMAL
3 CRITICAL
4 AMR
SET QC REFERENCE LIMITS
1 LEVEL 1
2 LEVEL 2
3 LEVEL 3
4 Hct LEVELS
SET REFERENCE LIMITS 1/2
QC LEVEL 1
LOT #XXXXXXXX
pH X.XXX---X.XXX
PCO2 XXX.X---XXX.X mmHg
PO2 XXX ---XXX mmHg
CONFIRM ?
SET REFERENCE LIMITS 2/2
QC LEVEL 1
LOT #XXXXXXXX
Na+ XXX.X---XXX.X mmol/L
K+ X.XX---X.XX mmol/L
Ca++ X.XX---X.XX mmol/L
CONFIRM ?
SET REFERENCE LIMITS
QC Hct LEVEL 1
LOT #XXXXXXXX
Hct XX---XX %
QC Hct LEVEL 2
LOT #XXXXXXXX
Hct XX ---XX %
CONFIRM ?
SET Rili-BAK LIMITS
1 LEVEL 1
2 LEVEL 2
3 LEVEL 3
4 Hct LEVEL 1
5 Hct LEVEL 2
SET REFERENCE LIMITS 1/6
Rili-BAK LEVEL 1
LOT #XXXXXXXX
pH
TARGET X.XXX mmHg
DEVIATION X.X %
RILIBAK X.XXX--- X.XXX mmHg
CONFIRM ?
SET REFERENCE LIMITS 2/6
Rili-BAK LEVEL 1
LOT #XXXXXXXX
pCO2
TARGET X.XXX mmHg
DEVIATION X.X %
RILIBAK X.XXX---- X.XXX mmHg
CONFIRM ?
SET REFERENCE LIMITS
Rili-BAK LEVEL 1
LOT #XXXXXXXX
Hct
TARGET XX %
DEVIATION XX %
RILIBAK XX---- XX %
CONFIRM ?
SET REFERENCE LIMITS
Rili-BAK LEVEL 2
LOT #XXXXXXXX
Hct
TARGET XX %
DEVIATION XX %
RILIBAK XX----XX %
CONFIRM ?
SET AMR LIMITS 1/2
pH X.XXX ---- X.XXX
PCO2 XXX.X---- XXX.X mmHg
PO2 XXX ---- XXX mmHg
Hct XX ---- XX %
CONFIRM ?
SET AMR LIMITS 2/2
Na+ XXX.X---XXX.X mmol/L
K+ X.XX---X.XX mmol/L
Ca++ X.XX---X.XX mmol/L
CONFIRM ?
SET NORMAL LIMITS
1 ARTERIAL
2 MIXED VENOUS
3 VENOUS
SET REFERENCE LIMITS 1/2
NORMAL
ARTERIAL
pH X.XXX---X.XXX
PCO2 XXX.X---XXX.X mmHg
PO2 XXX ---XXX mmHg
Hct XX ---XX %
CONFIRM ?
SET REFERENCE LIMITS 2/2
NORMAL
ARTERIAL
Na+ XXX.X---XXX.X mmol/L
K+ X.XX---X.XX mmol/L
Ca++ X.XX---X.XX mmol/L
CONFIRM ?
SET CRITICAL LIMITS
1 ARTERIAL
2 MIXED VENOUS
3 VENOUS
SET REFERENCE LIMITS 1/2
CRITICAL
ARTERIAL
pH X.XXX---X.XXX
PCO2 XXX.X---XXX.X mmHg
PO2 XXX ---XXX mmHg
Hct XX ---XX %
CONFIRM ?
SET REFERENCE LIMITS 2/2
CRITICAL
ARTERIAL
Na+ XXX.X---XXX.X mmol/L
K+ X.XX---X.XX mmol/L
Ca++ X.XX---X.XX mmol/L
CONFIRM ?
PATIENT INFORMATION 1/2
1 PATIENT ID OFF
2 PATIENT TEMP OFF
3 Hb OFF
4 FI2O OFF
5 TIME DRAWN OFF
CONFIRM ?
PATIENT INFORMATION 2/2
1 SAMPLE TYPE OFF
2 SAMPLE SITE OFF
3 OPERATOR ID OFF
CONFIRM ?
DELETE DATA
1 ALL QC LEVEL 1
2 ALL QC LEVEL 2
3 ALL QC LEVEL 3
4 ALL QC Hct LEVEL 1
5 ALL QC Hct LEVEL 2
6 ALL PATIENT RESULTS


STORED INFORMATION
1 PATIENT RESULTS
2 QC RESULTS
3 REFERENCE LIMITS
4 CAL/SAMPLE # DATA
5 REAGENT MODULE
6 PRINTOUTS
PATIENT RESULTS
1 LAST
2 ALL
3 ENTER ID#
QC RESULTS
1 LAST CONTROL
2 PRINT QC STATS
3 PRINT QC RESULTS
4 PLOT QC CHARTS
5 FAILED QC
LAST CONTROL
1 LEVEL 1
2 LEVEL 2
3 LEVEL 3
4 Hct LEVEL 1
5 Hct LEVEL 2
PRINT QC STATS
1 LEVEL 1
2 LEVEL 2
3 LEVEL 3
4 Hct LEVEL 1
5 Hct LEVEL 2
6 ALL LEVELS
PLOT QC CHARTS
1 pH 5 Na+
2 PCO2 6 K+
3 PO2 7 Ca++
4 Hct 8 ALL CHARTS
FAILED QC
1 LEVEL 1
2 LEVEL 2
3 LEVEL 3
4 Hct LEVEL 1
5 Hct LEVEL 2
DEC-16 13:57 1/XX
pH X.XXX
PCO2 XXX.X
PO2 XXX
Na+ XXX.X
K+ X.XX
Ca++ X.XX
REMOVE FROM STATS ?
* DEC-16 13:57 1/XX
CONFIRM ?
DEC-12 16:25 2/XX
DEC-16 13:57 1/XX
Hct LEVEL 1
X.XX %
REMOVE FROM STATS ?
DEC-16 13:57 1/XX
Hct LEVEL 2
X.XX %
REMOVE FROM STATS ?
REFERENCE LIMITS
1 QC
2 NORMAL
3 CRITICAL
4 AMR
QC REFERENCE LIMITS
1 LEVEL 1
2 LEVEL 2
3 LEVEL 3
4 Hct LEVELS
REFERENCE LIMITS 1/2
QC LEVEL 1
LOT # XXXXXXXX
pH X.XXX — X.XXX
PCO2 XXX.X — XXX.X mmHg
PO2 XXX — XXX mmHg
REFERENCE LIMITS 2/2
QC LEVEL 1
LOT # XXXXXXXX
Na+ XXX.X — XXX.X mmol/L
K+ X.XX — X.XX mmol/L
Ca++ X.XX — X.XX mmol/L
REFERENCE LIMITS
QC Hct LEVEL 1
LOT #XXXXXXXX
Hct XX ---- XX %
QC Hct LEVEL 2
LOT #XXXXXXXX
Hct XX ---- XX %
CONFIRM ?
Rili-BAK LIMITS
1 LEVEL 1
2 LEVEL 2
3 LEVEL 3
4 Hct LEVEL 1
5 Hct LEVEL 2
REFERENCE LIMITS 1/6
Rili-BAK LEVEL 1
LOT #XXXXXXX
pH
TARGET X.XXX mmHg
DEVIATION X.XX %
RILIBAK X.XXX — X.XXX mmHg
REFERENCE LIMITS 2/6
Rili-BAK LEVEL 1
LOT #XXXXXXX
pCO2
TARGET X.XXX mmHg
DEVIATION X.XX %
RILIBAK X.XXX — X.XXX mmHg
REFERENCE LIMITS
Rili-BAK LEVEL 1
LOT #XXXXXXX
Hct
TARGET XX %
DEVIATION X.X %
RILIBAK XX ---- XX %
REFERENCE LIMITS
Rili-BAK LEVEL 2
LOT #XXXXXXX
Hct
TARGET XX %
DEVIATION X.X %
RILIBAK XX---XX %
REFERENCE LIMITS 1/2
AMR
pH X.XXX — X.XXX
PCO2 XXX.X — XXX.X mmHg
PO2 XXX — XXX mmHg
REFERENCE LIMITS 2/2
AMR
Na+ XXX.X — XXX.X mmol/L
K+ X.XX — X.XX mmol/L
Ca++ X.XX — X.XX mmol/L
Hct XX — XX %
NORMAL LIMITS
1 ARTERIAL
2 MIXED VENOUS
3 VENOUS
REFERENCE LIMITS 1/2
NORMAL
ARTERIAL
pH X.XXX — X.XXX
PCO2 XXX.X — XXX.X mmHg
PO2 XXX — XXX mmHg
Hct XX — XX %
REFERENCE LIMITS 2/2
NORMAL
ARTERIAL
Na+ XXX.X — XXX.X mmol/L
K+ X.XX — X.XX mmol/L
Ca++ X.XX — X.XX mmol/L
CRITICAL LIMITS
1 ARTERIAL
2 MIXED VENOUS
3 VENOUS
REFERENCE LIMITS 1/2
CRITICAL
ARTERIAL
pH X.XXX ---- X.XXX
PCO2 XXX.X ---- XXX.X mmHg
PO2 XXX ---- XXX mmHg
Hct XX ---- XX %
REFERENCE LIMITS 2/2
CRITICAL
ARTERIAL
Na+ XXX.X ---- XXX.X mmol/L
K+ X.XX ---- X.XX mmol/L
Ca++ X.XX ---- X.XX mmol/L
CAL / SAMPLE # DATA
1 SLOPES
2 mV's
3 PUMP / BUBBLE DETECTOR
4 SAMPLE COUNTER
SLOPES
pH 23.99 PASS
PCO2 34.00 PASS
PO2 99.99 PASS
Hct 87.34 PASS
Na+ 10.78 PASS
K+ 41.00 PASS
Ca++ 30.00 PASS
CAL / SAMPLE # DATA 1/2
mV'S
CAL A CAL B CAL C
pH XX.X XX.X XX.X
PCO2 XX.X XX.X XX.X
PO2 XX.X XX.X XX.X
Hct XX.X XX.X XX.X
CAL / SAMPLE # DATA 2/2
mV'S
CAL A CAL B CAL C
Na+ XX.X XX.X XX.X
K+ XX.X XX.X XX.X
Ca++ XX.X XX.X XX.X
REAGENT MODULE
1 STATUS
2 CONCENTRATIONS
REAGENT MODULE
STATUS
S/N 0001-0200-03-001
INSTALLED DEC-05-01
UNIT S/N 0123456789
98 %, 30 DAYS
PRINTOUTS
1 USER OPTIONS
2 CONFIGURATION
3 PRINTER OPTIONS
4 PATIENT LIMITS
5 QC LIMITS
6 PATIENT INFORMATION
REAGENT MODULE 1/3
CONCENTRATIONS
Cal pH PCO2 PO2
mmHg mmHg
A X.XXX XXX.X XXX
B X.XXX XXX.X XXX
C X.XXX XXX.X XXX
REAGENT MODULE 2/3
CONCENTRATIONS
Cal Hct +Na K
% nmol/L nmol/L
A XX XXX.X XX.X
B XX XXX.X XX.X
C XX XXX.X XX.X
REAGENT MODULE 3/3
CONCENTRATIONS
Cal Ca++
nmol/L
A X.XXX
B X.XXX
C X.XXX

MEDICA EasyStat

Operator's Manual

REF 7415

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If the system is used in a manner differently than specified by Medica Corporation, performance of the equipment may be impaired. See all Hazards, Precautions and Warnings.

Preface

This Operator's Manual will assist you in using the EasyStat analyzer. Easy-to-follow instructions guide you through analyzer setup and operation. Display messages and flow charts are combined with the written instructions for quick reference.

Symbols used throughout the manual

DISPLAY TYPE EasyStat display messages

▲ important information

★ conditions which may cause data loss or analyzer malfunction

 biohazard warning

 sampler positioning required by operator

 access door must be closed for proper operation

 syringe sample mode

 capillary sample mode

 compression plate positioning required by operator

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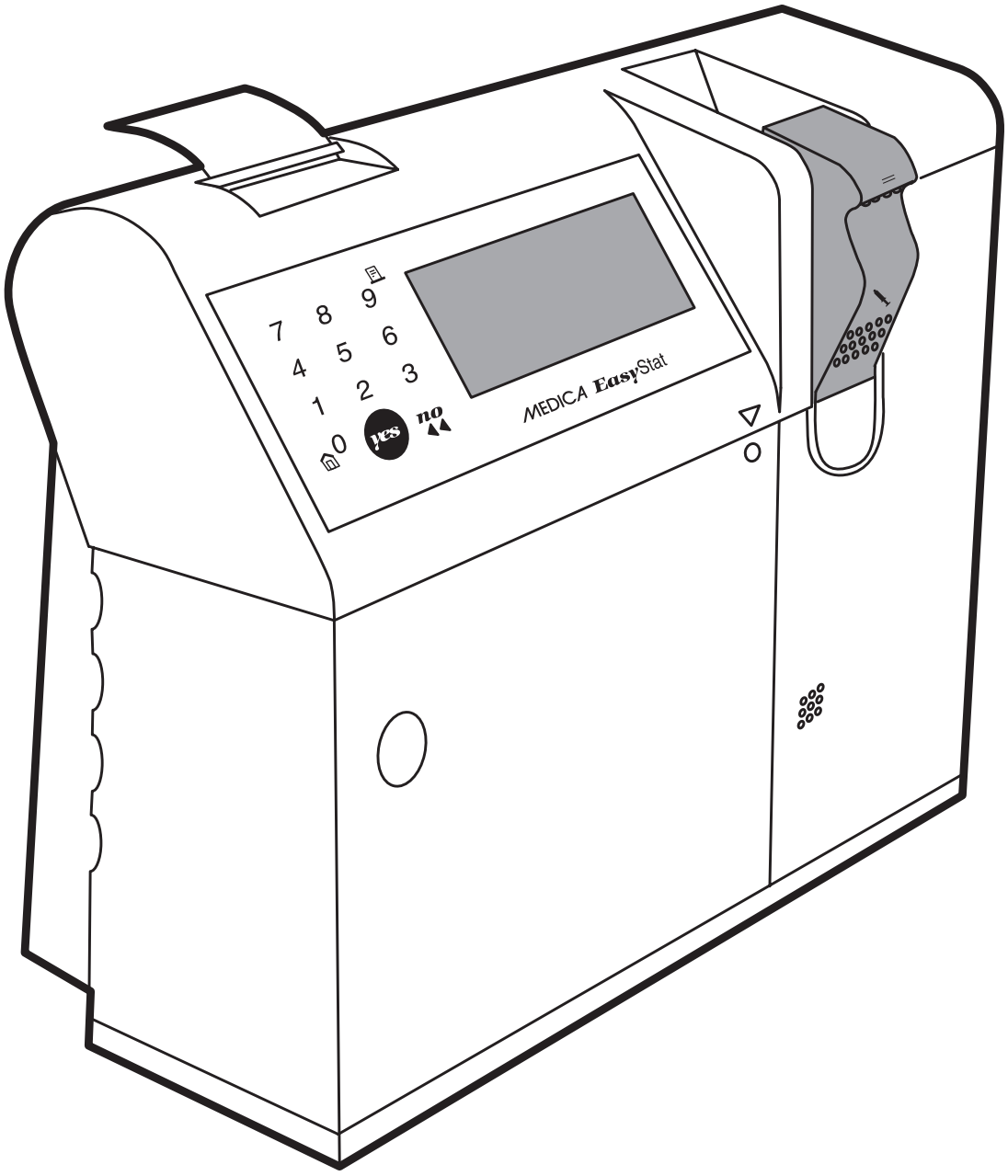

7 8 9
4 5 6
1 2 3
0
yes
no
MEDICA EasyStat

1. Understanding the EasyStat Analyzer

Intended Use

The EasyStat analyzer is designed for clinical laboratory use, making direct measurements of pH (hydrogen ion activity), PCO_2 (partial pressure of carbon dioxide), PO_2 (partial pressure of oxygen), Hct (Hematocrit), Na^+ (sodium), K^+ (potassium), and Ca^{++} (ionized Calcium) or Cl^- (chloride) on whole blood samples from syringes or capillary tubes.

Ca^{++} (ionized calcium) and Cl^- (chloride) electrodes are interchangeable on the analyzer. The EasyStat can only measure Ca^{++} (ionized calcium) or Cl^- (chloride) at one time. After switching to the EasyStat (Chloride) mode, the new Cl^- electrode will occupy the same position as the Ca^{++} electrode.

This analyzer is used by laboratory trained technicians in clinical laboratories to aid in the diagnosis and treatment of patients with electrolyte, blood gas and/or acid-base disturbances. The patient results obtained from the EasyStat analyzer must be used in conjunction with the overall patient clinical condition before corrective/therapeutic action is taken.

The EasyStat analyzer also calculates the following parameters, based on the equations outlined under Calculations in Principles of Operation/Theory.

- Total Hemoglobin: THb
- Temperature corrected pH: pH(T)
- Temperature corrected PCO_2: PCO_2(T)
- Temperature corrected PO_2: PO_2(T)
- Total Carbon Dioxide: TCO_2
- Bicarbonate: HCO_3^-
- Base Excess of blood: BE_b
- Base Excess in extracellular fluid: BE_{ecf}
- Standard Bicarbonate: SBC
- Oxygen Saturation calculated at normal P_{50}: $\%SO_2c$

- Total Oxygen Content: ctO_2
- Alveolar-Arterial O_2 Gradient: A-aDO_2
- Respiratory Index: RI
- Normalized calcium at pH = 7.4: Ca^{++} (7.4) when Ca^{++} channel is selected
- Anion Gap, when Cl^- channel is selected

Operational Hazards and Precautions

Read the Operator's Manual before setting up or operating the EasyStat analyzer.

Observe all Warnings, Notes, and Key Information in this manual.

Failure to leave the analyzer connected to power with a reagent module in place could damage the electrodes, sensor module, valve module, and pump tubing.

There are no operator serviceable parts inside the analyzer. When electromechanical problems beyond the scope of this Operator's Manual are suspected, DO NOT open the back cover. Contact your EasyStat dealer.

Use only the supplied 3-wire (UL approved) power cord, or equivalent. The power cord of the analyzer must be connected to a matching grounded outlet supplying 110~VAC, 50/60 Hz or 220~VAC, 50/60 Hz. The analyzer contains sensitive electronics and must be properly grounded.

DO NOT plug the analyzer into a circuit protected by a Ground Fault Interrupter (GFI).

The safety protection provided by the analyzer may be impaired when the analyzer is used in any way other than as is outlined in this manual.



BIOHAZARD
All biological samples should be considered biohazardous.

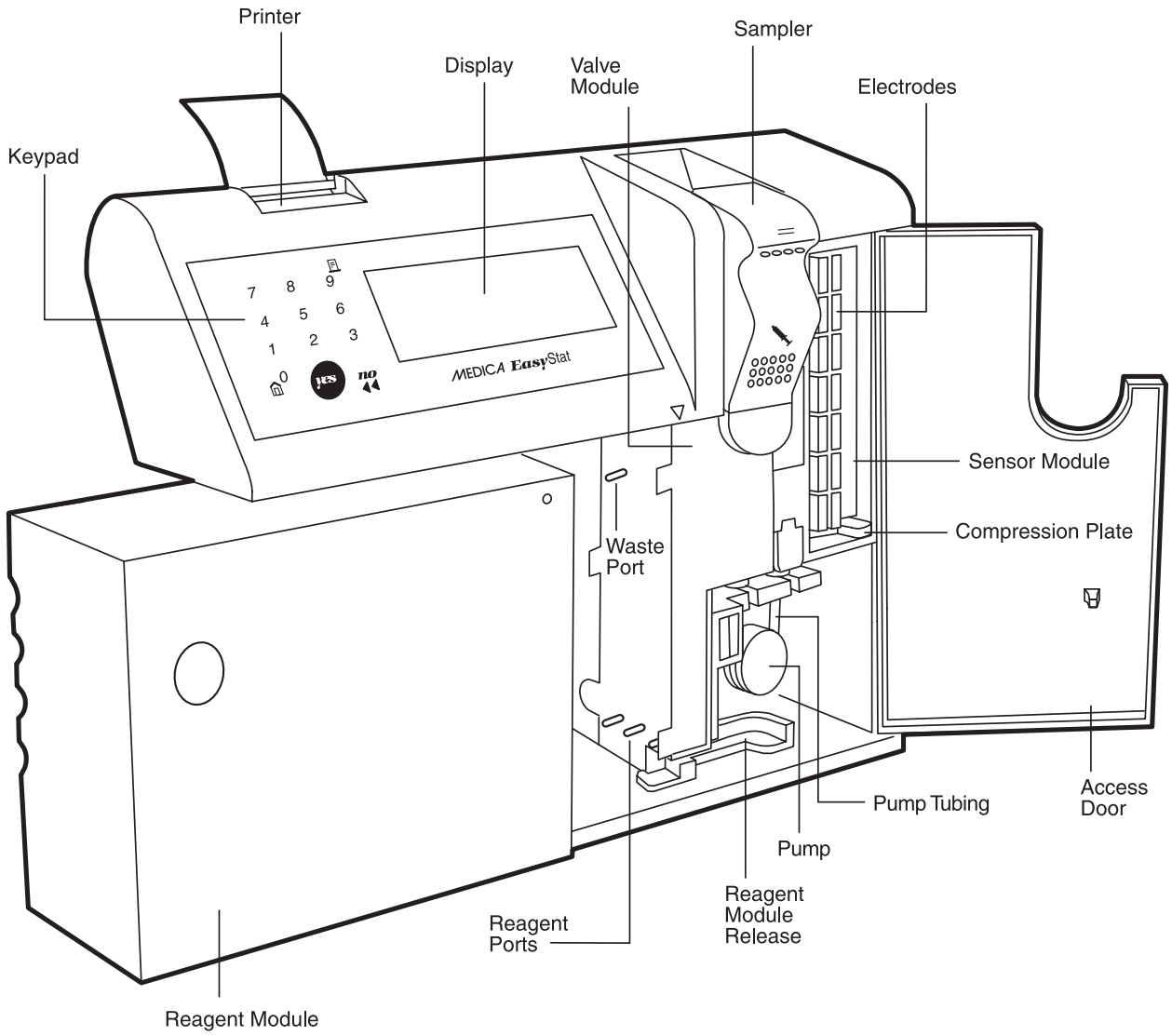
Any replaceable component which comes in contact with biological samples, including the sample probe, electrodes, sensor module, pump tubing, valve module and reagent module may contain contaminated material. Treat all components, during use and disposal, as you would any biohazardous material.

To clean the outside surfaces of the EasyStat analyzer, use a cleaning agent consisting of a 10% bleach (0.4-0.6% NaClO) solution. Dampen a cloth with solution to wipe down all outside surfaces. Protective clothing and gloves are recommended. Refer to the Analyzer Surface Cleaning/Storage instructions outlined under Replace Components in Operating the Analyzer.

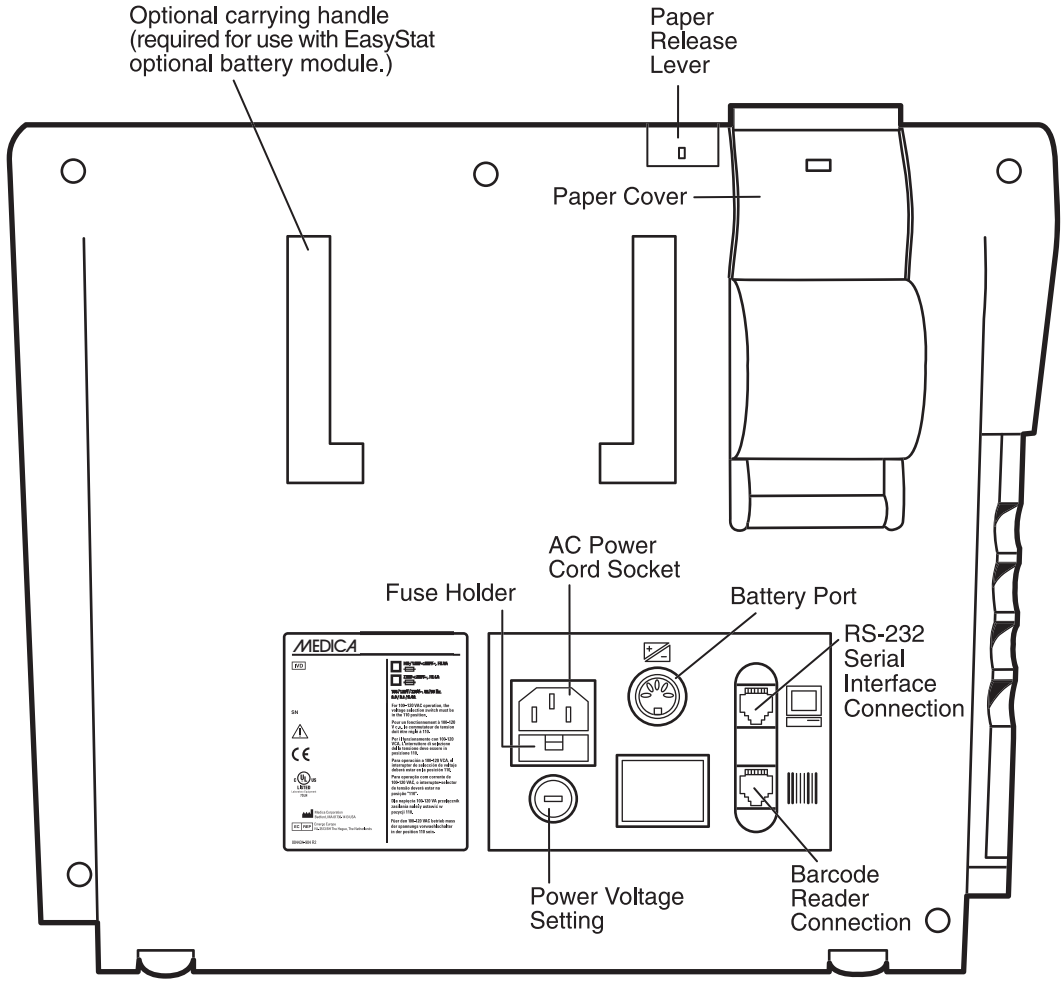
To clean any component, use only water or bleach (NaClO) solutions. DO NOT use solvents (examples: methyl alcohol, ethyl alcohol, isopropyl alcohol).

2. Analyzer Layout

Front View

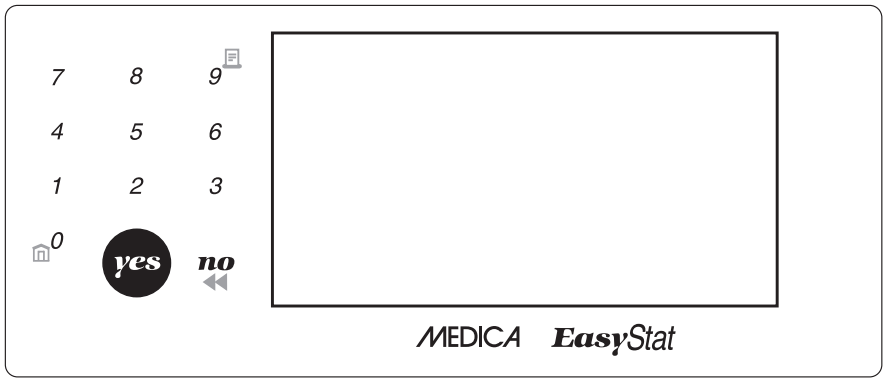


Rear View



Fuse	
V	Voltage
Hz	Frequency
A	Current
~	Single phase alternating current
⚠	See operator's manual for instructions.
	RS-232 serial interface connection.
	Barcode reader connection. (Use only an EasyStat barcode reader.)
	Battery port connection. (Use only an EasyStat battery module.)

Keypad



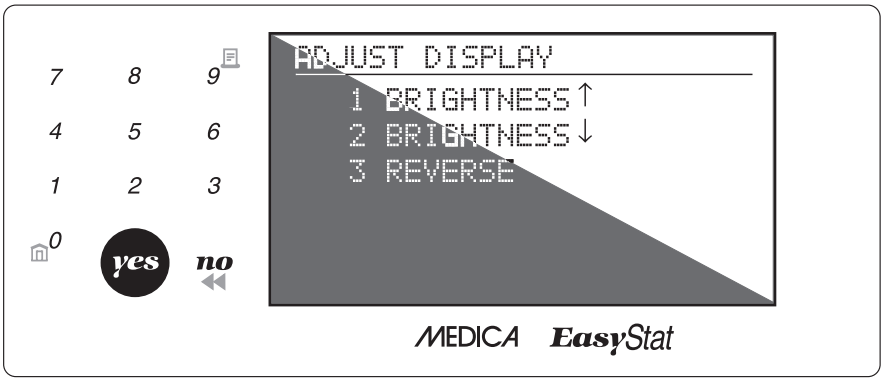
◀◀ Press to correct an entry or return to the previous screen.

In addition to numerical inputs, the 0 and 9 keys each have one additional function.

Press to return to HOME MENU.

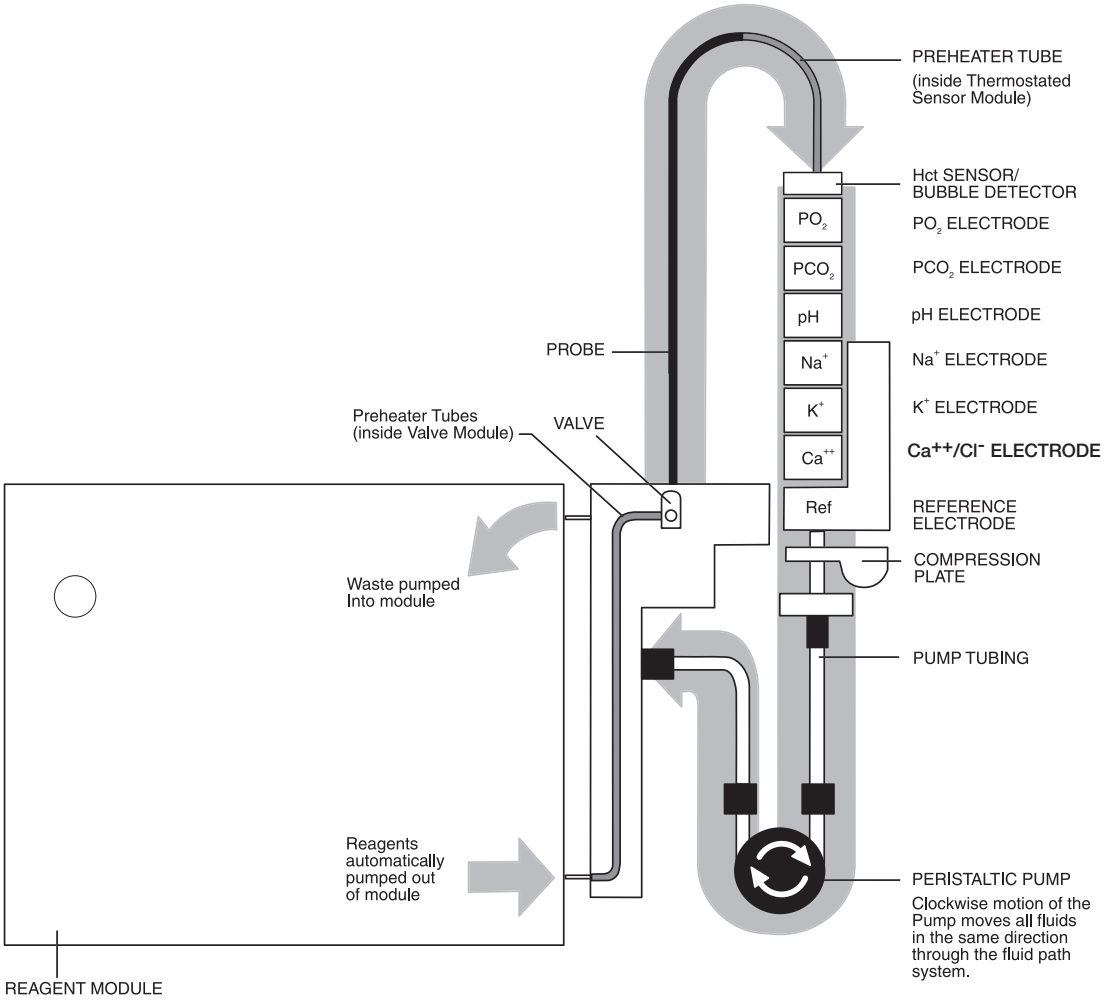
Press to advance printer paper.

Display



To adjust the display, proceed to the SECOND MENU and select ADJUST DISPLAY. Press the number 1 or number 2 keys to adjust the brightness. Press the number 3 key to reverse the contrast of the display.

Fluid Path / Module Description



▲ Cl^- electrode should be installed when Cl^- mode is selected.

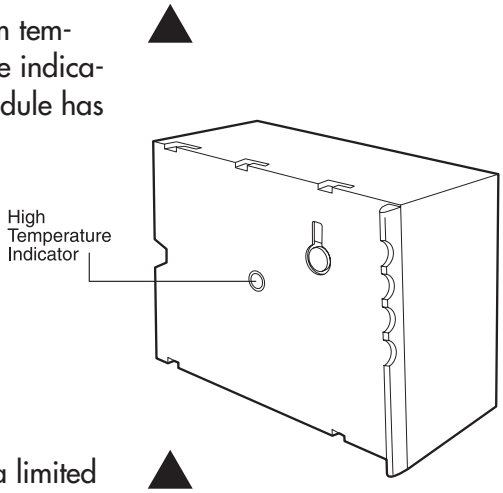
Reagent Module

Disposable module contains all reagents and a waste container.

The reagent module is equipped with an electronic chip which contains encoded information which is automatically read by the analyzer upon installation of the reagent module. This information includes:

- calibrant concentrations for pH, PCO_2, PO_2, Hct, Na^+, K^+, Ca^{++}, and Cl^-;
- current reagent module serial number and installation date;
- analyzer serial number that the reagent module was first installed on;
- reagent volume % remaining with the number of days remaining before calibrants expire.

Prior to installation, a reagent module must be stored at room temperature for a minimum of four hours. When the center of the indicator on the back of the reagent module becomes dark, the module has been exposed to excessive heat and must not be used.



After initial installation, the reagent module is functional for a limited number of days (see reagent module insert sheet). After each calibration, the reagent module % and days remaining are printed. When the reagent module has 0% remaining, RGNT MODULE EMPTY is displayed. If the reagent module has exceeded the allowable usage period, RGNT MODULE EXPIRED is displayed. Both of these conditions require reagent module replacement.

Valve Module

Selects reagents from the reagent module, preheats and directs them through the probe.

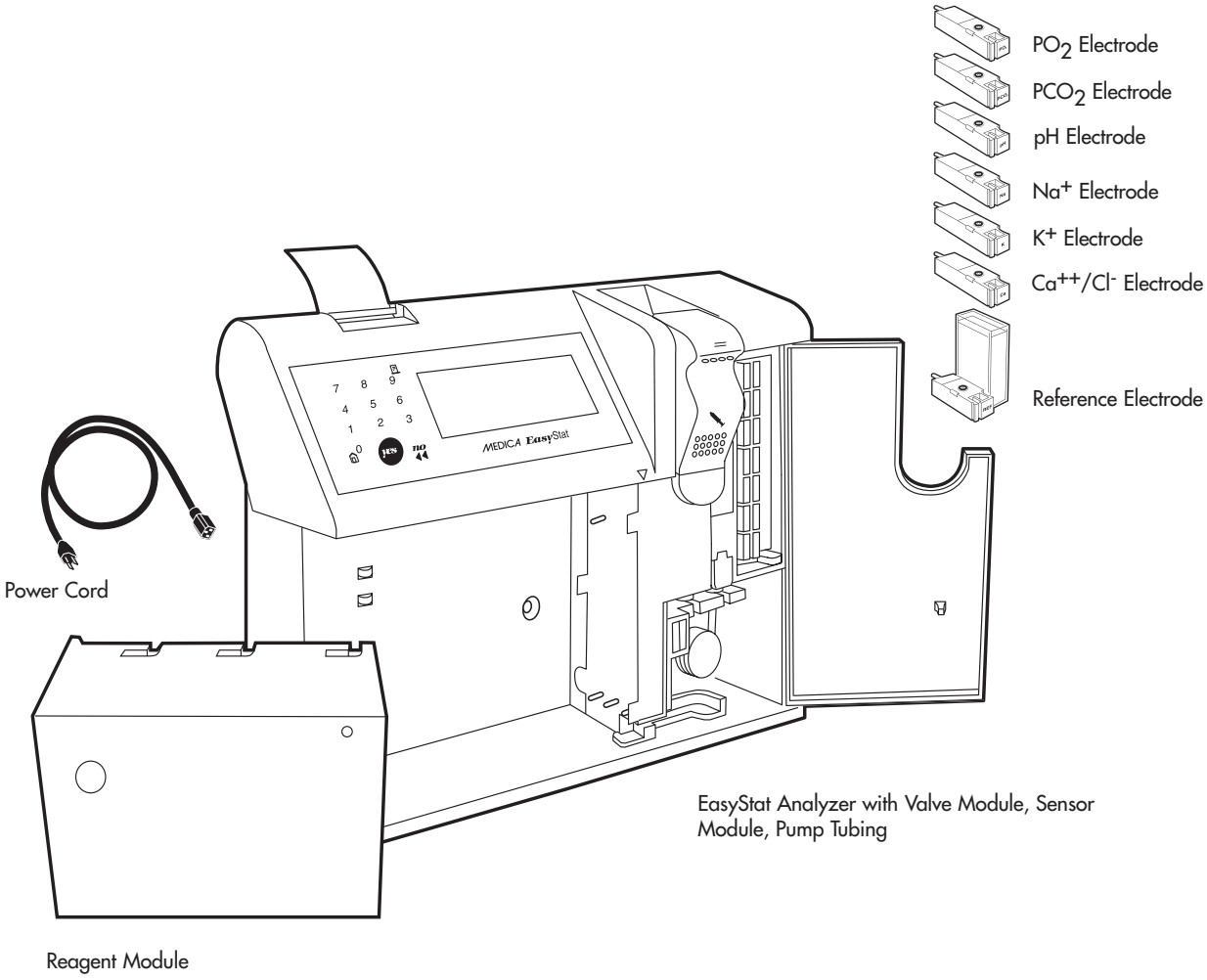
Sensor Module

Thermostated housing for the electrodes. The sampler containing the probe is attached. A bubble detector above the electrodes detects fluid or air in the fluid path.

3. Analyzer Installation

Unpacking

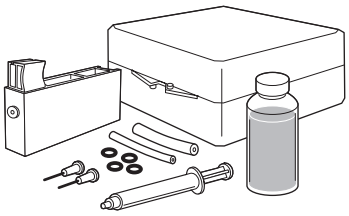
Carefully remove the EasyStat analyzer and accessories from the shipping containers and place them on a solid work surface. Visually inspect for any damage sustained during shipment. If damage is found, or if items are missing, promptly notify your dealer.



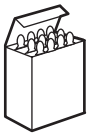
▲ Cl^- electrode should be installed when Cl^- mode is selected.

Location

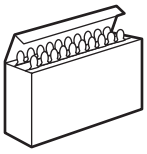
The analyzer operates in the ambient (room) temperature range from 15° to 30°C (59° to 86°F) with a maximum relative humidity of 85%, and a barometric pressure range of 500-800 mmHg. The analyzer must operate in a normal atmosphere of 21% oxygen. Choose a location which provides good ventilation and is free from vibration and electrical interferences.



Troubleshooting Kit



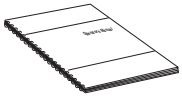
Quality Controls



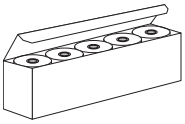
Hct Controls, Bi-Level



Daily Cleaning Solution Kit



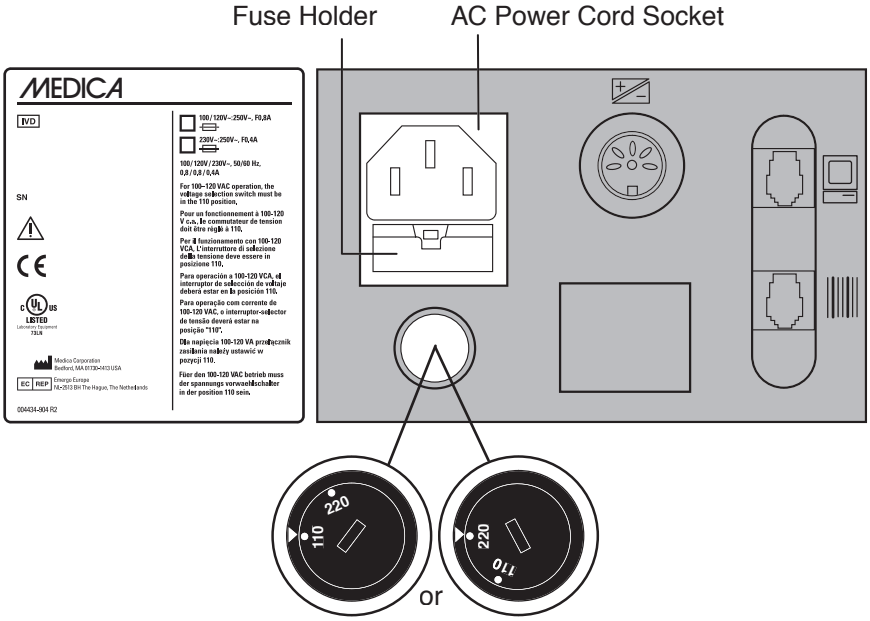
Operator's Manual



Printer Paper

Power Up

Before connecting the analyzer to power, confirm that the factory set voltage (110V or 220V) of the EasyStat analyzer matches the grounded outlet supplying the power. When factory set to 110V, the installed fuses are 0.8 amp. When factory set to 220V, the installed fuses are 0.4 amp. If it is necessary to switch the EasyStat voltage setting, the correct fuses must be installed. Refer to Replace Components/Fuses, or contact your EasyStat dealer.



Factory-set Power Voltage Setting

★ Do not install reagent module or electrodes at this time.

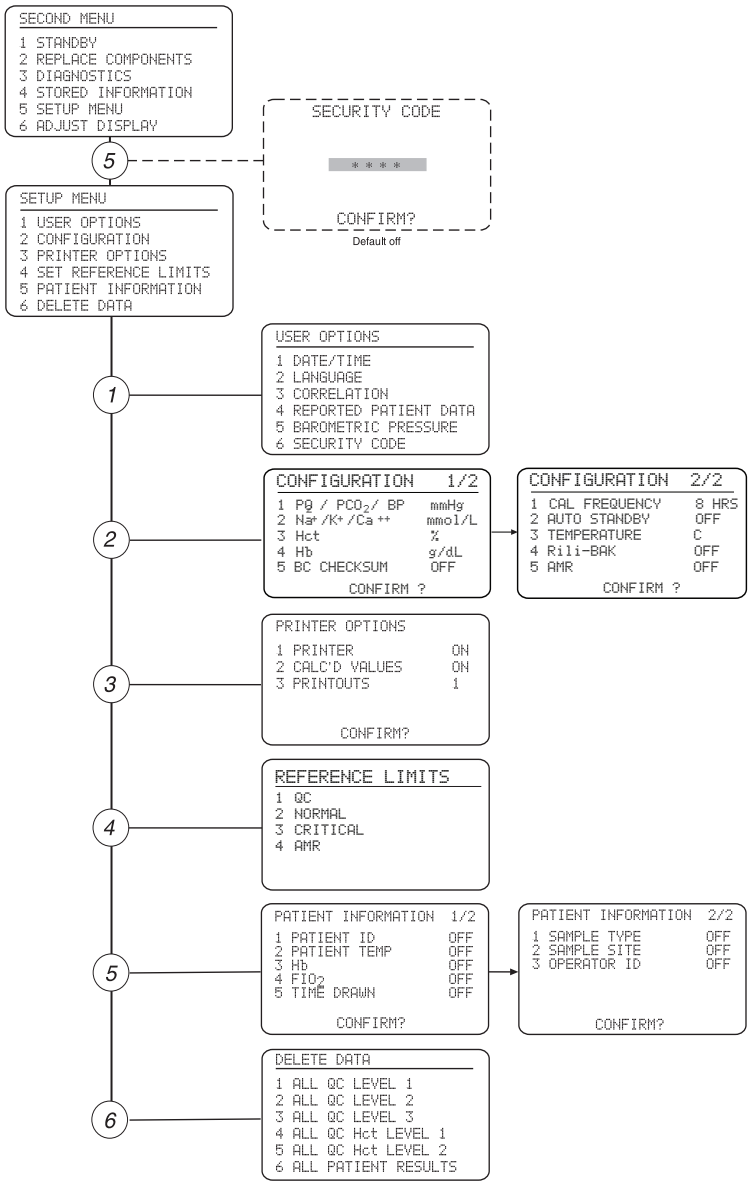
When the analyzer is powered up, the display will prompt you to set the correct date and time.

Date/Time



The EasyStat analyzer has a 24 hour internal clock.
At the DATE/TIME display, press NO to change the month and YES to accept. Press the number keys to enter the day, year and time, accepting each with YES, or pressing NO to move to the left to correct an entry. Press YES to CONFIRM? to accept the DATE/TIME.

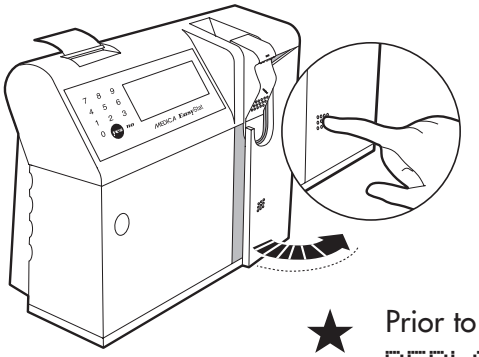
For optional operator-selected settings, proceed to SECOND MENU, SETUP MENU. ▲



▲ Ca^{++} is replaced with Cl^{-} when Cl^{-} mode is selected.

Components

Press the raised dots on the access door to open, and familiarize yourself with the EasyStat analyzer components. The access door must remain closed during operation to maintain a temperature of 37.0° C.



★ Prior to installing the electrodes, select ELECTRODES under REPLACE COMPONENTS in the SECOND MENU.

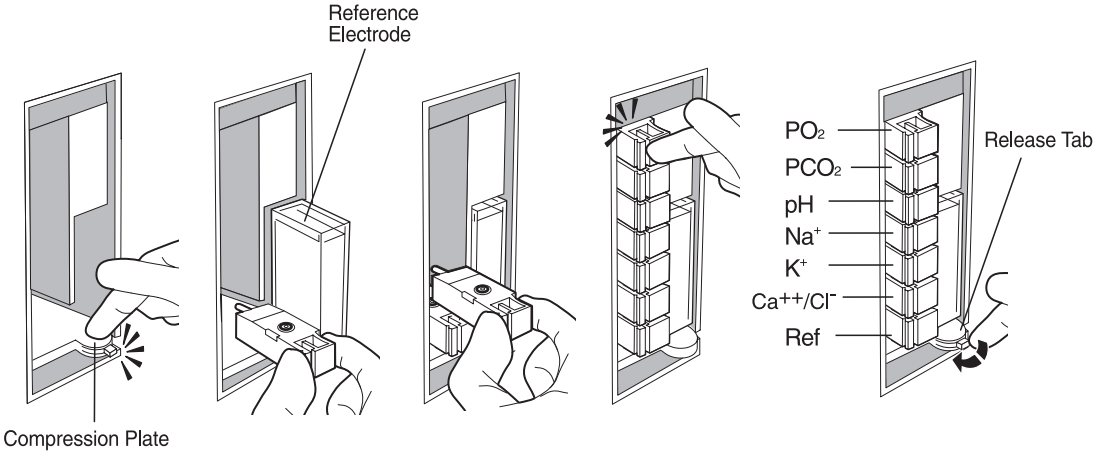
Electrodes

To install the electrodes, push the compression plate down until the latch locks into the open position.

Install the reference electrode first, pushing it in above the compression plate. The handle snaps into the sensor module.

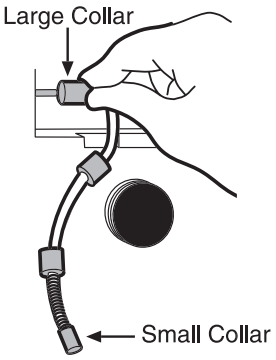
Next, install the Ca^{++}, K^{+}, Na^{+}, pH, PCO_2 and PO_2 electrodes, beginning from the bottom and proceeding upward. Each handle should snap into the sensor module. The electrodes are keyed to assure correct placement. DO NOT FORCE. Refer to the illustration and the access door label for correct electrode order and location.

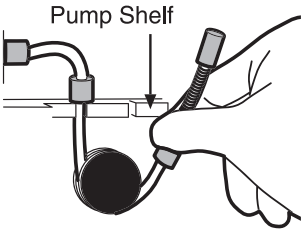
Release the compression plate to compress the electrodes within the sensor module.



Pump Tubing

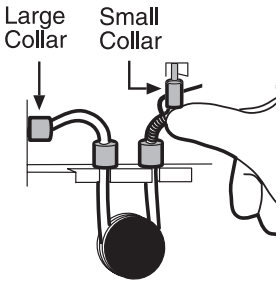
Install the pump tubing.

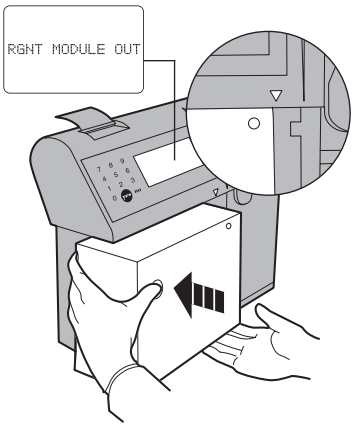


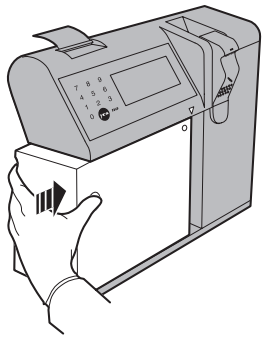


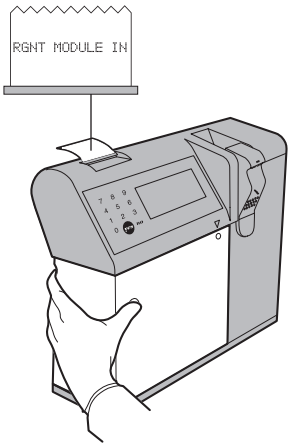
▲

Push the two middle collars completely into the back of the slots on the pump shelf.







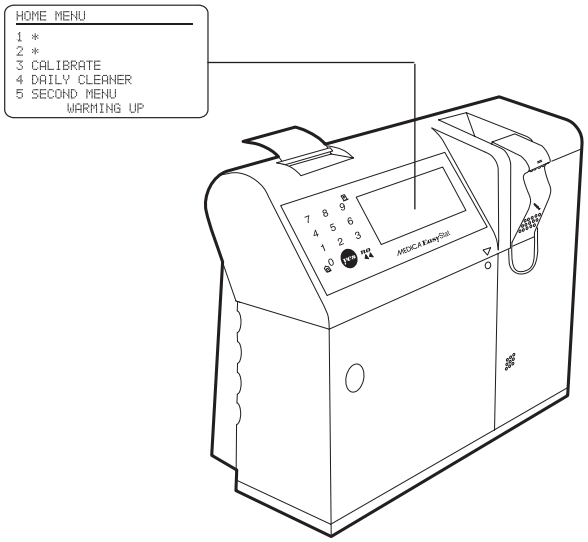


Reagent Module

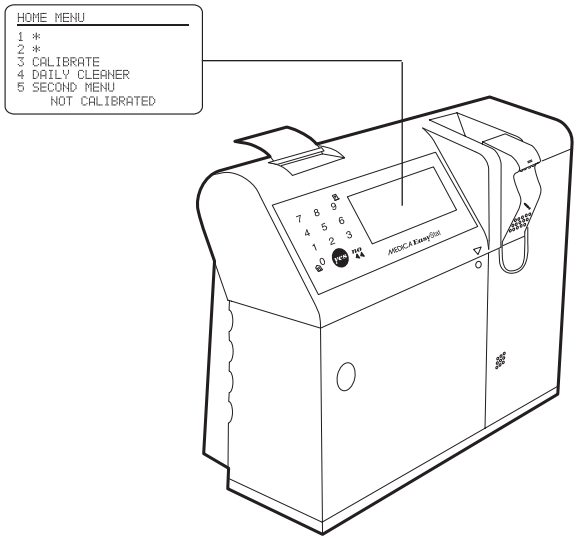
Place the reagent module into the front of the analyzer. The guide arrow must point to the right side of the reagent module. Push the module straight back, then firmly to the right to lock it into place against the valve module. When correctly installed, the message RGNT MODULE IN is printed. When the reagent module is installed, press yes to CONFIRM?.

When the installed reagent module has less than 10% remaining, the HOME MENU display will flash the % remaining. Prepare to install a new reagent module when the % remaining reaches zero.

When all components are installed, confirm that the access door is closed. WARMING UP appears at the bottom of the HOME MENU display. When the sensor module reaches 37.0°C and the valve module reaches 39.0°C (approximately 30 minutes from a cold start) the WARMING UP message disappears. Calibration can now be performed. Refer to Calibrate in Operating the Analyzer for further instructions.

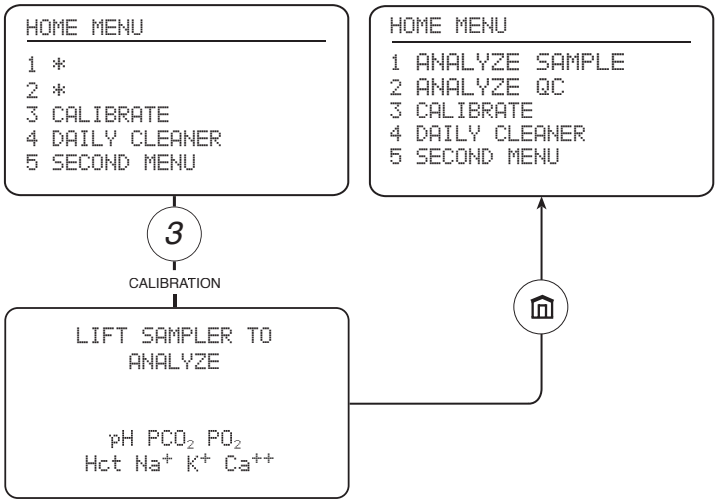


New electrodes require a short stabilization period to prevent drift errors. This stabilization is minimized by the analyzer, which performs calibrations every hour for 8 hours. After this stabilization period, the analyzer will calibrate at the calibration frequency selected under CAL FREQUENCY in the CONFIGURATION section of the SETUP MENU.



4. Operating the Analyzer

Calibrate




```
    CALIBRATION
BUBBLE DETECTOR CAL
        air fluid
  BD PASS 171 030

     PUMP CAL
  PUMP PASS 0799

      SLOPES
pH      61.02
PCO2    53.17
PO2      3.01
Hct     18.88
Na+     58.98
K+      61.50
Ca++    24.62

  REAGENT MODULE
      STATUS
   021%, 15 DAYS
JUNE-05-20  ;13:35
```

The EasyStat analyzer requires a two-point calibration after installation and warm-up. Automatic two-point calibrations occur at pre-selected intervals chosen under CAL FREQUENCY in the CONFIGURATION section of the SETUP MENU. Automatic Hct calibrations are included in each two-point calibration. On-demand two-point calibrations can be initiated in the HOME MENU by choosing CALIBRATE. If not calibrated, the HOME MENU only displays options 3, 4 and 5.



The ACCESS DOOR must be closed during warm-up, calibration, and sampling.

Select CALIBRATE to perform a two-point calibration and prepare the EasyStat analyzer for sample analysis. The analyzer displays the calibration status. Bubble detector and pump cal results are printed at completion. After a successful calibration, the analyzer displays and prints the slope of each electrode, the % of calibrants remaining, and the number of days before expiration. After completion of a successful calibration, the analyzer displays LIFT SAMPLER TO ANALYZE pH PCO_2 PO_2 Hct Na^+ K^+ Ca^{++}.

▲ Ca^{++} is replaced with Cl^- when Cl^- mode is selected.

In addition to calibration, analysis of quality control material is required to verify the performance of the EasyStat analyzer. This procedure is outlined under Analyze QC in this chapter.

The EasyStat analyzer is factory set to perform automatic two-point calibrations every eight hours. To change the setting, proceed to the SECOND MENU and select SETUP MENU, then CONFIGURATION, and CAL FREQUENCY.

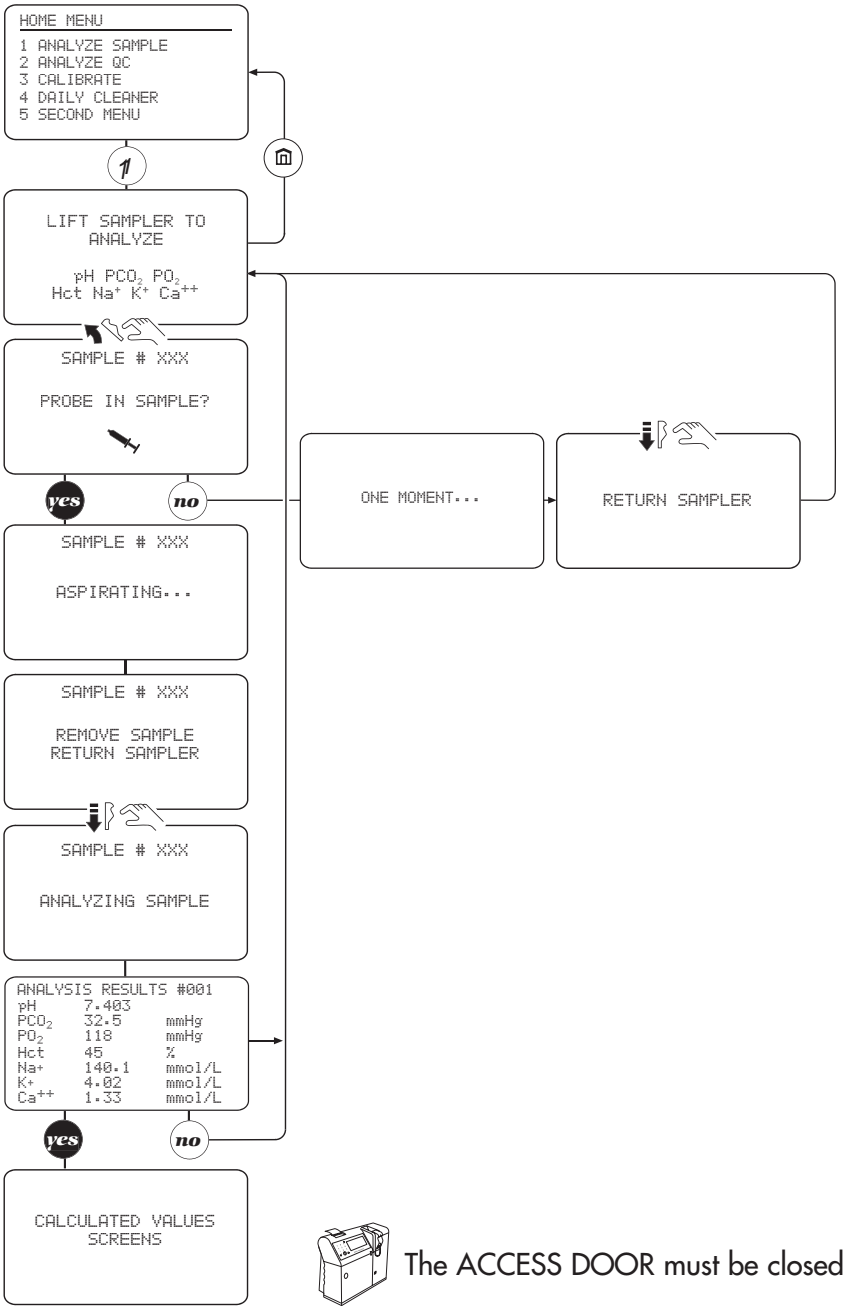
A two-point calibration can be interrupted to perform stat samples. Press NO and STOP CALIBRATION? is displayed. Press YES and SYSTEM CALIBRATION INTERRUPTED is displayed before returning to the HOME MENU for sample analysis. When the sampler is raised during calibration, the display prompts you to RETURN SAMPLER. When the sampler is returned to the closed position, the message SYSTEM CALIBRATION INTERRUPTED appears for 10 seconds before returning to the HOME MENU. No more than three interruptions are permitted during a scheduled calibration.

When an electrode does not calibrate successfully, that parameter will not appear on the screen. A parameter will not be displayed or printed if PATIENT DATA is turned off under USER OPTIONS in the SETUP MENU. The reporting of specific analytes is disabled under REPORTED PATIENT DATA. No sample results (including dependent calculated results) are given for that electrode. Refer to ELECTRODES in Troubleshooting.

The analyzer will display any error detected during calibration. If an error occurs, the analyzer will automatically attempt a second two-point calibration. If this fails, troubleshooting may be required.

During each sample analysis, the EasyStat analyzer performs a one-point calibration.

Analyze Sample



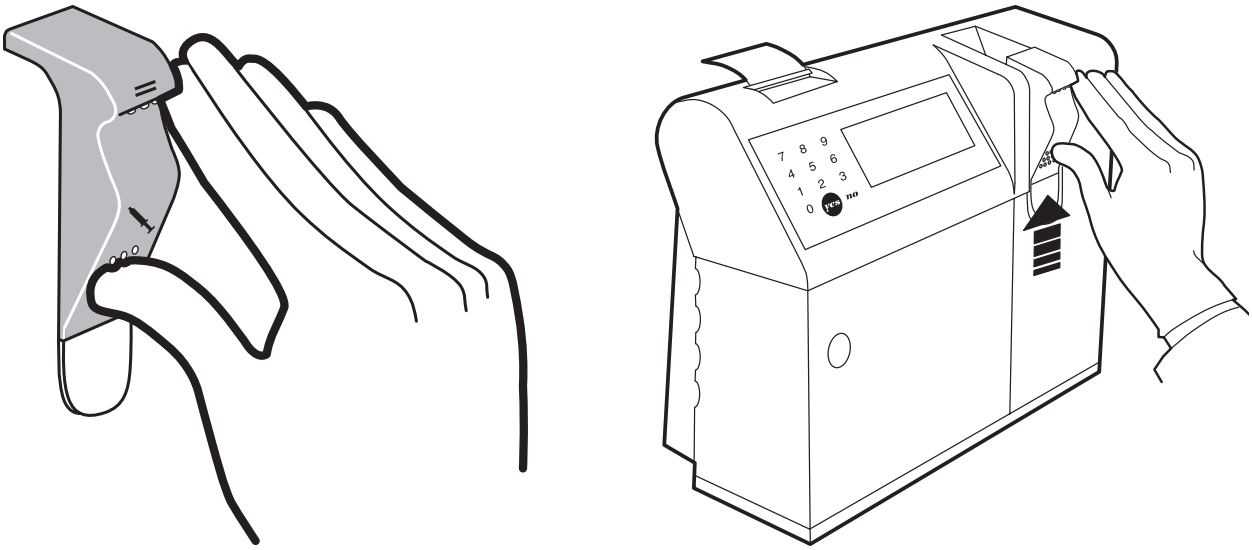
The ACCESS DOOR must be closed during sample analysis.

Select ANALYZE SAMPLE. The display shows LIFT SAMPLER TO ANALYZE pH PCO_2 PO_2 Hct Na^+ K^+ Ca^{++}. When an electrode does not calibrate successfully, that parameter will not be displayed on the screen. No sample results (including dependent calculated results) are given for that electrode. Refer to ELECTRODES in Troubleshooting.

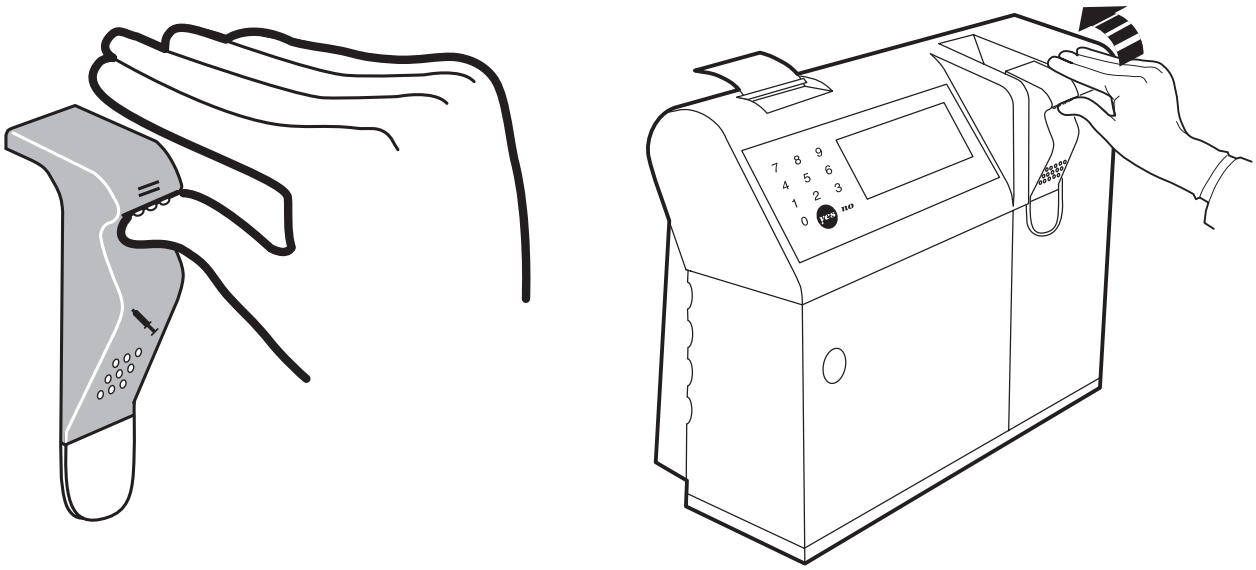
▲ Ca^{++} is replaced with Cl^- when Cl^- mode is selected.

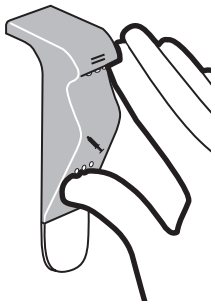
The EasyStat sampler is designed for two separate sample entry modes. To select the sampling mode, place your thumb on the raised dots under the corresponding symbol, and push up to lift the sampler for syringe or capillary samples.

Thumb placement for syringe samples. Push up.



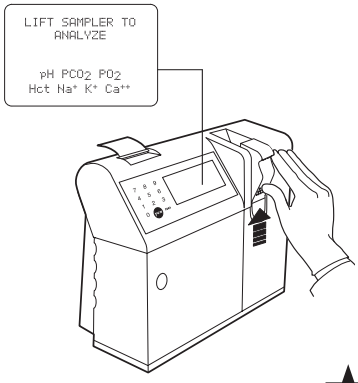
Thumb placement for capillary samples. Push up.



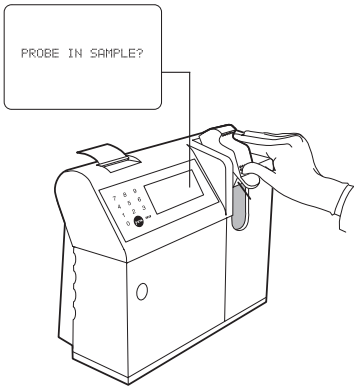


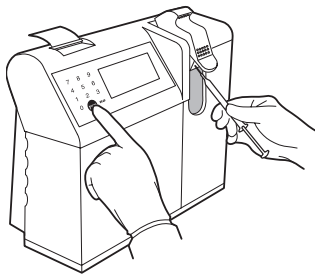
Syringe Mode

To analyze samples from blood gas syringes (120 µL minimum), lift the sampler until PROBE IN SAMPLE? is displayed.

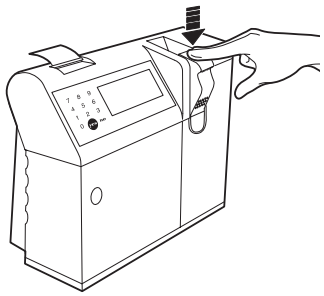


★ When using a syringe, it is important that the sample probe does not touch the plunger of the syringe. If this occurs, the resulting vacuum can damage the electrodes. The air in the syringe should be expelled immediately and completely upon sampling. Samples unexposed to air and preserved in ice water must be analyzed within 30 minutes.





Place the probe in the sample and press YES. Hold the syringe in place, keeping the probe submerged in the sample until REMOVE SAMPLE RETURN SAMPLER is displayed.



Push the sampler down into the closed position. If PATIENT INFORMATION settings are turned ON in the SETUP MENU, the ENTER PATIENT DATA? screen displays for 30 seconds. Press YES to enter patient information (2 minutes is allowed), or NO to continue. Analysis begins when the sample is automatically positioned inside the electrodes.

If the sampler is not returned within two minutes of aspiration the sample will be pumped to waste ▲

Sample analysis can be interrupted by pressing NO. STOP ANALYSIS? is displayed. Press YES and ANALYSIS INTERRUPTED is displayed before returning to the LIFT SAMPLER TO ANALYZE pH PCO_2 PO_2 Hct Na^+ K^+ Ca^{++} screen. ▲

When analysis is complete, the measured results are printed with the current sample number. The measured results are reported in mmHg for blood gas parameters and mmol/L for electrolytes. When alternate units are on (refer to CONFIGURATION in the SETUP MENU), blood gas results are expressed in KPa and electrolytes are expressed in mEq/L.

Results are automatically printed after each analysis if the printer is turned on under CONFIGURATION in the SETUP MENU. The measured results are compared to the normal and critical limits set under SET REFERENCE LIMITS in the SETUP MENU. When analysis results are in the critical range, they are flagged as low (↓↓) or high (↑↑) on both the display and the printout. Patient results that are outside the normal range, and not in the critical range will be flagged as low (↓) or high (↑) on the display and printout. If any result is not within the analyzer's measurement range, the result is displayed and printed as — e.g., pH < 6.50 ↓↓ or pH > 8.00 ↑↑. The display will show < 6.50 ↓↓ or > 8.00 ↑↑ blinking on and off. The analyzer displays CALCULATED VALUES?. The calculated results print with the measured results. View the calculated values by pressing YES.

```
ANALYSIS RESULTS 005
    - - - - - - - -
 PATIENT INFORMATION

NAME
ID   123456789

PAT. TEMP  37.0 C
FIO2        21%
SAMPLE TYPE  ARTERIAL
B.P.        753.4 mmHg
    - - - - - - - -

pH         7.203      ↓
PCO2      64.4  mmHg  ↑
PO2       70    mmHg  ↓
Hct       43    %
Na+      110.0  mmol/L
K+         2.16 mmol/L
Ca++       1.49 mmol/L

CALCULATED VALUES

THb       15.3   g/dL
pH(T)      7.203
PCO2(T)   64.4 mmHg
PO2(T)      70 mmHg

TCO2      27.3 mmol/L
HCO3      25.3 mmol/L
BEb     - 4.2 mmol/L
BEecf   - 2.8 mmol/L
SBC       21.4 mmol/L

%SO2 c    88.8 %
O2 ct     18.1 mL/dL
A-aDO2       1 mmHg
RI        0.02
Ca(7.4) 1.40 mmol/L
 FEB-28-20__ :13:16
```

▲ Ca^{++} is replaced with Cl^- when Cl^- mode is selected.

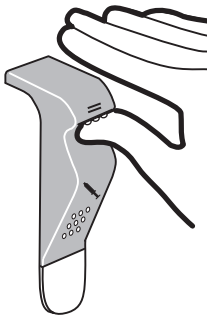
Calculated values for THb, pH(T), PCO_2(T), PO_2(T), TCO_2, HCO_3^-, and BE_b are displayed. MORE DATA? appears at the top of the display screen. Press YES to view the calculated results for BE_{ecf}, SBC, $\%SO_2c$, O_2ct, A-aDO_2, RI and Ca^{++} (7.4). The calculated results use the following default values, if patient values were not entered (see PATIENT INFORMATION screen in the SETUP MENU):

Patient Temp	37°C
Hb	14.5 g/dL
FIO_2	21%

▲ User entered correlation values are applied to the measured results to provide the displayed and printed results. If correlations are applied, reported results will be printed as CORRELATION APPLIED results. Refer to CORRELATION under USER OPTIONS in the SETUP MENU for more information.

▲ In Cl^- mode, Ca^{++} (7.4) is replaced with Anion Gap.

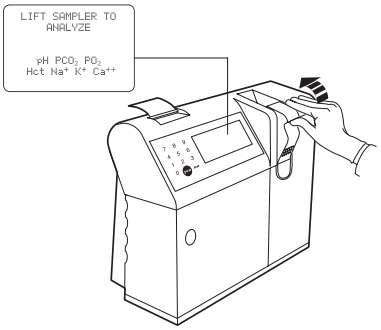
Capillary Mode ═



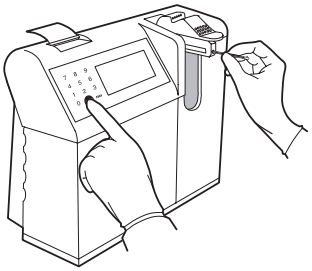
To analyze samples from capillary tubes (95 µL minimum), lift the sampler until CAPILLARY INSERTED? ═ is displayed.

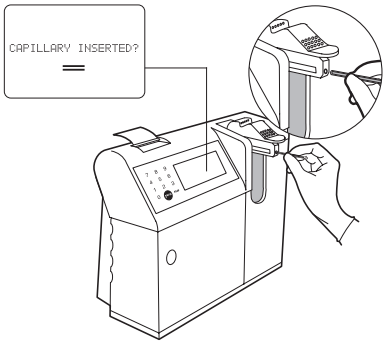
Note: Use only the Medica capillary kit. Use of other capillary tubes may result in erroneous results or damage to the analyzer and electrodes.

★ The capillary should be filled entirely with no visible air bubbles. Seal the ends with caps. Analyze the capillary sample within 10 minutes of sampling.



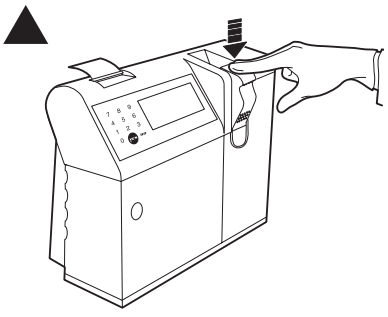
Insert the capillary tube into the capillary port. When inserted, press YES and the sample is aspirated. REMOVE CAPILLARY RETURN SAMPLER is displayed.



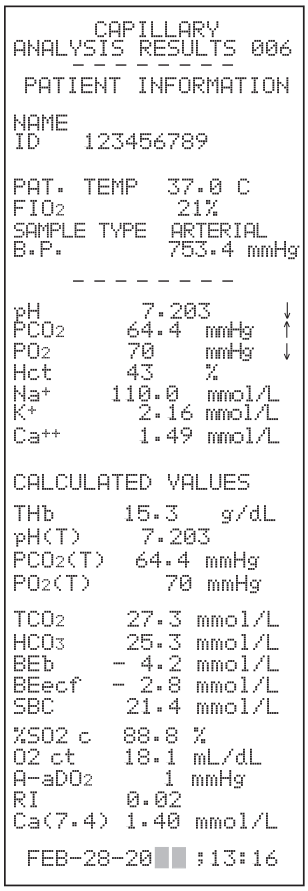


Push the sampler down into the closed position. If PATIENT INFORMATION settings are turned ON in the SETUP MENU, the ENTER PATIENT DATA? screen displays for 30 seconds. Press YES to enter patient information (2 minutes is allowed), or NO to continue. Analysis begins when the sample is automatically positioned inside the electrodes.

Sample analysis can be interrupted by pressing NO. STOP ANALYSIS? is displayed. Press YES and ANALYSIS INTERRUPTED is displayed before returning to the LIFT SAMPLER TO ANALYZE pH PCO_2 PO_2 Hct Na^+ K^+ Ca^{++} screen.



▲ Ca^{++} is replaced with Cl^- when Cl^- mode is selected.



```
      CAPILLARY
ANALYSIS RESULTS 006
     - - - - - - - -
 PATIENT INFORMATION

NAME
ID   123456789

PAT. TEMP  37.0 C
FIO2        21%
SAMPLE TYPE  ARTERIAL
B.P.        753.4 mmHg
    - - - - - - - -

pH        7.203      ↓
PCO2     64.4  mmHg  ↑
PO2      70    mmHg  ↓
Hct      43    %
Na+     110.0  mmol/L
K+        2.16 mmol/L
Ca++      1.49 mmol/L

CALCULATED VALUES
THb      15.3   g/dL
pH(T)     7.203
PCO2(T)  64.4 mmHg
PO2(T)      70 mmHg

TCO2     27.3 mmol/L
HCO3     25.3 mmol/L
BEb     - 4.2 mmol/L
BEecf   - 2.8 mmol/L
SBC      21.4 mmol/L

%SO2 c   88.8 %
O2 ct    18.1 mL/dL
A-aDO2      1 mmHg
RI       0.02
Ca(7.4) 1.40 mmol/L

 FEB-28-20■■ ;13:16
```

When analysis is complete, the measured results are printed with the current sample number. The measured results are reported in mmHg for blood gas parameters and mmol/L for electrolytes. When alternate units are on (refer to CONFIGURATION in the SETUP MENU), blood gas results are expressed in KPa and electrolytes are expressed in mEq/L.

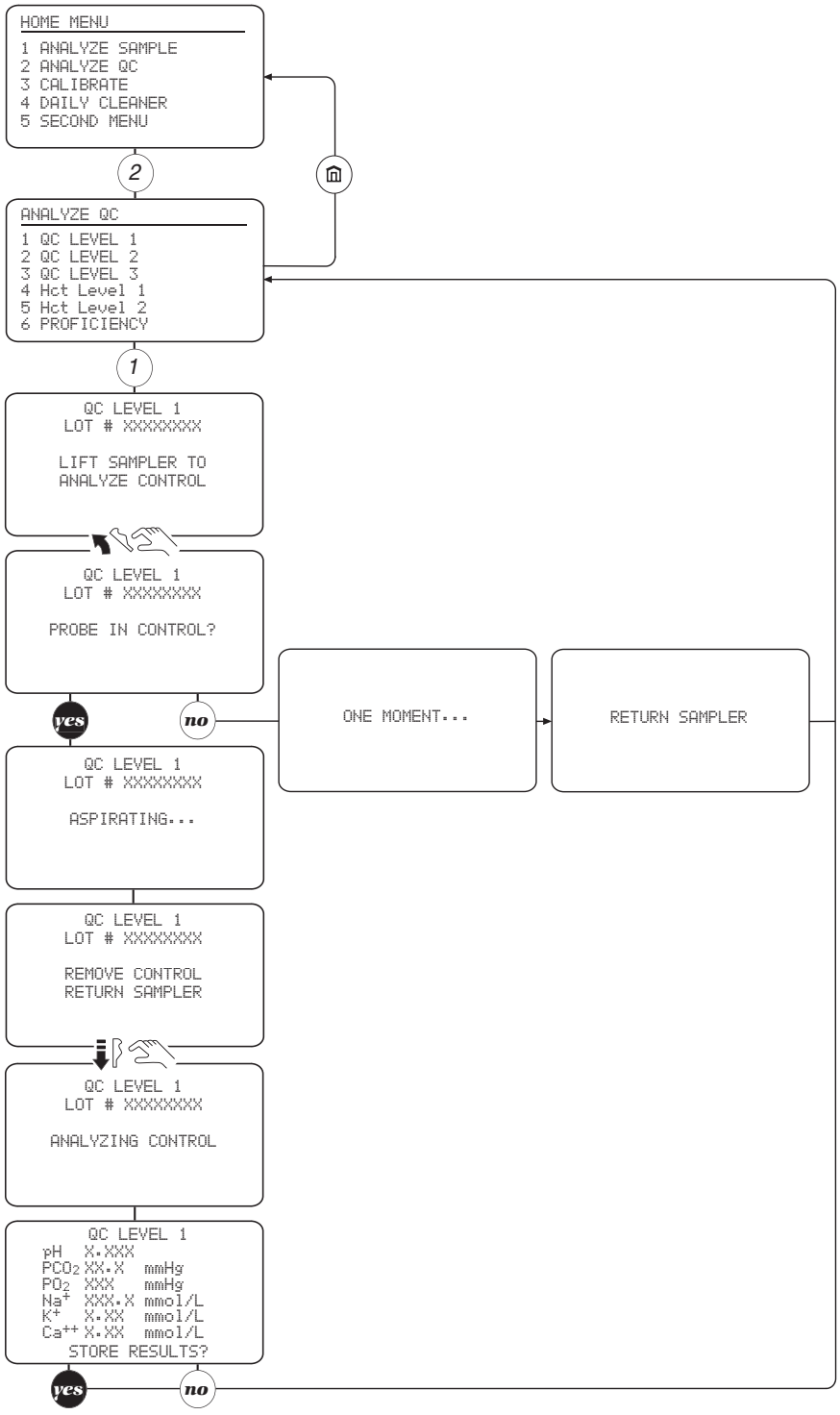
Results are automatically printed after each analysis if the printer is turned on under CONFIGURATION in the SETUP MENU. The measured results are compared to the normal and critical limits set under SET REFERENCE LIMITS in the SETUP MENU. When analysis results are in the critical range, they are flagged as low (↓↓) or high (↑↑) on both the display and the printout. Patient results that are outside the normal range, and not in the critical range will be flagged as low (↓) or high (↑) on the display and printout. If any result is not within the analyzer's measurement range, the result is displayed and printed as — e.g., pH < 6.50 ↓↓ or pH > 8.00 ↑↑. The display will show < 6.50 ↓↓ or > 8.00 ↑↑ blinking on and off.

The analyzer displays CALCULATED VALUES?. The calculated results are printed with the measured results. View the calculated values by pressing YES. Calculated values for THb, pH(T), PCO_2(T), PO_2(T), TCO_2, HCO_3^-, and BE_b are displayed. MORE DATA? appears at the top of the display screen. Press YES to view the calculated results for BE_{ecf}, SBC, $\%SO_2c$, O_2ct, A-aDO_2, RI, and Ca^{++} (7.4). In Cl^- mode, Ca^{++} (7.4) is replaced with Anion Gap.The calculated results use the following default values, if patient values were not entered (see PATIENT INFORMATION screen in the SETUP MENU):

Patient Temp	37°C
Hb	14.5 g/dL
FIO_2	21%

User entered correlation values are applied to the measured results to provide the displayed and printed results. If correlations are applied, reported results will be printed as CORRELATION APPLIED results. Refer to CORRELATION under USER OPTIONS in the SETUP MENU for more information.

Analyze QC





The ACCESS DOOR must be closed during analysis.

As with all clinical instrumentation, the performance of the EasyStat analyzer must be monitored using quality control samples. Each laboratory should establish their own quality control program. Medica requires the use of quality controls every day patient samples are analyzed and after any troubleshooting.

Medica controls are designed to contain pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, and Cl^- values that are within the typical patient population. Each lot of EasyStat control contains an insert sheet indicating the expected ranges for pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, and Cl^-. Using the 3 levels of controls as part of the laboratory quality control program will aid in verifying analyzer performance. If controls have results outside the expected ranges, the performance of the analyzer may not be optimum. If necessary, corrective action should be taken before reporting patient results. Factors that can shift control results from the insert sheet ranges are:

- control material temperature when ampule is opened (PO_2 control values increase by 1.3% for every 1°C decrease in storage temperature from 23°C or PO_2 control values decrease by 1.3% for every 1°C increase in storage temperature from 23°C)
- elevation (PO_2 control values decrease by 1% for every 1000 feet (305m) above sea level)
- correlation factors applied to quality control samples

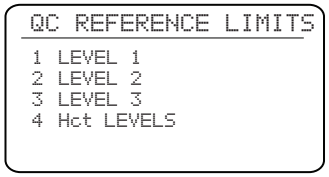
The hematocrit controls are assayed quality control materials used to monitor the measurements of hematocrit in the EasyStat analyzer. Electrical conductivity methodologies are used to determine hematocrit.

Medica hematocrit controls are designed to contain hematocrit values that are within the typical patient population. Each lot of control contains an insert sheet indicating the expected ranges for hematocrit. The values for each control analyte are based on multiple determinations performed on randomly selected samples from each lot. The expected range and mean values shown are provided as a guide in evaluating analyzer performance. The mean value established should fall within the expected value range shown on the chart provided.

As part of a good quality control program, each laboratory should establish their own ranges for each lot of controls over multiple days. The ranges must be examined for clinical significance.

Once established, enter the limits into the EasyStat analyzer under SET REFERENCE LIMITS in the SETUP MENU.

The EasyStat stores quality control results for 3 levels (a maximum of 93 for each level) when control samples are analyzed through ANALYZE QC. The results for pH, PCO_2, PO_2, Hct, Na^+, K^+, Ca^{++}, and Cl^- are compared to the quality control reference limits previously entered for the chosen level of quality control. Levey-Jennings charts can be printed to document the performance of the stored quality control sample results over time.



Quality Control Settings

Quality control limits and lot numbers must be entered for each new lot of quality controls, before selecting ANALYZE QC from the HOME MENU. Proceed to the SECOND MENU and select SETUP MENU, then REFERENCE LIMITS. Select QC, then LEVEL 1, LEVEL 2, or LEVEL 3, or Hct Levels.

▲ It is recommended that any stored quality control results be deleted prior to entering information for a new lot of quality controls. Refer to DELETE DATA in the SETUP MENU.

Select LEVEL 1, 2, 3, or Hct LEVELS to enter the limits and lot number each time a new lot of controls is introduced. The display lists pH, PCO_2, PO_2, Hct, Na^+, K^+, or Ca^{++} limits.* Press NO, then use the number keys to enter the new lot number and limits. Press YES to confirm each and move to the next entry. When all entries are complete, press YES to CONFIRM?. If NO is pressed as a response to CONFIRM?, the settings can be corrected. Repeat for each level of control. To proceed with quality control analysis, press ⌂ to return to HOME MENU.

▲ If RiliBAK feature is on, press NO and use the number keys to enter the lot number and the target from the package insert. The analyzer calculates the limits using the RiliBAK percent deviation and target value. The percent deviation or the RiliBAK limits can be changed manually using the number keypad. Press YES to confirm the entry and advance to the next entry.

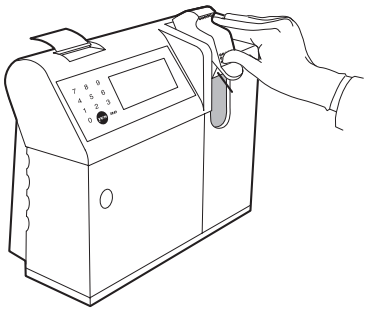
▲ To enter quality control information using the barcode reader, Medica quality controls must be used.

To enter quality control information using the barcode reader, Select LEVEL 1, 2, 3, or Hct LEVELS. LOT # is highlighted on the display. Using the barcode reader, scan in the lot number provided on the quality control insert sheet. Next, the parameter will be highlighted. Scan in the parameter range (verify that the displayed range matches the insert sheet). Repeat for remaining parameters. When all entries are complete, press YES to CONFIRM?. When NO is pressed as a response to CONFIRM?, the settings can be corrected. Repeat for each level of control. To proceed with quality control analysis, press ⌂ to return to HOME MENU.

▲ *Cl^- limits will be listed for Cl^- (Chloride) mode.

Quality Control Analysis

Follow the manufacturer's storage and handling instructions for quality control material before proceeding with quality control analysis.



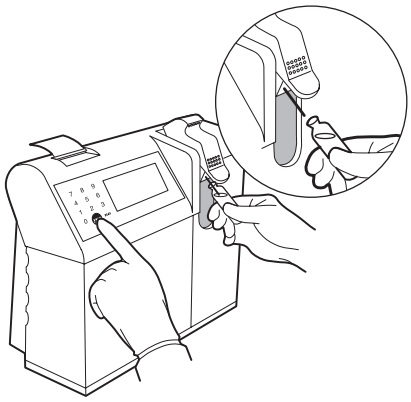
The Easy QC materials are aqueous solutions with gasses dissolved in them along with other components necessary to qualify the electrodes. Prior to the testing of these materials, careful attention needs to be paid to the instructions. If the ampules are not prepared and handles as instructed, erroneous readings may result.

Refer to the insert sheet enclosed in the Easy QC package for proper handling instructions.

The sampler must be in the syringe mode position.

Select ANALYZE QC for Level 1, 2, 3 or Hct. Select the desired level. Break open the quality control ampule and analyze *immediately*.

Lift the sampler and PROBE IN CONTROL? is displayed.



Place the probe in the quality control material and press YES. Hold the ampule in place, keeping the probe submerged in the ampule until REMOVE CONTROL RETURN SAMPLER is displayed. Push the sampler down into the closed position. The quality control is analyzed and results for each parameter are displayed and printed. Results falling outside the quality control limits are flagged as (↓) low or (↑) high.

Three quality control results for each level are automatically stored each day when no errors are detected. When more than three of a control level are performed on the same day, the three most recent results replace the results previously stored for that day. The EasyStat analyzer stores up to 93 quality control results for each level.

If a result is outside the limits or an error occurs, a STORE RESULTS? prompt is displayed. Press YES to store quality control results, or NO to reject the results.

If selected, quality control correlation factors will be applied to results.

Proficiency

To analyze proficiency samples, select PROFICIENCY under ANALYZE QC. These samples are analyzed without applying correlation values to the measured results, which enables the EasyStat results to be grouped together on the proficiency program's interlaboratory reports. The proficiency results are not stored.

Stored QC Information

Select STORED INFORMATION from the SECOND MENU, then QC RESULTS to view the last quality control results, print QC statistics or plot QC charts. PRINT QC STATS prints the results by date, mean, standard deviation, and coefficient of variation for the stored quality control results. PLOT QC CHARTS prints the stored quality control results as a Levey-Jennings chart. The statistics are calculated according to the following definitions:

▲ A minimum of 5 stored quality control results is required to calculate statistics.

Definitions

Mean: The mean (x) is the value derived by dividing the sum (Σ) of the observed values by the number of observations (n) stored in memory (between 5 and 93 values).

$$\bar{x} = \frac{\Sigma \text{ values}}{n}$$

SD: The standard deviation (SD) measures dispersion within the distribution of data stored.

where: $$SD = \sqrt{\frac{(x-\bar{x})^2}{n-1}}$$

$\Sigma(x-x)^2$= sum of the square of each difference from the mean

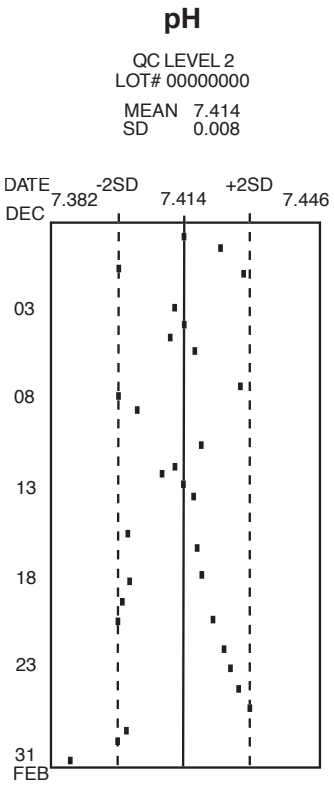
n = number of observations

CV: The coefficient of variation (CV) is a measure (as a percentage) of the variation from the mean within the set of stored data.

$$CV = \frac{100\ SD}{\bar{x}}$$

Levey-Jennings Chart:

Levey-Jennings charts plot the measured quality control results for each day. The calculated mean value is shown by the solid, vertical center line. The +/- 2 SD values are shown by the dashed lines. The limits of the charts are the mean +/- 4 SD. The Levey-Jennings charts plot data for the last 31 days. (See example below.)



The statistics reported above each chart require a minimum of 5 stored quality control results. The maximum number of stored results is 93 for each level.

Random Errors

An isolated result which falls outside the +/- 3 SD control limits is classified as a random error. When a single random error occurs, disregard the result. When there is an increase in the frequency of random errors, the quality control sampling technique should be reviewed.

Systematic Errors

A recurring measurable deviation from the mean is classified as a systematic error. One example of a systematic error is when a progressive increase or decrease in control results is noted. Possible causes are:

- aging or protein contaminated electrode
- bubbles beneath an electrode membrane
- a change in calibrant
- a change in temperature
- a change in quality control material
- aging reference electrode

If the sampling technique is acceptable and random errors continue, refer to ELECTRODES in Troubleshooting.

Users should follow applicable agency requirements for quality control testing. ▲

Recommended Material

EasyQC Quality Controls:

- Level 1
- Level 2
- Level 3
- Hct Level 1
- Hct Level 2

Do not use perfluorocarbon-based control materials on the EasyStat analyzer. This type of control material will damage the electrodes. ▲

Precautions

Refer to the package insert provided with the quality control material.

Recommended Procedure

Run all control levels each day the analyzer is in use. Data is stored for future statistical analysis.

Use Instructions

Refer to the package insert provided with the quality control material.

Storage and Stability

Refer to the package insert provided with the quality control material.

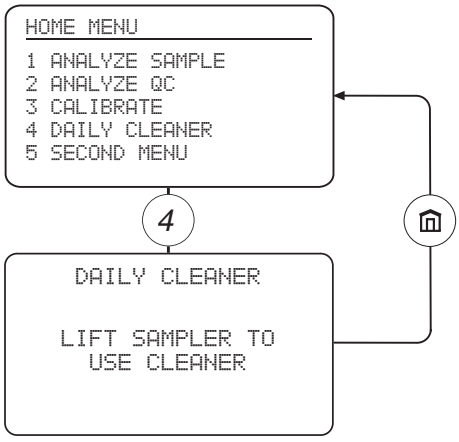
Handling

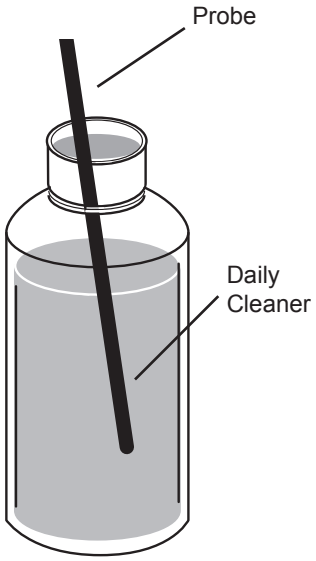
Refer to the package insert provided with the quality control material.

Expected Results

Refer to the package insert provided with the quality control material.

Daily Cleaner





The fluid path *must* be cleaned with daily cleaning solution to remove protein deposits. The analyzer will display CLEANER REQUIRED if more than 10 samples have been analyzed and more than 24 hours have elapsed since the last cleaning cycle.

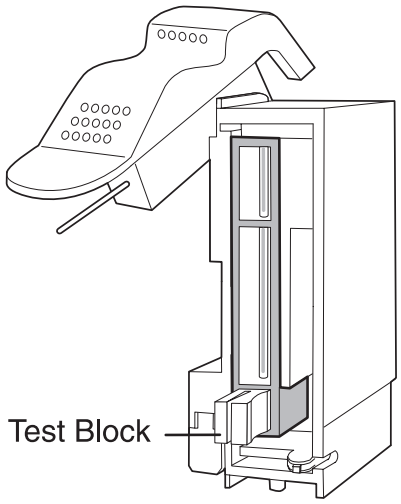
Select DAILY CLEANER. The display shows LIFT SAMPLER TO USE CLEANER. The sampler must be in the syringe mode position. Lift the sampler until PROBE IN CLEANER? appears. Insert the probe into the cleaning solution and press YES to aspirate. Hold the container in place until REMOVE CLEANER RETURN SAMPLER is displayed.

Push the sampler down into the closed position. The cleaning cycle is followed by an automatic two-point calibration to prepare the analyzer for sample analysis. LIFT SAMPLER TO ANALYZE pH PCO_2 PO_2 Hct Na^+ K^+ Ca^{++} is displayed when calibration is successful.

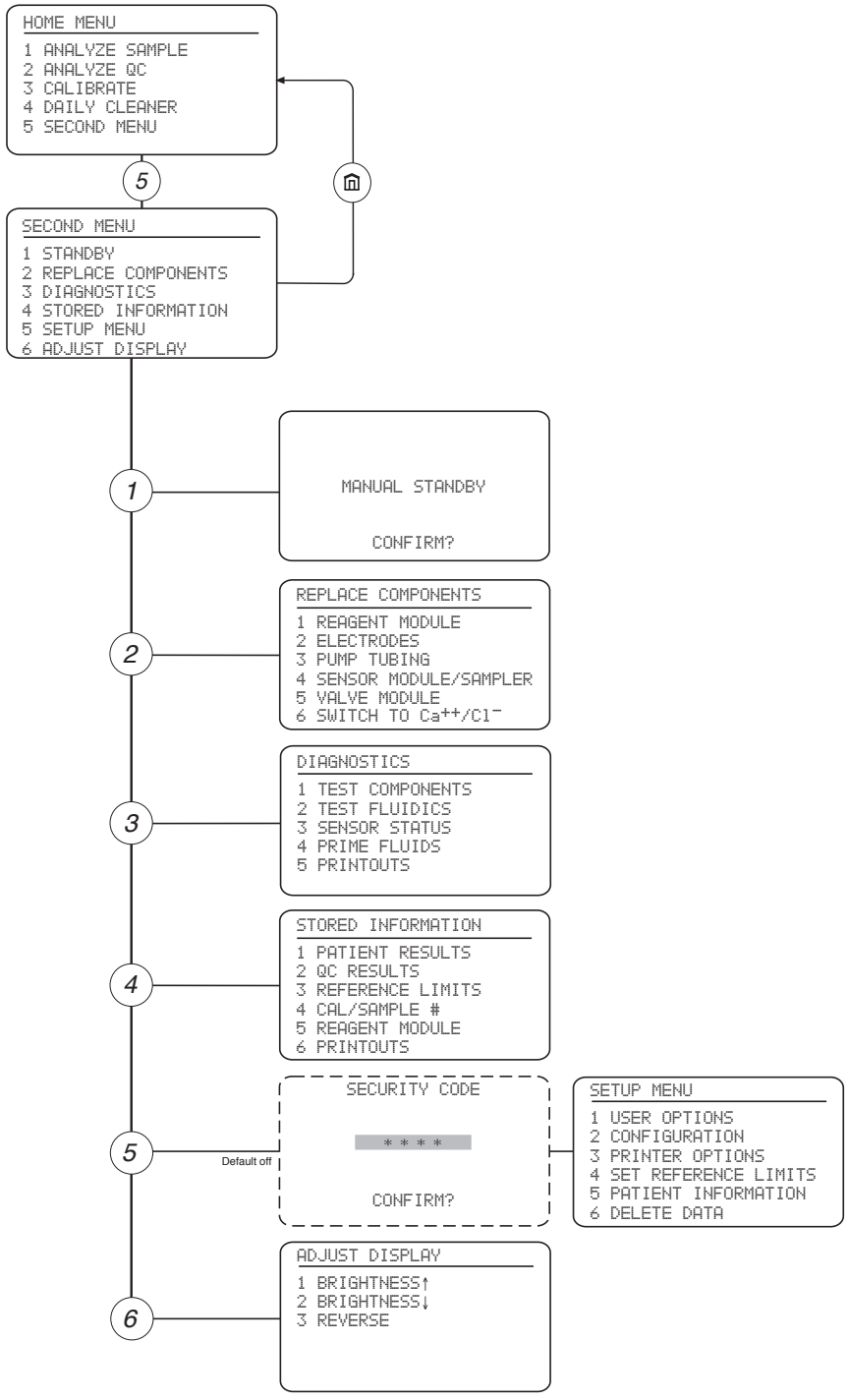
▲ Ca^{++} is replaced with Cl^- when Cl^- mode is selected.

When CLEANER REQUIRED is displayed, a cleaning cycle must be completed before calibration or sample analysis is permitted. Performing a cleaning cycle is the only daily maintenance required, and is essential to promote trouble-free analyzer operation.

As preventive maintenance or when a PCO_2 or PO_2 electrode is being replaced, a more aggressive cleaning procedure can be performed to remove accumulated protein within the sampler and preheater. The frequency of this procedure is dependent on the number and quality (high protein concentrations) of patient samples run. This procedure can be performed infrequently (once every 6 months) or as frequently as once per month. Each laboratory should establish their own preventative maintenance program. To perform this preventative maintenance, refer to the Sample probe/sensor module obstructions procedure found under FLOW in Troubleshooting.

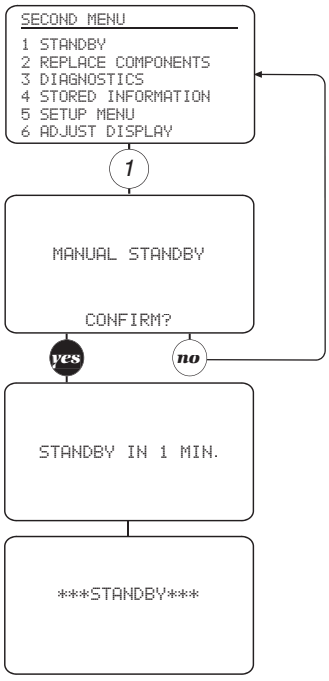


Second Menu


HOME MENU
1 ANALYZE SAMPLE
2 ANALYZE QC
3 CALIBRATE
4 DAILY CLEANER
5 SECOND MENU
5
SECOND MENU
1 STANDBY
2 REPLACE COMPONENTS
3 DIAGNOSTICS
4 STORED INFORMATION
5 SETUP MENU
6 ADJUST DISPLAY
1
MANUAL STANDBY
CONFIRM?
2
REPLACE COMPONENTS
1 REAGENT MODULE
2 ELECTRODES
3 PUMP TUBING
4 SENSOR MODULE/SAMPLER
5 VALVE MODULE
6 SWITCH TO Ca++/Cl-
3
DIAGNOSTICS
1 TEST COMPONENTS
2 TEST FLUIDICS
3 SENSOR STATUS
4 PRIME FLUIDS
5 PRINTOUTS
4
STORED INFORMATION
1 PATIENT RESULTS
2 QC RESULTS
3 REFERENCE LIMITS
4 CAL/SAMPLE #
5 REAGENT MODULE
6 PRINTOUTS
5
Default off
SECURITY CODE
* * * *
CONFIRM?
SETUP MENU
1 USER OPTIONS
2 CONFIGURATION
3 PRINTER OPTIONS
4 SET REFERENCE LIMITS
5 PATIENT INFORMATION
6 DELETE DATA
6
ADJUST DISPLAY
1 BRIGHTNESS↑
2 BRIGHTNESS↓
3 REVERSE

Standby

Standby is activated manually or automatically to conserve fluids during long periods of inactivity. When in STANDBY, the analyzer discontinues automatic calibrations. The sensor module remains at 37.0°C, the valve module remains at 39.0°C, and fluid maintenance is performed.



Manual Activation

Select STANDBY from the SECOND MENU. The display reads MANUAL STANDBY CONFIRM?. Press YES to CONFIRM?. The display will read STANDBY IN 1 MIN. If NO is pressed, Standby is cancelled.

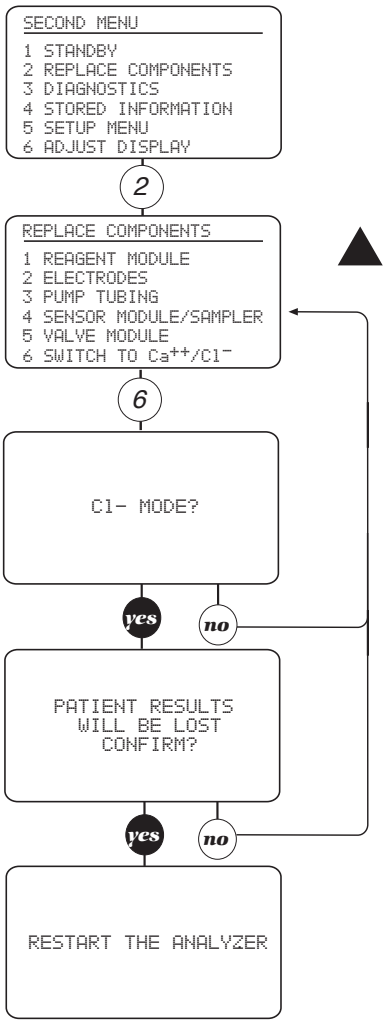
Automatic Activation

Turn AUTO STANDBY ON under CONFIGURATION in the SETUP MENU. The analyzer will enter STANDBY at the next scheduled calibration if no patient or quality control samples have been analyzed since the last calibration.

During Standby, the display reads STANDBY or STANDBY NOT CALIBRATED. When STANDBY NOT CALIBRATED is displayed, a calibration is required before sample analysis, after deactivating Standby. When STANDBY is displayed, the analyzer remains calibrated and sample analyses can be performed after deactivating Standby.

Deactivation

From the STANDBY or STANDBY NOT CALIBRATED display, press NO or ⌂. STANDBY OFF? is displayed. Press YES to deactivate Standby. Press NO to continue Standby. Once Standby is deactivated, the HOME MENU is displayed. If ANALYZE SAMPLE is displayed in the HOME MENU, sample analysis can be performed. If ANALYZE SAMPLE is not displayed, a calibration is required before sample analysis.



Replace Components

The EasyStat analyzer contains components which require periodic replacement. These components include the electrodes (pH, PCO_2, PO_2, Na^+, K^+, Ca^{++} , Cl^-, and Reference) and reagent module. The replacement schedule below must be followed to properly maintain the EasyStat analyzer.

It is recommended that quality control material be analyzed after component replacement to verify performance.

Switch to Ca^{++}/Cl^-, select SWITCH TO Ca^{++}/Cl^-. The display will show either Cl^- MODE (if the analyzer is currently in Ca^{++}) or Ca^{++} MODE (if the analyzer is currently in Cl^- mode). Press YES to move to next screen. Then press YES to confirm. PATIENT RESULTS WILL BE LOST. All the stored information will be erased. The analyzer will restart in the selected mode. Replace the correct electrode for the selected mode. Follow the instructions in this chapter to operate the analyzer.

PUMP TUBING	Replace every 6 months
VALVE MODULE	Replace as required
SENSOR MODULE	Replace as required
SAMPLER	Replace as required
pH ELECTRODE	Replace as required
PCO_2 ELECTRODE	Replace as required
PO_2 ELECTRODE	Replace as required
Na^+ ELECTRODE	Replace as required
K^+ ELECTRODE	Replace as required
Ca^{++} ELECTRODE	Replace as required
Cl^- ELECTRODE	Replace as required
REFERENCE ELECTRODE	Replace every 6 months
REAGENT MODULE	Replace when empty or expired
PRINTER PAPER	Replace as required
PROBE WIPER	Replace every 3 months



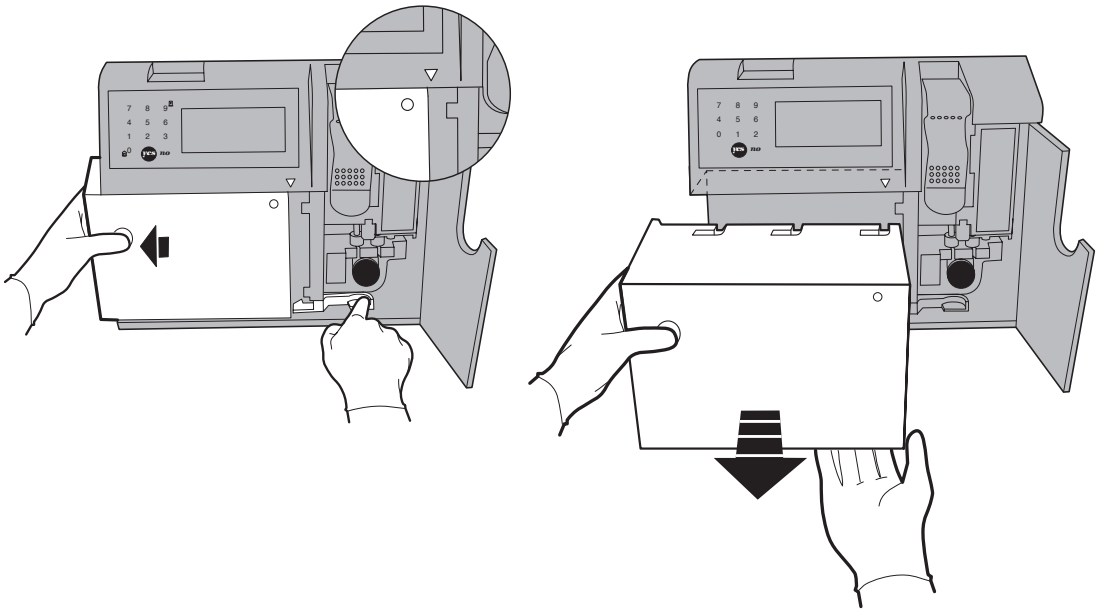
To replace EasyStat components, first select REPLACE COMPONENTS from the SECOND MENU, then proceed with component replacement as described in this section. If any replacement procedure exceeds 20 minutes, the analyzer beeps and NEED MORE TIME? is displayed. Press YES to return to the previous screen. When all replacements are complete, press the HOME key to return to the HOME MENU.

After any component replacement procedure, the WARMING UP message may appear for up to 30 minutes. During this time, the EasyStat will not calibrate or analyze samples.

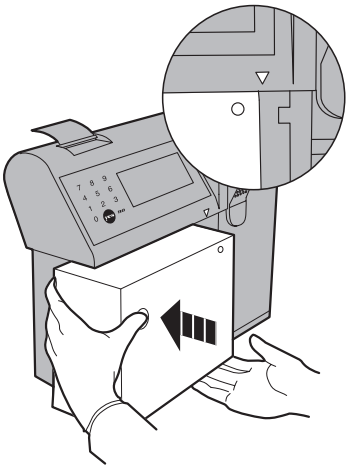
★ Failure to select the proper component from the REPLACE COMPONENTS menu could result in multiple reliability issues, including flow problems and/or slope, noise or drift errors.

Reagent Module

If the EasyStat displays RGNT MODULE EMPTY or RGNT MODULE EXPIRED, it is necessary to install a new reagent module. Select REAGENT MODULE from the REPLACE COMPONENTS menu. Fluid is automatically purged from the sample path. The display prompts you to REMOVE REAGENT MODULE. Open the access door. Push in the reagent module release lever while holding the reagent module on the left side. Pull the module to the left. When the guide arrow points to the edge of the reagent module, pull the module straight out from the front of the analyzer.

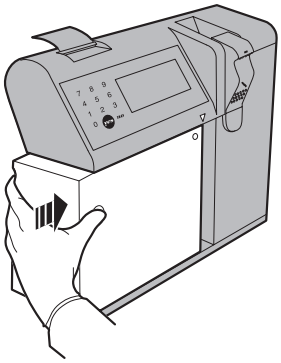


Used reagent module contains biohazardous waste.



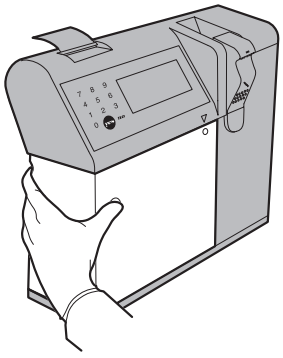
★ Prior to installation, a reagent module must be stored at room temperature for a minimum of four hours. When the center of the indicator on the back of the reagent module becomes dark, the module has been exposed to excessive temperature and must not be used.

Place the new reagent module into the front of the analyzer. The guide arrow must point to the right side of the reagent module. Push the module straight back, then firmly to the right to lock it into place against the valve module. Press YES to REPLACEMENT COMPLETED?. The reagents are automatically primed from the reagent module. When priming is complete, the display indicates the detection of each fluid with PASS, then automatically returns to the REPLACE COMPONENTS screen.



The reagent module contains encoded information which is read by the analyzer upon installation of the reagent module. This information includes: reagent pH, PCO_2, PO_2, Hct, Na^+, K^+, Ca^{++}, and Cl^- values, and install by date of the reagent module.

Electrodes

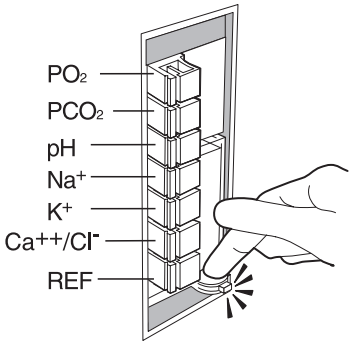


The best indicator that an electrode (pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, Cl^- or reference) requires replacement is when the EasyStat displays SLOPE ↑/↓, mV OUT OF RANGE or DRIFT for a *single* electrode. These messages generally indicate that the electrode is not functioning correctly. For detailed information, refer to the Troubleshooting chapter of this manual.

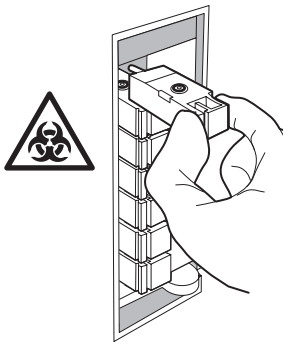
To remove or replace an electrode, select ELECTRODES from the REPLACE COMPONENTS menu. Fluid is automatically purged from the sample flow path. When the purge cycle is complete, REPLACEMENT COMPLETED? is displayed. Proceed with electrode replacement.

Failure to select the proper component from the REPLACE COMPONENTS menu could result in multiple reliability issues, including flow problems and/or slope, noise or drift errors.

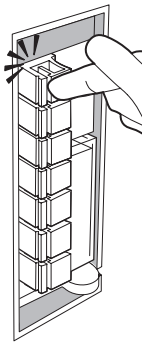
To remove an electrode, push the compression plate down until the latch locks into the open position.



Grip the desired electrode handle, squeeze, and pull it straight out from the sensor module.

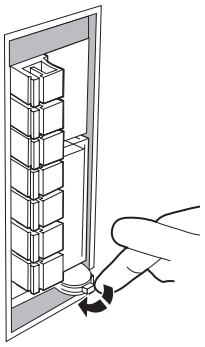


To install a new electrode, push the electrode into its designated position. The handle snaps into the sensor module. Each electrode is keyed to assure correct placement. DO NOT FORCE. Refer to the illustration and the access door label for correct electrode order and location.



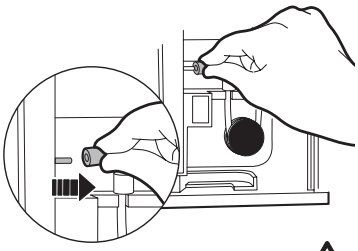
Release the compression plate to compress the electrodes within the sensor module.

Press YES to REPLACEMENT COMPLETED?. Reagents are automatically primed from the reagent module. When priming is complete, the display indicates the detection of each fluid with PASS, then automatically returns to the REPLACE COMPONENTS screen.



A WARMING UP message may appear for up to 30 minutes. During this time, the EasyStat will not calibrate or analyze samples.

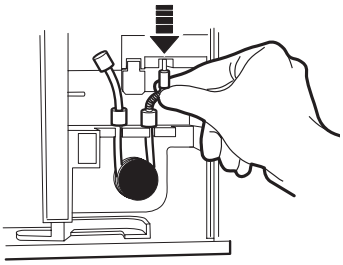
New electrodes require a short stabilization period to prevent drift errors. This stabilization is minimized by the analyzer, which performs calibrations every hour for 8 hours. After this stabilization period, the analyzer will calibrate at the calibration frequency selected under CAL FREQUENCY in the CONFIGURATION section of the SETUP MENU.



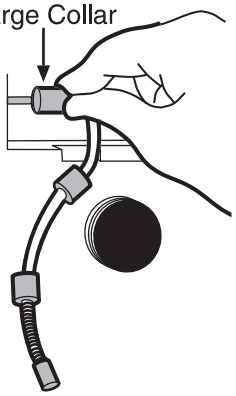
Pump Tubing

Replace the pump tubing every six months, or earlier if the pump tubing appears worn or flattened. Select PUMP TUBING. Fluid is automatically purged from the sample flow path. When the purge cycle is complete, proceed with pump tubing replacement.

Remove the pump tubing.



Large Collar

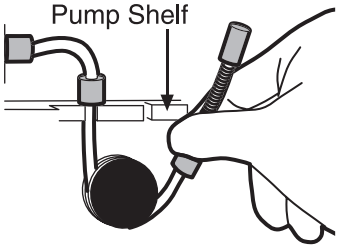


Install the new pump tubing.

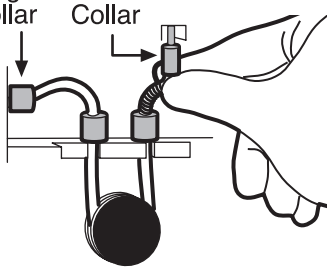
Push the two middle collars completely into the back of the slots on the pump shelf.

Press YES to REPLACEMENT COMPLETED? Reagents are automatically primed from the reagent module. When priming is complete, the display indicates the detection of each fluid with PASS, then automatically returns to the REPLACE COMPONENTS screen.

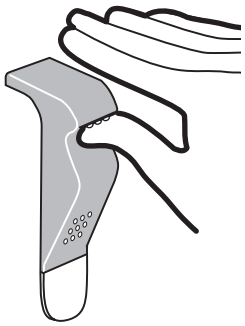
Pump Shelf



Large Collar Small Collar

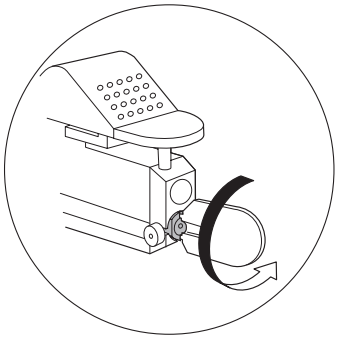


Probe Wiper Replacement

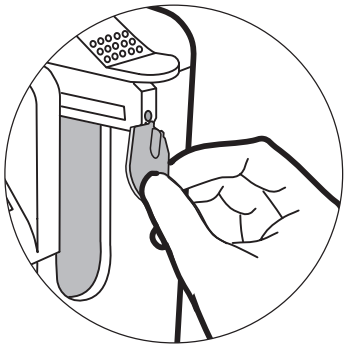


Probe wipers should be changed every 3 months. In some cases they may last longer, as the frequency of probe wiper replacement depends on the number and type of samples analyzed. If the motion of the sampler becomes difficult, wipe the probe with an oil wipe (provided in the probe wiper replacement kit). If the sampler's motion continues to be difficult, the probe wiper may need replacement.

Raise the sampler to the capillary sample position.

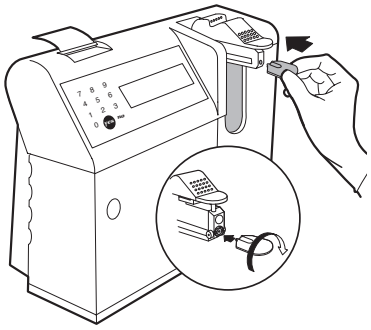


Using the tool supplied in the probe wiper replacement kit, turn the probe wiper 90° to unlock. This will align the notches on the probe wiper with the notch on the sampler.



Use the tool to pry the used probe wiper from the sampler.

Push the sampler down into the closed position, then raise the sampler to the sample container mode. Wipe the probe with an oil wipe (provided in the probe wiper replacement kit).

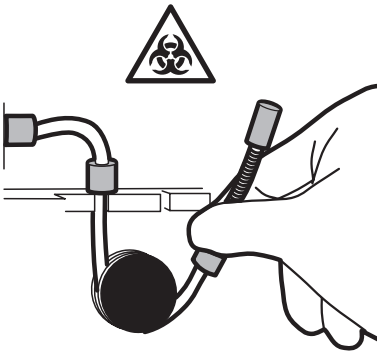


Insert the new probe wiper with the notches aligned. With the tool, turn the probe wiper 90° into the locked position. Lower and raise the probe into the sample container mode several times to verify proper probe motion.

Sensor Module/Sampler

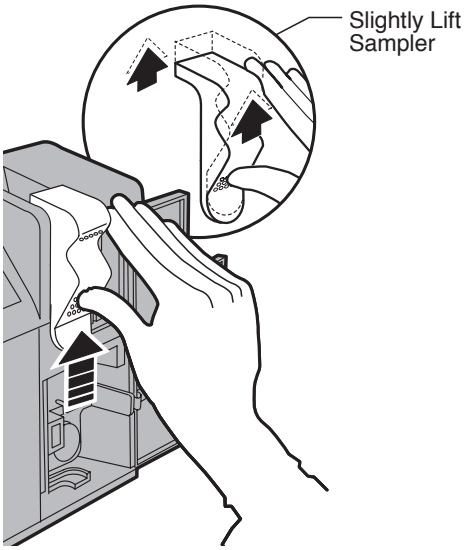
Sensor module or sampler replacement should be infrequent. Sensor Module replacement will be necessary only if certain display messages become chronic (refer to SENSOR MODULE in Troubleshooting). Sampler replacement is necessary if the sample probe is bent, damaged or obstructed (refer to FLOW in Troubleshooting), or if the sampler movement is defective.

Select SENSOR MODULE/SAMPLER. Fluid is automatically purged from the sample flow path. When the purge cycle is complete, proceed with sensor module and/or sampler replacement.

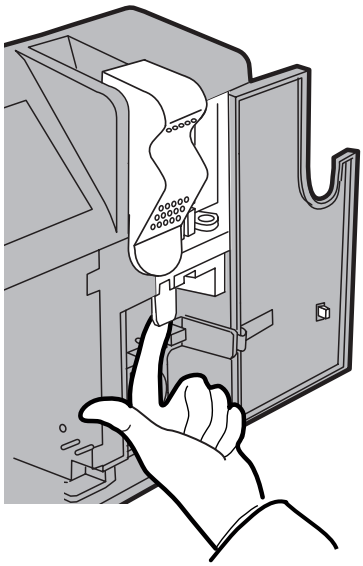


To remove the sensor module from the analyzer, first remove the pump tubing.

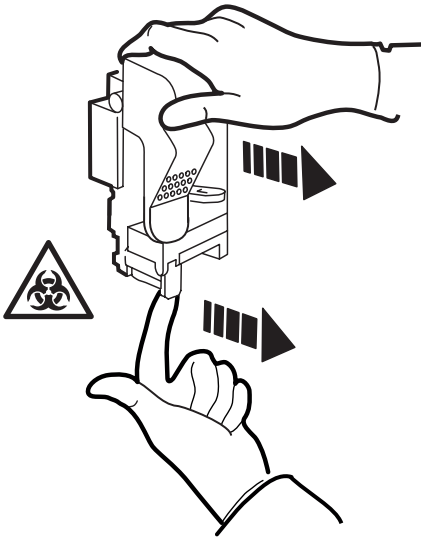
Disengage the sampler by slightly lifting the sampler until it unlocks from the valve module.



Pull the release lever and the sensor module is disengaged.

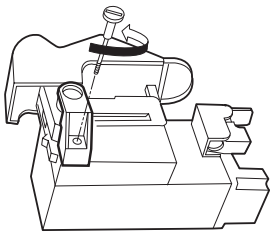


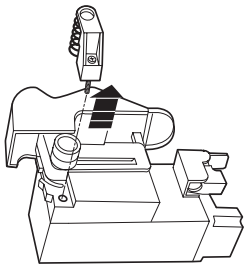
Remove from the analyzer.



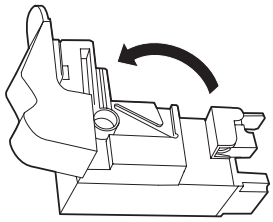
Sampler Removal

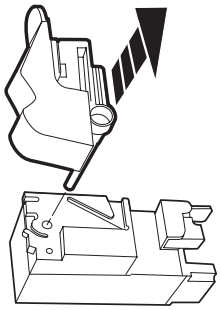
To remove the sampler from the sensor module, place the sensor module on its side with the sampler side up. Using a coin or fingers, remove the retaining screw from the sensor module. Remove the screw mount (includes spring).





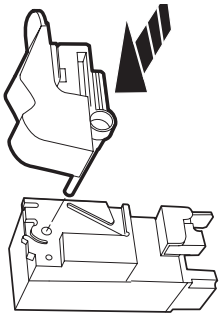
Rotate the sampler into the capillary mode position, then pull it out of the sensor module.

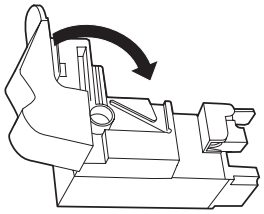




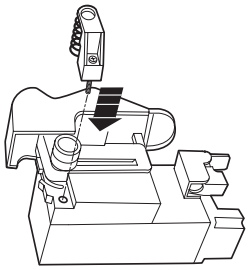
Installation

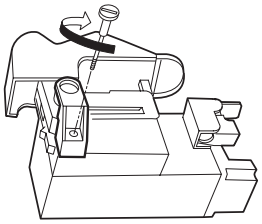
Install the new sampler (includes sample probe and wiper) in the sensor module. Insert the sampler alignment pin into the sensor module. Rotate the sampler into the closed position.



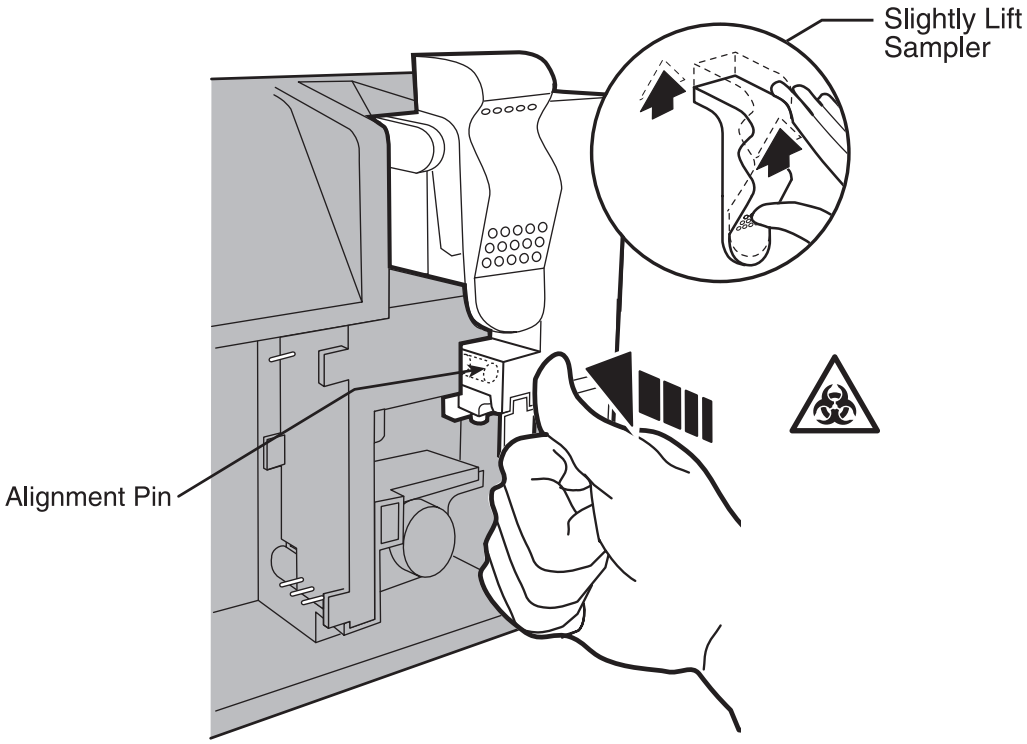


Install the screw mount (includes spring) into the sampler. Replace the retaining screw and tighten. DO NOT over tighten.

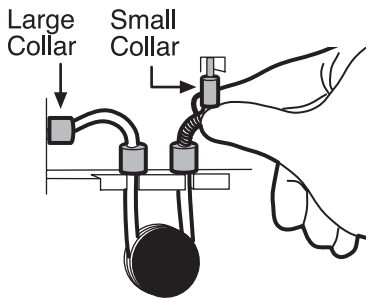


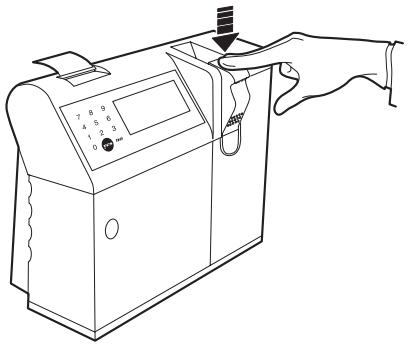


After installing a new sampler, reinstall the complete sensor module. Lift the sampler up slightly. Place the sensor module on the alignment pin and, using your thumb, push it straight back into position.



Reconnect the pump tubing to the valve module and sensor module. Push the sampler down into the closed position.



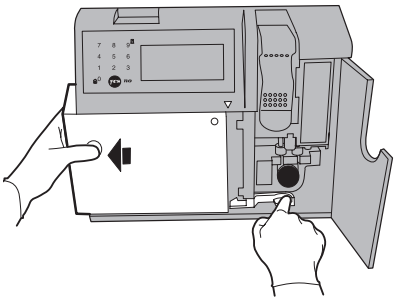


Press YES to REPLACEMENT COMPLETED?. Reagents are automatically primed from the reagent module. When priming is complete, the display indicates the detection of each fluid with PASS, then automatically returns to the REPLACE COMPONENTS screen.

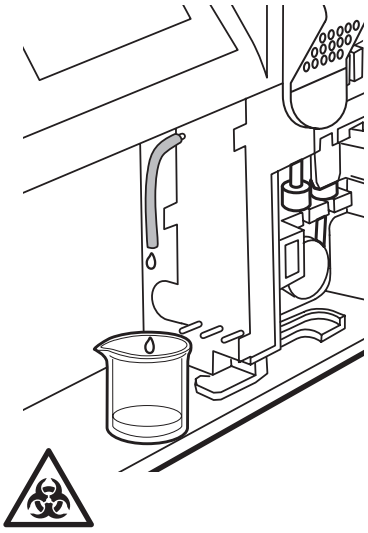
▲ A WARMING UP message may appear for up to 30 minutes. During this time, the EasyStat will not calibrate or analyze samples.

If the sampler was replaced, the sampler switches may be checked for proper function. Select the SAMPLER SWITCHES test outlined under Diagnostics in Operating the Analyzer.

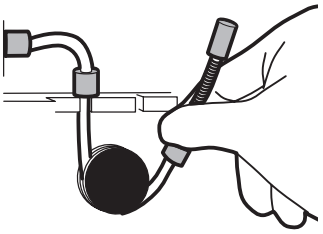
Valve Module



Valve Module replacement is necessary when VALVE ERROR or VALVE TEMPERATURE error messages become chronic (refer to VALVE MODULE in Troubleshooting).

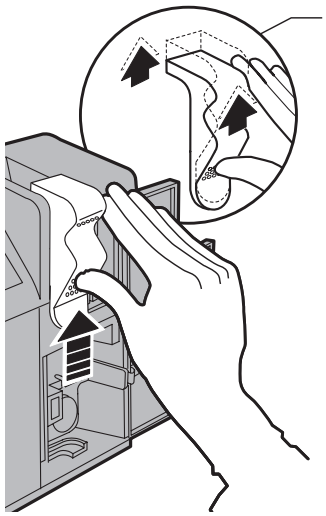


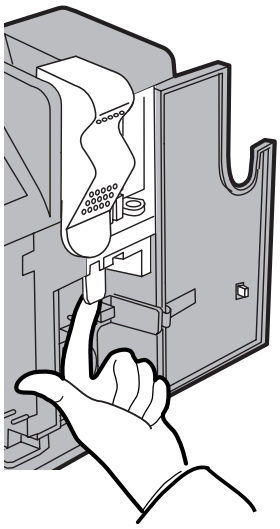
To remove or replace the valve module, select VALVE MODULE. Fluid is automatically purged from the sample path. REMOVE REAGENT MODULE is displayed. Remove the reagent module. PURGE WITH AIR, READY? is displayed. Connect the tubing from the troubleshooting kit to the valve module waste port with the open end placed into a waste receptacle. Press YES. Calibrant A, Calibrant B and Calibrant C are automatically purged from the valve module. When the purge cycle is complete, REPLACEMENT COMPLETED? is displayed. Proceed with valve module replacement.



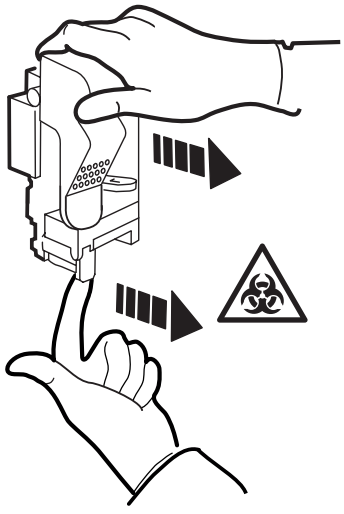
Remove the pump tubing.

Disengage the sampler by slightly lifting the sampler until it unlocks from the valve module.



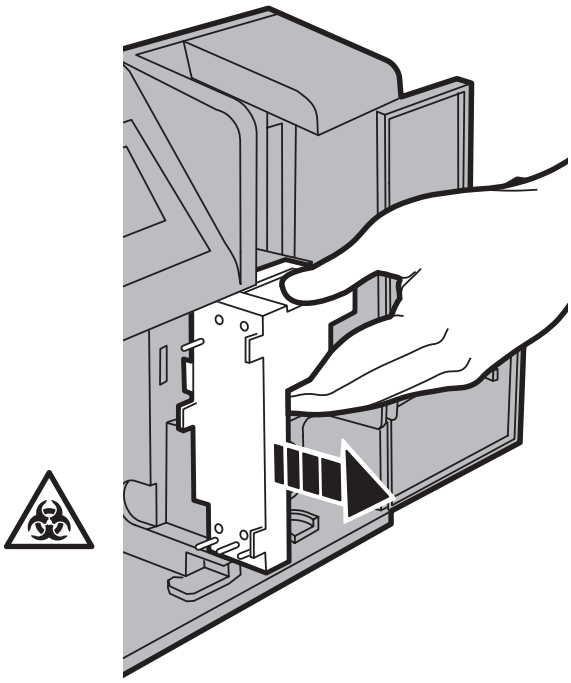


Pull the release lever and the sensor module is disengaged.

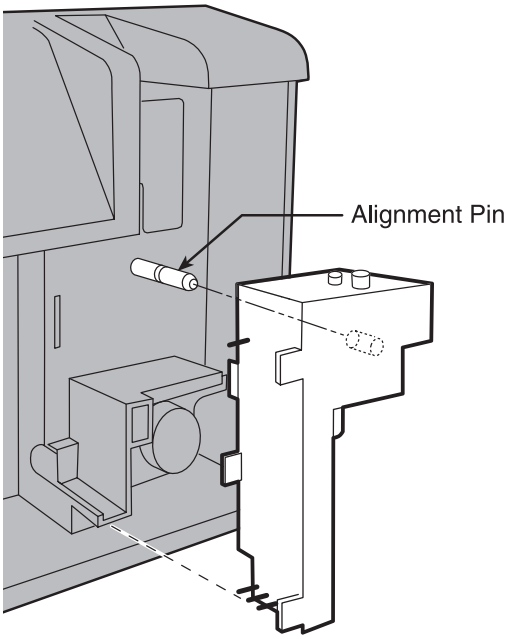


Remove from the analyzer.

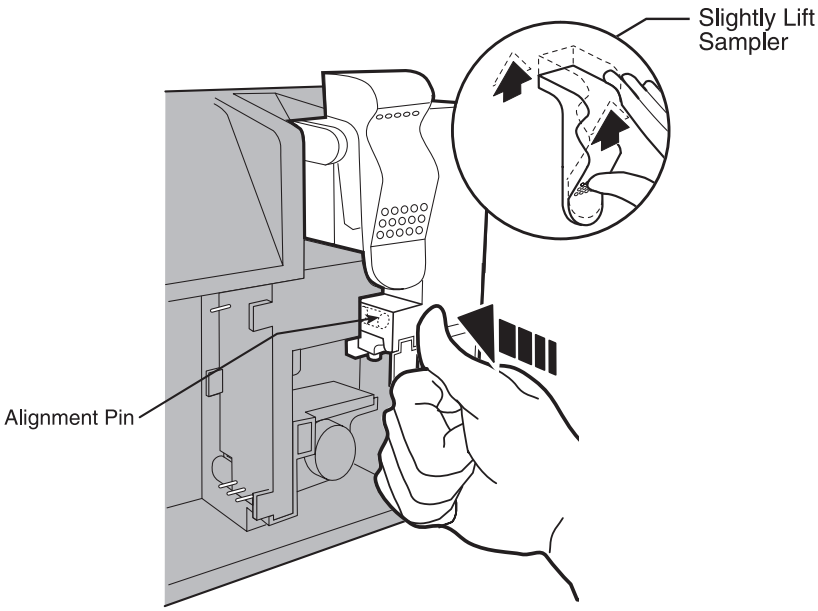
Remove the valve module by pulling it straight out.



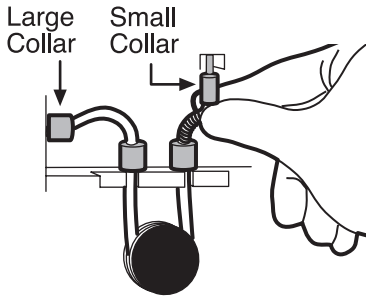
To install a new valve module, place the valve module onto the alignment pin and push straight back.

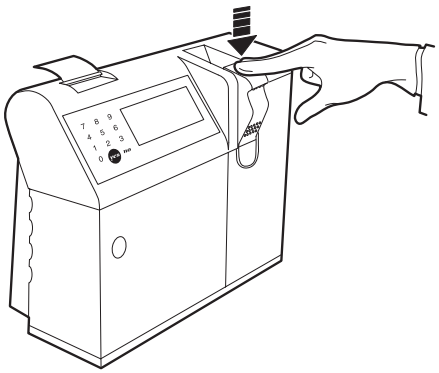


Reinstall the sensor module. Place the sensor module on the alignment pin and, using your thumb, push it straight back into position.



Reconnect the pump tubing to the valve module and sensor module. Push the sampler down into the closed position. Close the access door.



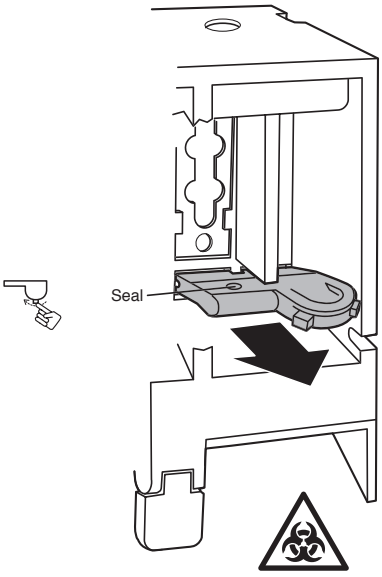


Reinstall the reagent module. Press YES to REPLACEMENT COMPLETED?. Reagents are automatically primed from the reagent module. When priming is complete, the display indicates the detection of each fluid with PASS, then automatically returns to the REPLACE COMPONENTS screen.

▲ A WARMING UP message may appear for up to 30 minutes. During this time, the EasyStat will not calibrate or analyze samples.

Compression Plate

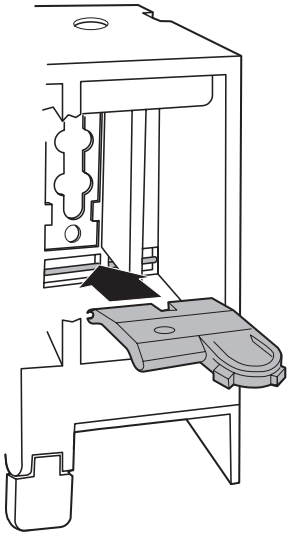
Compression plate replacement is necessary when the latch, spring mechanism, or seal is damaged. Follow the previous instructions for electrode or sensor module replacement. To replace the compression plate, remove all the electrodes. This will ensure that all fluids are purged from the sample flow path.

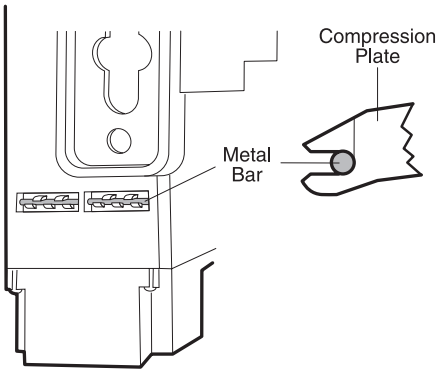


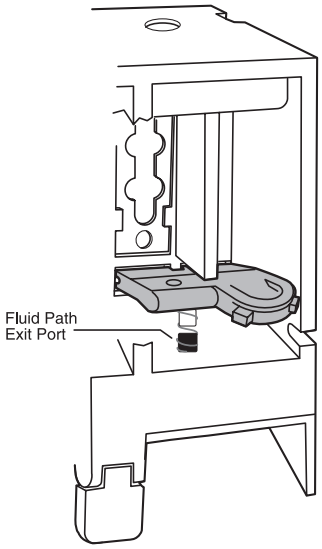
Release the compression plate.

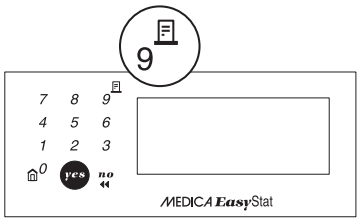
Grasp the compression plate and pull it out of the sensor module.

To install the compression plate, insert it into the sensor module. Make sure that the metal bar at the rear of the module is snapped inside the hinge tabs. Gently push down on the compression plate to engage the spring around the fluid path exit port. Reinstall the electrodes as described earlier in this section.





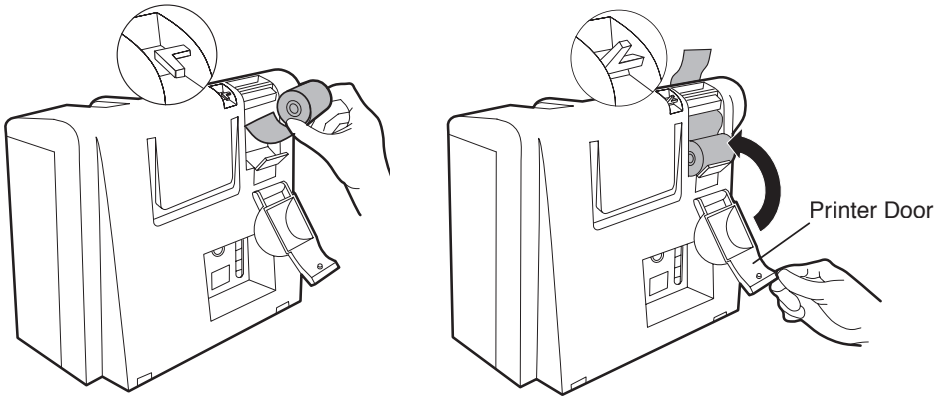




Printer Paper

To install a new paper roll, cut the tape or adhesive off the beginning of the paper. Open the printer door. Push the paper lever up. Gently push the edge of the paper into the slot behind the printer. Push the paper lever down. The paper is automatically fed through the printer. The paper roll rests in the tray behind the printer. Close the printer door to protect the paper roll.

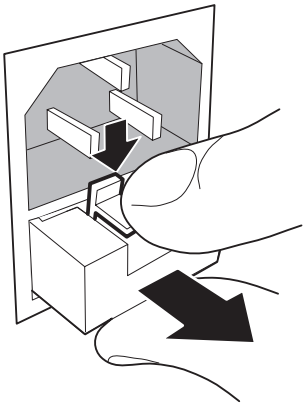
To advance the paper, press the button.



▲ Operation of the printer without paper will damage the printer head. To operate the analyzer for extended periods without paper, the printer must be turned off. To turn the printer off, refer to PRINTER OPTIONS in the SETUP MENU.

▲ Operation of the printer without Medica approved printer paper will result in the premature failure of the printer, voiding the warranty.

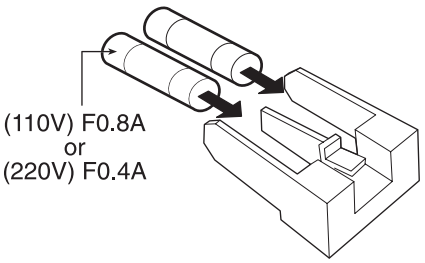
Fuses



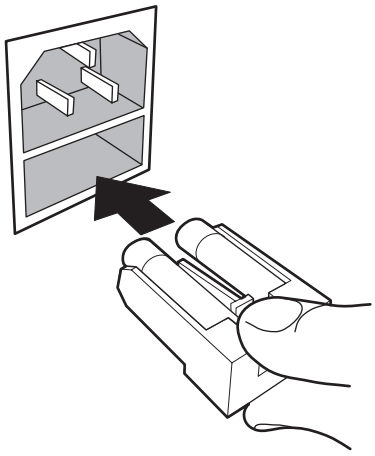
The EasyStat analyzer uses 250VAC fuses. When the voltage setting is 110V, 0.8 amp fuses must be installed. When set to 220V, 0.4 amp fuses must be installed. Correct fuses must be used with each voltage setting. To replace the fuse(s), remove the power cord, then push down on the fuse holder release tab and pull straight out.

★ The EasyStat analyzer will only accept slow blow or time delay fuses.

Remove the fuse(s) from the holder and insert the new fuse(s). Confirm that the fuse rating matches the voltage setting on the analyzer.

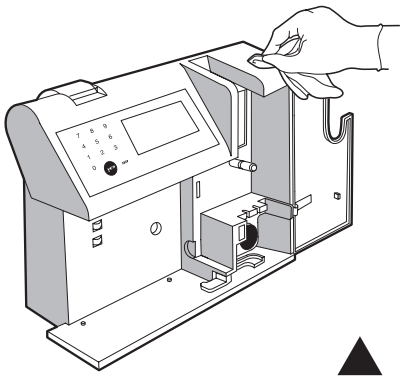


Reinstall the fuse holder, pushing in until it snaps into place. Connect the power cord.



Contact your EasyStat dealer when repeated fuse replacement is required. ▲

Analyzer Surface Cleaning/Storage/Moving



When complete chassis cleaning or analyzer storage is necessary, select VALVE MODULE from the REPLACE COMPONENTS menu. When the purge cycle is complete, remove the reagent module. PURGE WITH AIR, READY? is displayed. Connect the troubleshooting kit tubing to the valve module waste port with the open end placed into a waste receptacle. Press YES. Calibrant A, Calibrant B and Calibrant C are purged from the valve and sensor modules. Remove the electrodes, sensor module, valve module and pump tube from the analyzer.

Clean the analyzer with a 10% bleach (0.4-0.6% NaClO) solution. Apply the solution to a cloth to wipe down all outside surfaces.

▲ DO NOT use solvents (examples: methyl alcohol, ethyl alcohol, isopropyl alcohol) or cleaning agents containing benzalkonium chloride.

★ Failureto purge the flow path of air prior to storage could result in severe damage to the sensor and valve modules.



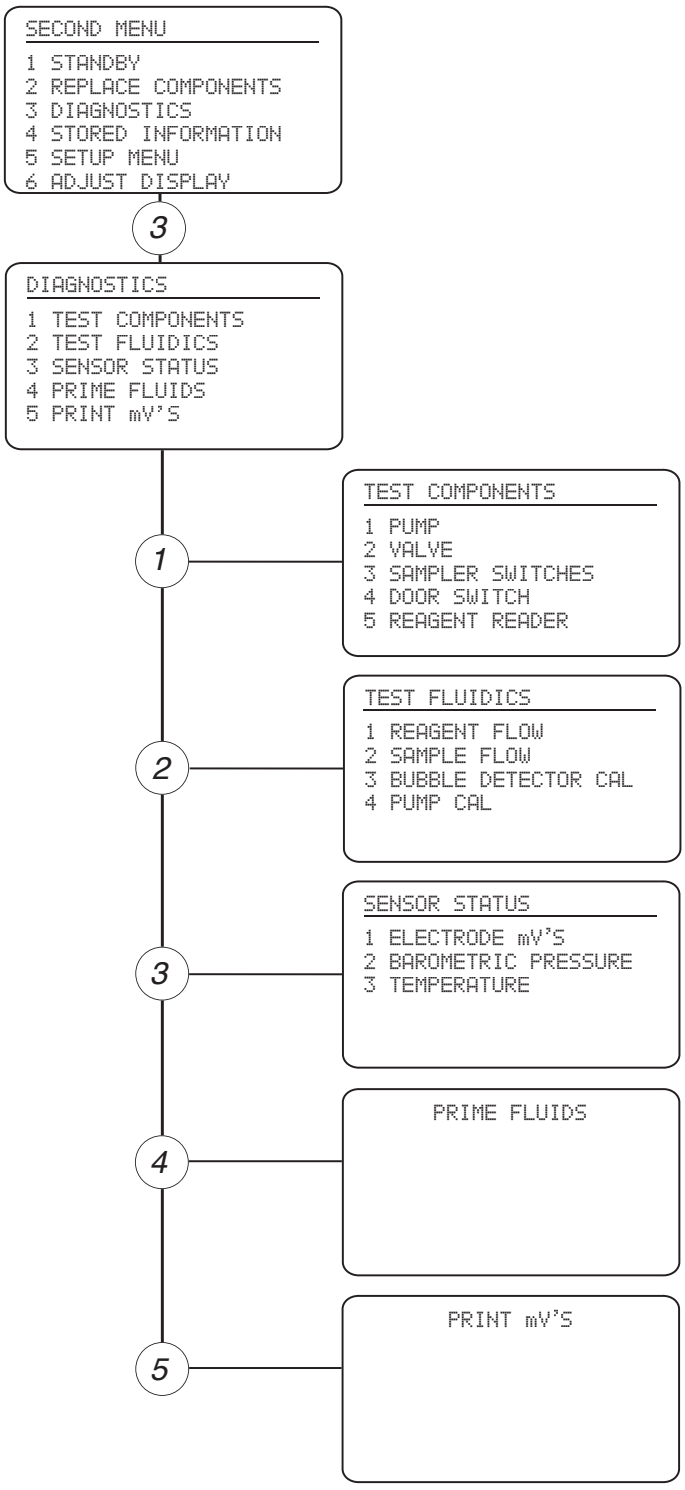
▲ Clean the sample port of the sampler. Clean all valve module surfaces. DO NOT run bleach solution through the sample path.

Reinstall the valve module and sensor module. The analyzer can now be stored or moved. The pump tube, reagent module, electrodes, and power cord should be stored separately.

To resume operation, insert the power cord and install the electrodes, pump tube and reagent module.

▲ A WARMING UP message may appear for up to 30 minutes. During this time, the EasyStat will not calibrate or analyze samples.

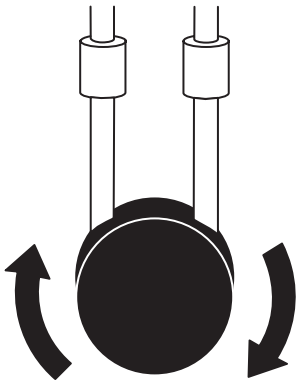
Diagnostics



The tests and data in this section are available to examine the function and status of individual EasyStat components and fluidics. To identify component defects or fluidic problems, refer to the Troubleshooting chapter in this manual.

TEST COMPONENTS

Select TEST COMPONENTS to test the operating status of the pump, valve, sampler switches, door switch and reagent reader.

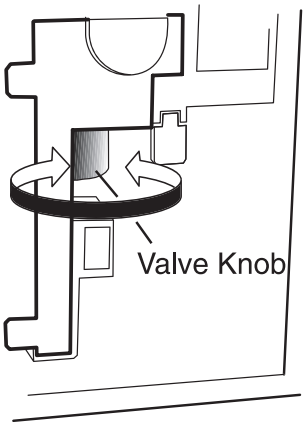


PUMP

Select PUMP to verify pump function. The screen displays ROTATING..., then FULL ROTATION?. Look for pump rotation. When full pump rotation occurs, press YES and PASS is displayed.

When there is no pump movement or partial pump movement, press NO and FAIL is displayed. Remove the pump tubing and repeat the PUMP test. If the test passes, install a new pump tubing, calibrate the analyzer and resume operation. If the test fails, contact your EasyStat dealer.

VALVE

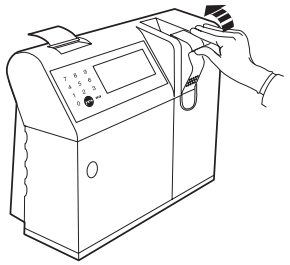


Select VALVE to verify valve function. The screen displays ROTATING..., then FULL ROTATION?. Look for rotation of the *valve knob*. When full valve knob rotation occurs, press YES and TESTING... is displayed. Internal testing verifies correct valve positioning for the Calibrant A, Calibrant B, Rinse, Air and Home positions. At test completion, PASS or FAIL is displayed.

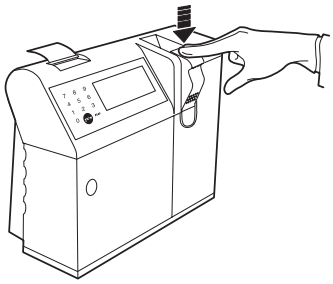
When there is no valve knob movement or partial valve knob movement, press NO and FAIL is displayed. Repeat the VALVE test. If the test fails again, the valve may have an obstruction. Refer to VALVE MODULE in Troubleshooting and follow the instructions for valve module obstructions.

SAMPLER SWITCHES

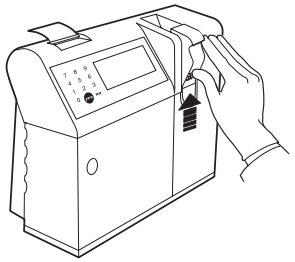
Select SAMPLER SWITCHES to verify the sampler positioning sensor and the sample mode switch.



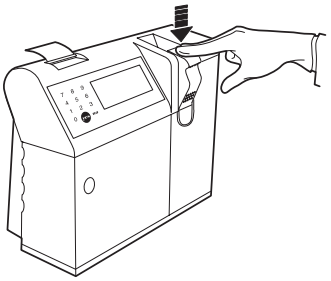
CAPILLARY MODE? is displayed. Lift the sampler to the capillary mode and press YES.



SAMPLER CLOSED? is displayed. Push the sampler down into the closed position.



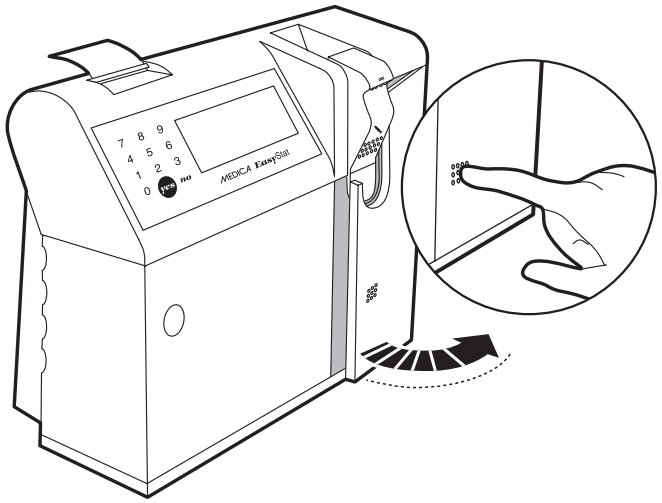
SYRINGE MODE? is displayed. Lift the sampler to the syringe mode and press YES.



RETURN SAMPLER is displayed. Push the sampler down into the closed position. POSITION PASS or FAIL and MODE PASS or FAIL are displayed. When the SAMPLER SWITCHES test fails, refer to SENSOR MODULE in Troubleshooting.

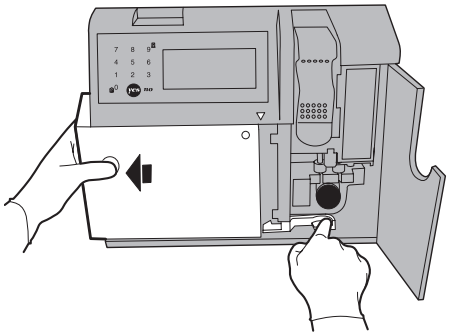
DOOR SWITCH

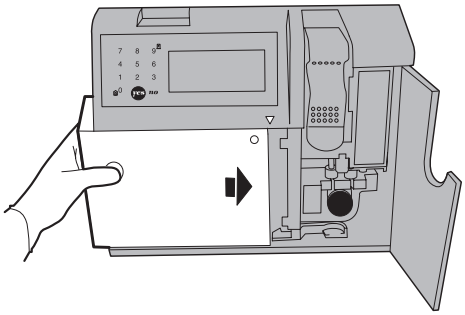
Select DOOR SWITCH to verify access door switch function. When DOOR OPEN? is displayed, open the access door and press YES. When DOOR CLOSED? is displayed, close the access door and press YES. The screen displays PASS or FAIL. When the test fails, refer to SENSOR MODULE in Troubleshooting for further instructions.



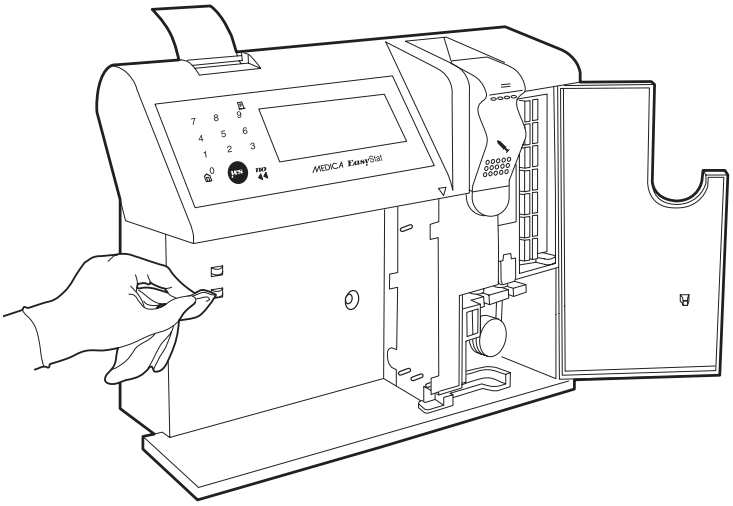
REAGENT READER

Select REAGENT READER to verify reagent reader function. REAGENT MODULE REMOVED? is displayed. Remove the reagent module and press YES. REAGENT MODULE INSTALLED? is displayed. Reinstall the same reagent module and press YES. PASS or FAIL is displayed.





If the above test fails, remove the reagent module and clean the metal contacts on the analyzer with a damp cloth. Then dry the contacts thoroughly. Repeat the REAGENT READER test. If it fails again, contact your EasyStat dealer.



★ Prior to installation, a reagent module must be stored at room temperature for a minimum of four hours.

Test Fluidics

The sampler must be in the closed position for the following tests. 

TEST FLUIDICS

Select TEST FLUIDICS to test the operating status of the reagent flow, sample flow, bubble detector and pump calibration.

REAGENT FLOW

Select REAGENT FLOW to verify the flow of Calibrant B, Calibrant A, and Calibrant C. When testing is complete, CALIBRANT B PASS or FAIL, CALIBRANT A PASS or FAIL and CALIBRANT C PASS or FAIL is displayed. When the test fails, refer to FLOW in Troubleshooting for further instructions.

SAMPLE FLOW

Select SAMPLE FLOW to verify the flow of the sample path. During testing, the screen will display LIFT SAMPLER TO TEST SAMPLE FLOW. Lift the Sampler in the Syringe Mode until PROBE IN TEST DYE? is displayed. Place the probe in the test dye and press YES. Hold the test dye in place, keeping the probe submerged in the test dye until REMOVE TEST DYE RETURN SAMPLER is displayed. Push the Sampler down in to the closed position. Testing will automatically occur. When testing is complete, SAMPLE FLOW PASS or SAMPLE FLOW FAIL is displayed. When the test fails, refer to FLOW in Troubleshooting for further instructions.

BUBBLE DETECTOR CAL

Select BUBBLE DETECTOR CAL to verify proper air and fluid detection. During testing, the screen will display BUBBLE CAL. When testing is complete, BD PASS or BD FAIL is displayed with readings for both air and fluid. The difference between the air and fluid readings must be greater than or equal to 60 for the bubble detector. In the event of a failure, refer to FLOW in Troubleshooting for further instructions.

PUMP CAL

Select PUMP CAL to verify proper pump calibration. The pump calibration counts the number of steps required to move fluid from the valve module to the bubble detector. The screen displays PUMP CAL. When testing is complete, PASS or FAIL is displayed with the number of pumping steps for each test. The number of steps must be between 460 and 900 for the first value. Refer to FLOW in Troubleshooting for further instructions.

SENSOR STATUS

Select SENSOR STATUS to view the electrode millivolts, the measured barometric pressure, or the sensor, valve, and room temperatures.

ELECTRODE mV's

Select ELECTRODE mV's to view the electrode millivolt readings for Calibrant A, Calibrant B or Calibrant C.

BAROMETRIC PRESSURE

Select BAROMETRIC PRESSURE to view the barometric pressure. When the displayed barometric pressure does not match a reference barometer, set the analyzer's barometric pressure by proceeding to the SETUP MENU and selecting USER OPTIONS, then BAROMETRIC PRESSURE.

Caution: The barometer is calibrated at the factory. The barometric pressure setting should only be changed to correlate it to a local reference barometer. The proper operation of the analyzer depends on a correct barometric pressure setting. ★

TEMPERATURE

Select TEMPERATURE to view the sensor, valve and room temperatures. The readings must be between:

Sensor	36.9° to 37.1°C
Valve	36.0° to 41.0°C
Room	15° to 30°C

If any temperature is not within range, refer to the Troubleshooting chapter in this manual.

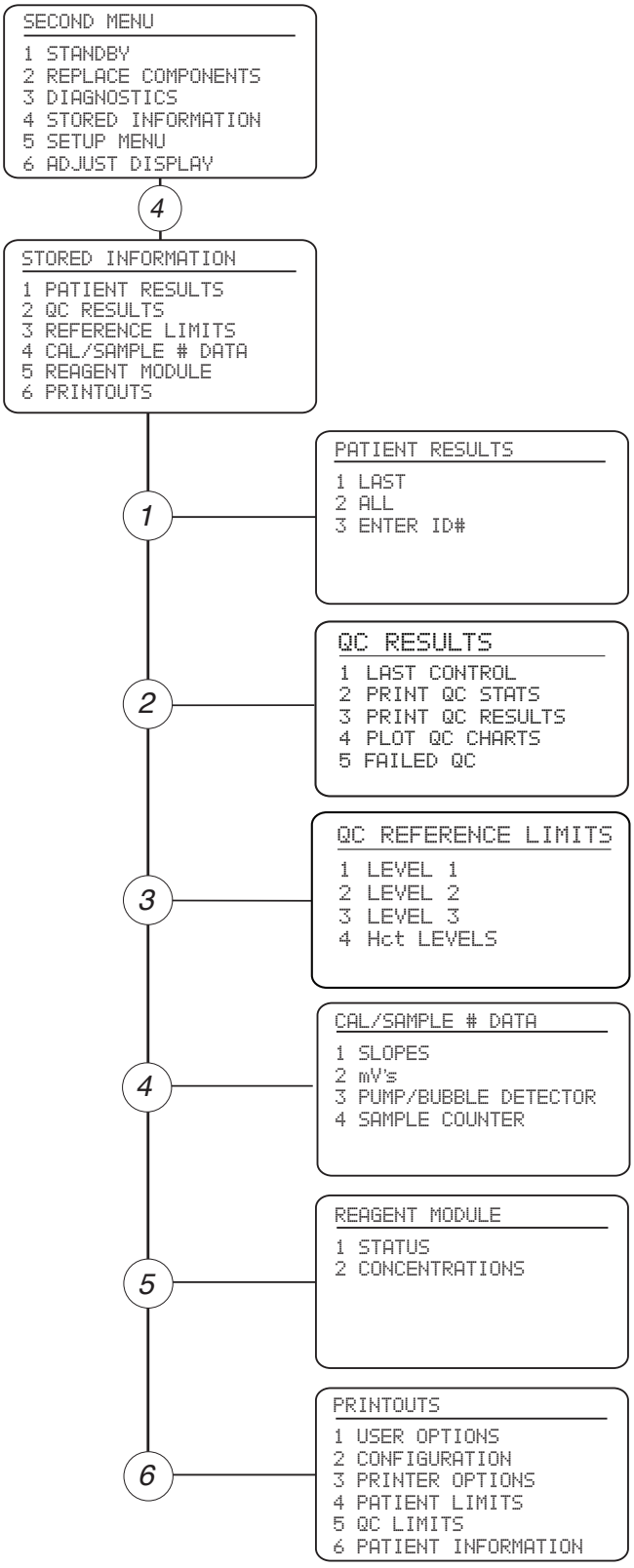
PRIME FLUIDS

Prime the fluid path by pumping Calibrant B, Calibrant A and Calibrant C from the reagent module.

PRINT mV'S

Select PRINT mV'S to display and print millivolt readings for each parameter. This feature is useful when reporting problems to your EasyStat distributor.

Stored Information



Select STORED INFORMATION from the SECOND MENU to obtain stored information on patient and quality control results, as well as view the reference limits, calibration, and reagent module information.

PATIENT RESULTS

View or print stored patient results. Up to 64 results are stored.

LAST

View and print the last patient's measured results.

ALL

Print all patient results.

ENTER ID#

Print the measured results for a specific patient using the keypad or barcode reader.

QC RESULTS

View the last quality control results, print quality control statistics, and plot quality control charts.

LAST CONTROL

View the results for the last control samples. Choose from QC Level 1, QC Level 2, QC Level 3, Hct Level 1 or Hct Level 2.

PRINT QC STATS

Print the statistics for stored quality control data by level.Printing can be cancelled by pressing NO.

PRINT QC RESULTS

Print the results for stored quality control data by level. Printing can be cancelled by pressing NO.

PLOT QC CHARTS

Print Levey-Jennings charts using stored quality control statistics. Plot three quality control levels for each measured parameter or plot all charts. Printing can be cancelled by pressing NO.

REFERENCE LIMITS

View the limits for quality control, normal, critical and AMR limits.

QC LEVEL 1,2 or 3, Hct Level 1 or 2

View the current quality control reference limits set for each control level.

NORMAL

View the analyzer's normal limits for arterial[1], mixed venous[3], or venous[1] samples. The preset limits are:

	Arterial	Mixed Venous	Venous
pH	7.350-7.450	7.340-7.360	7.340-7.360
PCO_2	35.0-45.0 mmHg	44.0-46.0 mmHg	44.0-46.0 mmHg
PO_2	83-108 mmHg	38-42 mmHg	38-42 mmHg
Hct	35-50%	35-50%	35-50%
Na^+	136.0-146.0 mmol/L	136.0-146.0 mmol/L	136.0-146.0 mmol/L
K^+	3.5-5.1 mmol/L	3.5-5.1 mmol/L	3.5-5.1 mmol/L
Ca^{++}	1.05-1.32 mmol/L	1.05-1.32 mmol/L	1.05-1.32 mmol/L
Cl^-	98.0–106.0 mmol/L	98.0–106.0 mmol/L	98.0–106.0 mmol/L

CRITICAL

View the analyzer's critical limits for arterial[2], mixed venous[3], or venous[2] samples. These limits have been set to be equal to normal limits. The lab should determine and set their own critical limits which are consistent with the site of venous sampling and other clinical factors. The preset limits are:

	Arterial	Mixed Venous	Venous
pH	<7.300, >7.600	<7.340, >7.360	<7.340, >7.360
PCO_2	<20.0, >50.0 mmHg	<44.0, >46.0 mmHg	<44.0, >46.0 mmHg
PO_2	<45, >250 mmHg	<38, >42 mmHg	<38, >42 mmHg
Hct	<25, >70%	<25, >70%	<25, >70%
Na^+	<115.0, >150.0 mmol/L	<115.0, >150.0 mmol/L	<115.0, >150.0 mmol/L
K^+	<3.0, >7.5 mmol/L	<3.0, >7.5 mmol/L	<3.0, >7.5 mmol/L
Ca^{++}	<0.8, >3.0 mmol/L	<0.8, >3.0 mmol/L	<0.8, >3.0 mmol/L
Cl^-	<90.0, >112.0 mmol/L	<90.0, >112.0 mmol/L	<90.0, >112.0 mmol/L

Proceed to SETUP MENU and select SET REFERENCE LIMITS to enter new values.

AMR

AMR is available when the feature is turned on in CONFIGURATIONS. View the analyzer limits for each electrode.

CAL/SAMPLE # DATA

View the slopes and millivolts for each electrode, and the calibration status for the pump and bubble detectors.

[1] Tietz: Fundamentals of Clinical Chemistry, 4th edition, (1996)

[2] B. Statland: Clinical Decision Levels for Lab Test, 2nd edition

[3] Fink: Clinical Practice in Respiratory Care

SLOPES

View the slope and calibration status for each electrode (PASS, FAIL or INVALID). Anelectrode with a PASS status indicates the last calibration was successful and the electrode is currently calibrated. A FAIL status indicates that an error occurred during the last calibration. INVALID indicates that the calibration status has become invalid after the calibration; for example, the reagent module has expired.

The acceptable slope ranges are:

pH	55.00 - 65.00
PCO_2	46.50 - 60.00
PO_2	1.00 - 5.00
Hct	13.00 - 22.00
Na^+	52.00 - 64.00
K^+	52.00 - 64.00
Ca^{++}	20.00 - 34.00
Cl^-	43.00 - 59.00

mV's

View the Calibrant A, Calibrant B and Calibrant C mV's for each electrode.

PUMP/BUBBLE DETECTOR

View the calibration status and values for the pump, and the calibration status for the bubble detectors, giving the air and fluid readings for both.

SAMPLE COUNTER

Number of samples that have been performed on analyzer.

REAGENT MODULE

Verify the status and the concentrations of the reagents in the reagent module.

STATUS

View the current reagent module serial number and installation date; the EasyStat analyzer serial number on which the reagent module was first installed; and the reagent volume (%) remaining with the number of days remaining before calibrants expire.

CONCENTRATIONS

View the calibrant concentration for Calibrant A, Calibrant B, and Calibrant C for each parameter.

PRINTOUTS

Print the settings for User Options, Configuration, Patient Limits, QC Limits, and Patient Information.

USER OPTIONS

Print the User Options settings.

CONFIGURATION

Print the Configuration settings.

PRINTER OPTIONS

Print the Printer Options settings.

PATIENT LIMITS

Print the normal and critical patient reference limits.

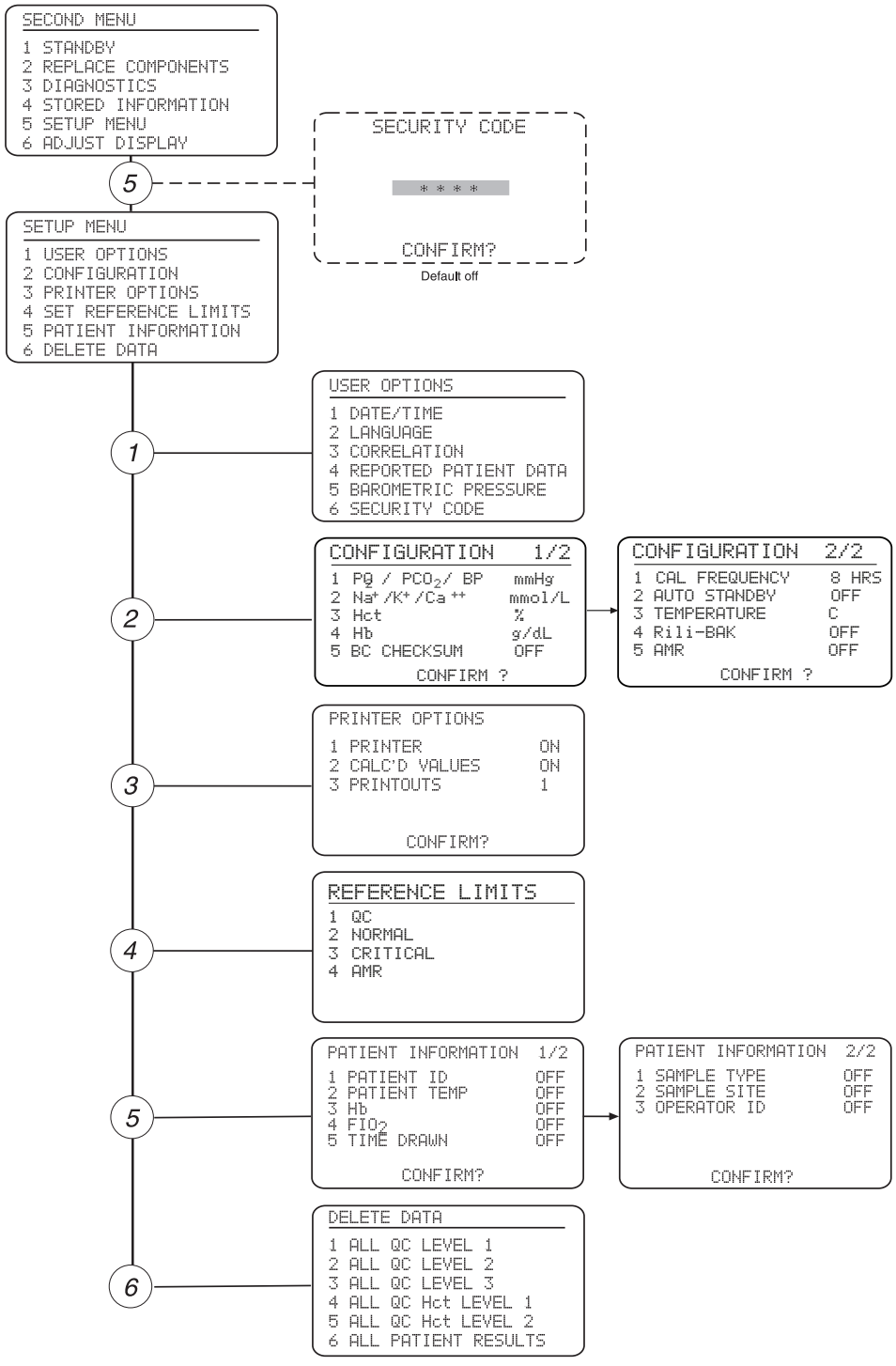
QC LIMITS

Print the quality control reference limits by level for both controls.

PATIENT INFORMATION

Print the patient information settings.

Setup Menu



▲ Ca^{++} is replaced with Cl^{-} when Cl^{-} mode is selected.

Select SETUP MENU from the SECOND MENU to set the functional parameters of the EasyStat analyzer.

Enter the security code if SECURITY CODE is turned ON under USER OPTIONS. Turning the SECURITY CODE ON prevents unauthorized personnel from entering and changing the SETUP MENU.

USER OPTIONS

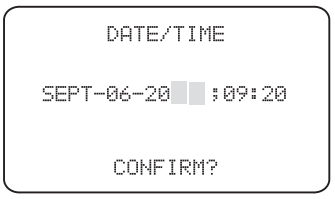
Set:

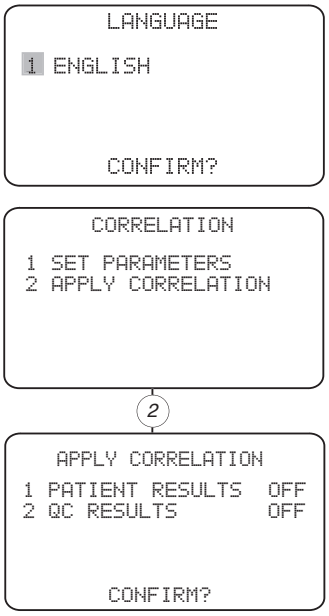
DATE/TIME, LANGUAGE, CORRELATION, REPORTED PATIENT DATA, BAROMETRIC PRESSURE, SECURITY CODE

Make sure you remove the reagent Module when changing the DATE/TIME.

DATE/TIME

Set the month, day, year and time (expressed as a 24 hour clock). Press NO to edit the current date and time. The cursor appears beneath the month. Each time NO is pressed, the month changes. When the correct month appears, press YES and the cursor moves to the day. Enter the correct day by pressing the number keys. Press YES to proceed to the year and time. Press NO to correct the previous entry and YES to advance. When all entries are confirmed, the display returns to USER OPTIONS.





LANGUAGE

Select the language by pressing the number keys. Press YES to CONFIRM?.

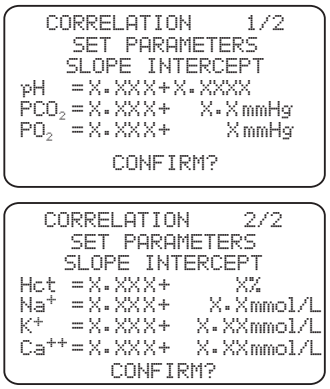
CORRELATION

The analyzer can be set to correlate with or match the results of another analyzer. To correlate the EasyStat analyzer to a reference analyzer, data must first be collected from samples run on both analyzers. The correlation values can be applied to patient and quality control results.

First, analyze a minimum of 10 patient samples in each of the low abnormal, normal, and high abnormal ranges for each of the analytes.

Each patient sample must be run on both analyzers. The EasyStat correlation equations must be set with the default (1.00x + 0.0) coefficients when analyzing the samples.

Next, determine the correlation factors by performing a regression analysis of the data. The EasyStat data must be the “x” data, and the reference analyzer must be the “y” data. The regression slope is entered as the correlation slope, and the regression intercept is entered as the intercept.



Next, select CORRELATION, then SET PARAMETERS to view the stored correlation equations. To change any of these values, press NO to CONFIRM?, and enter any new correlation slopes and/or intercepts for each analyte. The cursor highlights the selection. Press the number keys to set the slope and intercept, and press YES to confirm the correct individual values. Press NO to change "+" to "-", then press YES.

When entries are complete, press YES and CONFIRM? is displayed. To correct mistakes, press NO to return to the top of the list, and re-enter numbers. Press YES to confirm your entries. The pH, PCO_2, PO_2, Hct, Na^+, K^+, Ca^{++} and Cl^- slope input range is 0.90 to 1.10. The acceptable intercept input range for pH is -0.020 to 0.020, PCO_2 is +/-5 mmHg and PO_2 is +/-10 mmHg, Na^+ is +/-10 mM, K^+ is +/- 0.6 mM, Ca^{++} is +/- 0.6 mM, Cl^- is ± 10 mM, and Hct is +/- 4%. The default values are: slope =1.00 and intercept = 0.00.

Finally, analyze patient samples on each analyzer to confirm the correlation. Correlation values can be applied to patient and/or quality control results. Correlation is not applied to normal, critical, or quality control ranges.

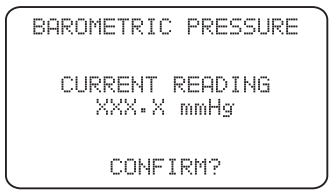
Using correlations does not change the measurement range, only the displayed range. The following is a detailed example for pH. The measurement range is 6.500 to 8.000. If the pH correlation is 1.00x + 0.020, the display range is: 1.00 (6.500) + 0.020 to 1.00 (8.000) + 0.020 or 6.520 to 8.020. Using this example, if a sample had a measured pH less than 6.500, the result would be reported as < 6.52↓↓.

▲ Ca^{++} is replaced with Cl^- when Cl^- mode is selected.

REPORTED PATIENT DATA

Select ANALYTES, then REPORTED DATA to enable or disable the reporting of specific analytes. A calibration is required after analytes are turned on or off under REPORTED DATA.

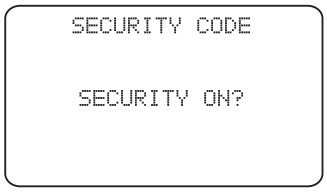
Select CALCULATED VALUES to enable or disable the reporting of specific calculated values.



BAROMETRIC PRESSURE

View or set the measured barometric pressure. The barometric pressure is measured using a factory calibrated electronic sensor. When the displayed barometric pressure matches a reference barometer, press YES to CONFIRM?. When it does not match a reference barometer, press NO. Press the number keys to enter the actual barometric pressure. Press YES when the entry is complete. If the barometric pressure does not change, verify the accuracy of the reference barometer. When the error remains, contact your EasyStat dealer.

SECURITY CODE



To activate this feature, press YES when SECURITY ON? is displayed.

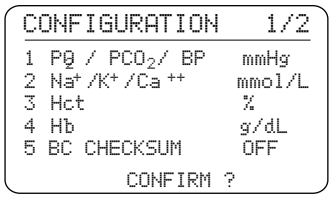
Enter up to a four digit code and press YES to CONFIRM?. The SETUP MENU is displayed. The security code will be required in the future for access to the SETUP MENU.

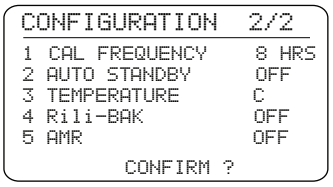


To turn the security code off, press YES when SECURITY OFF? is displayed. Answering NO to SECURITY OFF? will require entering the security code in the future for access to the SETUP MENU.

CONFIGURATION

Select CONFIGURATION to set analyzer options. Select from: PO_2/PCO_2/BP, Na^+/K^+/Ca^{++}, Hct, Hb, CAL FREQUENCY, AUTO STANDBY, and TEMPERATURE.





PO_2/PCO_2/BP

Change the measurement units (select mmHg or SI units) for PO_2, PCO_2 and barometric pressure. Results for SI units are shown in KPa.

Na^+/K^+/Ca^{++} or Cl^-

Change the measurement units (select mmol/L or mmEq/L units).

HCT

Change the measurement units (select % or V/V) for hematocrit.

Hb

Change the measurement units for Hb. Select mmol/L, g/L or g/dL.

BC Checksum

Turn the feature ON or OFF. When the feature is ON, the analyzer has the uses the last digit in the barcode to perform a barcode checksum calculation.

CAL FREQUENCY

Press the number keys to select and change an option. Press YES to CONFIRM? all configuration settings.

Select the time interval between automatic two-point calibrations. Select from: 2 hours, 4 hours, 8 hours

▲ Ca^{++} is replaced with Cl^- when Cl^- mode is selected.

AUTO STANDBY
Select ON or OFF. When ON, the analyzer will enter standby automatically. Standby is available manually with either selection.

TEMPERATURE
Change the temperature unit. Select Fahrenheit (F) or Celsius (C).

RILIBAK
Turn RiliBAK ON or OFF to use the statistic-based method for performing QC analysis required in Germany.

AMR
Turn AMR (Adjustable Measurement Range) ON or OFF. When ON, the default values are the low and high instrument range for each parameter. The ranges can be changed to ranges within the default limits.

PRINTER OPTIONS
Select printing options.

PRINTER
Turn the printer ON or OFF. When the analyzer runs out of printer paper, turn the printer OFF to prevent damage to the mechanism.

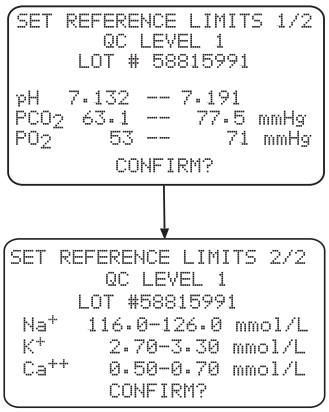
CALC'D VALUES
Turn printing of calculated values ON or OFF.

PRINTOUTS
Select up to four (4) sample printouts.

SET REFERENCE LIMITS
Select SET REFERENCE LIMITS to set the quality control limits for each level, and the normal and critical patient limits.

▲ It is recommended that any stored quality control results be deleted prior to entering information for a new lot of quality control. Refer to DELETE DATA in the SETUP MENU.

QC LEVEL 1, 2, 3, Hct



Enter, by level, quality control lot numbers and set the minimum and maximum values for each parameter. Press the number keys to set the values. Press YES to confirm the individual values and move to the next parameter. When the limits are correct for a particular level, press YES to confirm and move to the next electrode. When NO is pressed as a response to CONFIRM?, entries can be corrected.

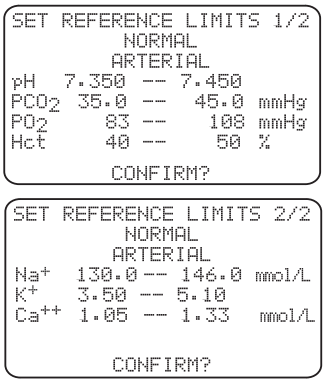
If RiliBAK is turned ON in CONFIGURATIONS, set the target and percent deviation for each parameter.

To enter quality control information using the barcode reader, EasyQC quality controls must be used.

To enter quality control information using the barcode reader, select QC LEVEL 1, 2, 3, Hct 1 or 2. LOT # is highlighted on the display. Using the barcode reader, scan in the lot number provided on the quality control insert sheet. Next, the parameter will be highlighted. Scan in the pH range (verify that the displayed range matches the insert sheet). Repeat for the remaining parameters. When all entries are complete, press YES to CONFIRM?. When NO is pressed as a response to CONFIRM?, the settings can be corrected. Repeat for each level of control. To proceed with quality control analysis, press ⌂ to return to HOME MENU.

Use the default limits as a guideline. Each laboratory should establish their own normal and critical limits. Press the number keys to select NORMAL or CRITICAL limits.

▲ Ca^{++} is replaced with Cl^{-} when Cl^{-} mode is selected.



NORMAL

Set the normal range for each parameter. Select arterial, mixed venous or venous. To change the ranges, press NO to CONFIRM?. Press the number keys to enter the desired limits, and YES to confirm each individual setting and advance to the next entry. When all limits are entered, press YES to CONFIRM? to accept all entries. When NO is pressed as a response to CONFIRM?, entries can be corrected.

When patient results fall within the normal range for the EasyStat analyzer, no arrows appear with the measured results. For example, when the normal pH range is 7.350 - 7.450, no flags are displayed/printed for patient pH results greater than or equal to 7.350 and less than or equal to 7.450.

▲ Ca^{++} is replaced with Cl^{-} when Cl^{-} mode is selected.

CRITICAL

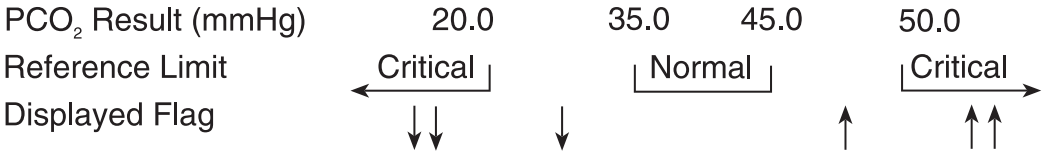
Set the critical ranges for each parameter. Select arterial, mixed venous, or venous. Press the number keys to enter the desired limits, and YES to confirm each individual setting and move to the next location. When all limits are entered, press YES to CONFIRM? to accept all entries. When NO is pressed as a response to CONFIRM?, entries can be corrected.

```
SET REFERENCE LIMITS
      CRITICAL
      ARTERIAL
pH   7.300  -- 7.600
PCO2 20.0   -- 50.0   mmHg
PO2    60   -- 250    mmHg
Hct    33   --  70    %
      CONFIRM?
```

```
SET REFERENCE LIMITS
      CRITICAL
      ARTERIAL
Na+  115.0 -- 150.0 mmol/L
Ca++  0.82 --  3.00 mmol/L
K+    3.00 --  7.50 mmol/L
      CONFIRM?
```

When analysis results are in the critical range, they are flagged as low (↓↓) or high (↑↑) on both the display and the printout. For example, when the critical pH limits are 7.300 and 7.600, a ↓↓ flag is displayed/printed for patient pH results less than or equal to 7.300 or a ↑↑ flag is displayed/printed for patient pH results greater than or equal to 7.600.

Patient results that are outside the normal range, and not within the critical range will be flagged as low (↓) or high (↑) on the display and printout.



RILIBAK

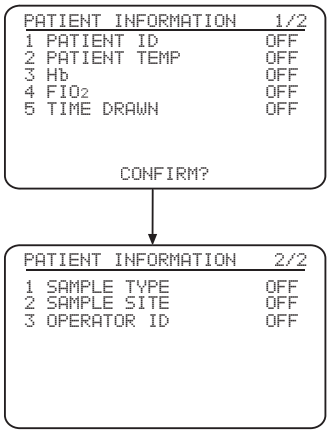
Set the RiliBAK target, percent deviation and range for each parameter. To change the setting, press NO to CONFIRM?. Press the number keys to enter the desired limit and press YES to CONFIRM? to accept all entries. When NO is pressed as a response to CONFIRM?, entries can be corrected.

```
REFERENCE LIMITS 1/6
  Rili-BAK LEVEL 1
   LOT #XXXXXXX
        pH
TARGET          X.XXX mmHg
DEVIATION       X.XX %
RILIBAK  X.XXX - X.XXX mmHg
```

AMR

Set the Adjustable Measurement Range for each parameter. To change the setting, press NO to CONFIRM?. Press the number keys to enter the desired limit and press YES to CONFIRM? to accept all entries. When NO is pressed as a response to CONFIRM?, entries can be corrected.

▲ Ca^{++} is replaced with Cl^{-} when Cl^{-} mode is selected.



PATIENT INFORMATION

Turn patient information options ON or OFF for all samples. The options are:

PATIENT ID, PATIENT TEMP Hb, FIO_2, TIME DRAWN, SAMPLE TYPE, SAMPLE SITE, OPERATOR ID

Press the number keys to select and change an option. Press YES to CONFIRM?.

When any options are turned ON, the EasyStat displays ENTER PATIENT DATA? after sample aspiration. Press YES to enter patient information. Use the number keys to enter values, and press YES to advance to the next option. When all entries are correct, press YES to CONFIRM?.

▲ When Hb is turned on under PATIENT INFORMATION, THb is not displayed or printed as a calculated result.

When PATIENT ID is turned ON, a patient ID may be entered for each patient sample. A maximum of 14 digits is accepted. The bar-code reader may be used to enter the patient ID.

When PATIENT TEMP, Hb and FIO_2 are OFF, the default values (Patient Temp = 37°C, FIO_2 = 21%) are used in the calculations.

When TIME DRAWN is turned on, the operator will be prompted to enter the time the sample was drawn.

When SAMPLE TYPE is turned on, the operator is prompted to select arterial, venous or mixed venous.

When SAMPLE SITE is turned on, the operator is prompted to select brachial, femoral, arterial line cord or other.

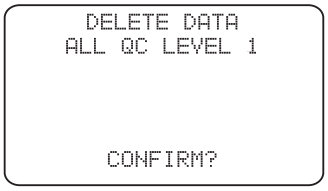
When OPERATOR ID is turned ON, the operator will be prompted to enter an operator ID for each patient and quality control sample. A maximum of 14 digits is accepted. The barcode reader may be used to enter the operator ID.

DELETE DATA
Delete all stored patient or quality control results.



ALL PATIENT RESULTS
Delete all stored patient results. Press YES to confirm deletion of all patient results.

ALL QC LEVEL 1, 2 or 3, ALL HCT LEVEL 1, 2 ALL PATIENT RESULTS
Delete stored quality control results or patient results.



Adjust Display

Adjust the brightness by continuing to press the number 1 or number 2 keys until acceptable. Reverse the contrast of the display by pressing the number 3 key.



5. Sample Handling and Collection

For complete sample handling and collection information, refer to a textbook of standard clinical chemistry procedures.



Biohazard: Human body fluid specimens may be contaminated with HIV or other pathogens. Treat all specimens, collection devices and tools as biohazardous.

The patient's status is extremely important when preparing to draw an arterial blood specimen. Patients receiving certain drugs, such as anticoagulants and thrombolytics, are at a greater risk for hematoma or external bleeding. The correct puncture location and sample timing is important in preventing bleeding.

▲ Blood gas samples must be collected into syringes/ capillary tubes containing heparin, including samples from patients receiving heparin treatments. A final heparin concentration of 15-50 IU/mL is recommended. Calcium balanced heparin is recommended. Ammonium heparin will shift the pH of the patient sample analyzed. Using sodium heparin will increase the sodium level of the patient sample.

Syringe Sample

1 Draw blood into a syringe which is pretreated with liquid heparin or use a prepackaged syringe treated with dry lyophilized heparin. The syringe must be completely filled to assure the proper anticoagulation concentration. When preparing an untreated syringe, only 0.05 mL of liquid heparin (1000 IU/mL) is necessary to anticoagulate 1 mL of blood. Too much heparin can alter the blood gas values obtained. Make sure that no air bubbles are present before sealing the syringe with an airtight cap. Note the time of collection.

2 Mix the specimen with anticoagulant by gently inverting the syringe several times. DO NOT SHAKE.

★ Failure to use the proper sampling materials and methods will result in microclots which will degrade the system and result in reliability issues such as PCO_2 and PO_2 electrode failures.

3 Analyze specimen within 5 minutes of collection, or immerse the syringe barrel in an ice water bath. The ice water bath maintains an accurate sample for up to 2 hours at a temperature between 1 and 5°C.

★ Note: Use only the Medica Capillary Kit. Use of other capillary tubes may cause erroneous results, or damage to the analyzer and electrodes.

Evacuated tubes are not recommended for blood gas specimen collection due to variations in technique. ★

Capillary Sample

Capillary tubes are available from your EasyStat dealer. Follow directions in capillary kit.

Errors occur from improper collection or handling procedures. When test results are inconsistent with a patient's present condition or test history, consider the following sources of error: non-heparinized samples, incorrect heparin concentration, syringe filling speed, syringe mixing method, sample storage technique, delayed sample analysis, multiple samples from the same syringe, bubbles in the sample. ★

Interfering Substances

To test interferences, serum or whole blood was spiked with a potentially interfering substance to the test concentrations shown in the product specification. The interference was calculated using the difference between the medians of the spiked and unspiked samples.

The results found that the potassium thiocyanate 20 mg/dL affected the chloride performance and caused chloride values increasing.

The EasyStat analyzer measures pH, PCO_2, PO_2, Na^+, K^+, and Ca^{++} using selective electrode technology and Hct using conductivity. The sodium, potassium, calcium, pH and PCO_2 ion-selective electrodes measure changes in voltage (a potentiometric measurement). The PO_2 electrode measures a change in current (an amperometric measurement). These changes are then compared with established chemical measurements to produce final results. During sample analysis, blood samples are held in the electrodes where they are maintained at a temperature of 37.0°C and protected from air contamination. (See Electrode Measurement/Diagrams in this chapter.)

pH, Na^+, K^+, Ca^{++}, Cl^- Electrodes[1]

Na^+ and K^+ electrolyte measurements in blood products were traditionally performed using flame photometry, in which a sample, diluted with a known concentration of a reference ion (usually cesium) is aerosolized and passed through a flame which excites the cations. The cation re-emits the energy as light of different frequencies; the amplitude of this emission is proportional to the ion concentration in the sample. The development of selective organic compounds for sodium, potassium, calcium, chloride or lithium, and other electrolytes has permitted the development of electrodes capable of directly measuring biological fluids throughout the physiological range. These electrodes are known as ion selective electrodes.

The EasyStat analyzer measures sodium, potassium, calcium, chloride and pH in biological fluids, using ion selective electrode technology. Refer to the Electrode Measurement Diagram in this chapter. The flow-through sodium electrode uses a selective membrane, specially formulated to be sensitive to sodium ions. The potassium, calcium, chloride and pH electrodes employ similar designs with appropriate selective membrane materials.

The potential of each electrode is measured relative to a fixed, stable voltage established by the double-junction silver/silver chloride reference electrode. An ion selective electrode develops a voltage that varies with the concentration of the ion to which it responds. The relationship between the voltage developed and the concentration of the sensed ion is logarithmic, as expressed by the Nernst equation.

Nernst equation:

$$E = E^{\circ} + \frac{RT \text{ Log } (\gamma C)}{nF}$$

where:

- E = The potential of the sensor in sample solution
- E° = The potential developed under standard conditions
- RT/nF = A temperature-dependent "constant" termed the slope, S
- n = 1 for sodium and potassium; 2 for calcium
- Log = Base ten logarithm function
- γ = Activity coefficient of the measured ion in the solution
- C = Concentration of the measured ion in the solution

A comparative method of measurement is utilized. First, the analyzer measures the potentials developed when the sample is positioned in the electrodes. Next, Calibrant A is positioned in the electrodes. The difference in the two potentials is related logarithmically to the concentration of sodium, potassium, calcium or hydrogen ions in the sample divided by their respective concentrations in the Calibrant solution. Since the difference in potentials and the concentration of the sodium, potassium, calcium-or hydrogen ions in the Calibrant solution are known, the analyzer can calculate the concentration of the ions in the sample, in accordance with the Nernst equation, rewritten as:

$$E_{(Samp)} - E_{(Cal\ A)} = S \log (C_i(x) / C_i(s))$$

or $$C_i(x) = C_i(s) * 10^{\wedge}((E_{(Samp)} - E_{(Cal\ A)})/S)$$

$E_{(Samp)}$	=	ISE potential developed in sample solution
$E_{(Cal\ A)}$	=	ISE potential developed in the standard solution
S	=	slope calculated during calibration
$C_i(x)$	=	Concentration of ion "i" in the sample
$C_i(s)$	=	Concentration of ion "i" in the calibrant

Using this definition of pH: pH = -Log (c) the equations for pH becomes:

$$pH_{(Samp)} = pH_{(Cal\ A)} - (E_{(Samp)} - E_{(Cal\ A)})/S$$

where

$pH_{(Samp)}$ = pH of this sample

$pH_{(Cal\ A)}$ = pH of Calibrant A

"S", the slope, is determined during calibration using Calibrants A, B or C (for calcium), which have known levels of sodium, potassium, calcium or pH.

When an automatic calibration is initiated, the slope is calculated from the difference between the Calibrant A reading and the Calibrant B or Calibrant C (for calcium) reading. Excessive drift or noisy readings will be flagged and the appropriate error message is printed.

PCO_2 Electrode[1]

The PCO_2 electrode is a modified pH electrode, using Severinghaus electrode technology. The sample is introduced to a CO_2 permeable membrane surrounding internal fill solution (bicarbonate solution) which is in direct contact with pH-sensitive glass and a silver/silver chloride electrode terminal (an internal reference electrode). A chemical reaction takes place in the bicarbonate solution after CO_2 has permeated the membrane. This reaction produces hydrogen ions and a change in the pH of the bicarbonate solution. The change in pH is in proportion to the PCO_2, creating a voltage change which is then converted into PCO_2 units.

PO_2 Electrode[1]

The PO_2 electrode uses Clark electrode technology. A positively charged silver/silver chloride electrode acts as an anode, and a negatively charged platinum electrode acts as a cathode. Oxygen measurement begins when a voltage is supplied between the anode and the cathode through the internal fill solution. When a sample is introduced to the oxygen permeable membrane, the oxygen passes through the membrane to the electrode (cathode). This causes a reaction which produces a current that is directly proportional to the PO_2 in the sample. The final calculation uses the electrode slope and measurements of Calibrant A and sample.

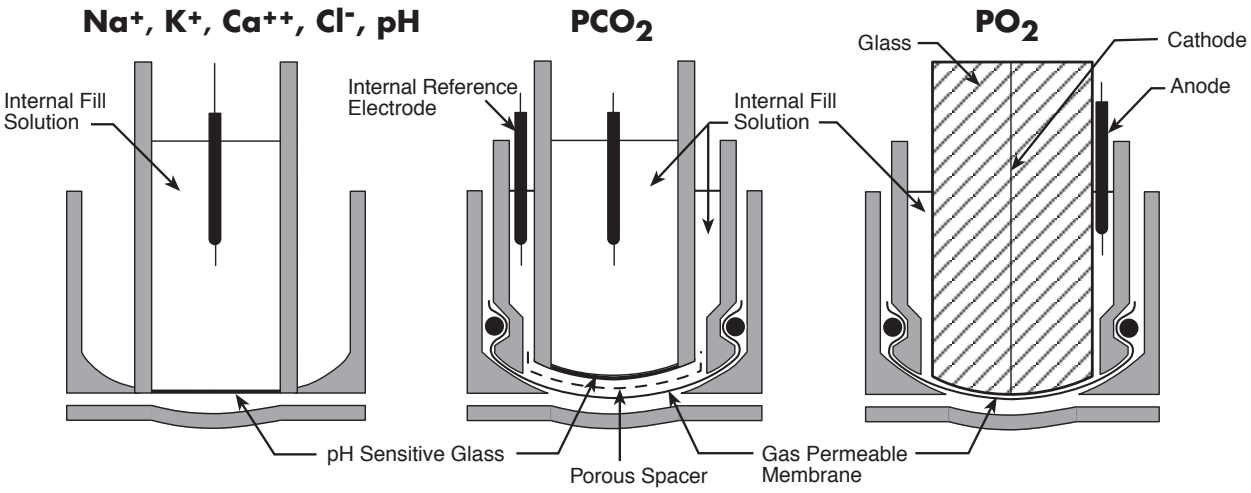
Hct Sensor

The percentage of red blood cells to the total blood volume is defined as hematocrit. It is quantified by measuring the electrical impedance of a blood sample. Two standard solutions are used to calibrate the hematocrit sensor. The analyzer then measures the electrical impedance of the blood sample to obtain the hematocrit value. Next, the hematocrit value obtained is corrected for the concentration of the sodium ion.

[1] Tietz: Fundamentals of Clinical Chemistry, 4th edition, (1996)

Electrode Measurement/Diagrams

The PO_2 electrode is electrically independent from the other electrodes during measurements. The PCO_2 electrode has an internal reference electrode that is used during measurements, and is also independent from the other electrodes.



The pH, Na^+, K^+, Ca^{++} and Cl^- electrodes make all measurements relative to the reference electrode. Errors in these electrodes may be caused by problems in the electrode, reference electrode, or both.

The pH, PCO_2, PO_2, Na^+, K^+, Ca^{++} and Cl^- electrodes used in the EasyStat analyzer have no replaceable parts and are designed to require no maintenance.

Tonometered Reagents

The reagent module contains reagents that have been tonometered to known partial pressures of PO_2 and PCO_2.

Tonometry is the process of bubbling a gas through a liquid until equilibrium is reached. Equilibrium is when the partial pressures of the gases dissolved in the liquid equal the partial pressures of the gases bubbled through the liquid. The tonometered liquid is then placed into hermetically sealed reagent modules.

Calculations

Temperature Corrections

The measured results are often corrected to the patient body temperature. The temperature corrected results more accurately reflect the *in vivo* conditions. The EasyStat analyzer performs these calculations using the following equations[1]:

$$\Delta pH/\Delta T = 0.0065\ (7.4 - pH) - 0.0147$$

$$\frac{\Delta \log PCO_2}{\Delta T} = 0.019$$

$$\frac{\Delta \log PO_2}{\Delta T} = \frac{5.49 \times 10^{-11}\ (PO_2^{3.88}) + 0.071}{9.72 \times 10^{-9}\ (PO_2^{3.88}) + 2.30}$$

where: ΔT is expressed in °C

PCO_2 and PO_2 are expressed in mmHg

pH is expressed in pH units

Calculated Parameters

The following calculated results are reported by the EasyStat analyzer. The measured pH, PCO_2, PO_2, and entered (or default) Hb and FIO_2 are applied to the subsequent equations:

TCO_2

The following equation is used to calculate the total carbon dioxide concentration[1]:

$$TCO_2 = [HCO_3^-] + 0.0307\ PCO_2$$

where: TCO_2 and HCO_3^- are expressed in mmol/L

PCO_2 is expressed in mmHg

THb

The hemoglobin is calculated based on the following calculation[2]:

$$Hb = Hct/3$$

where: Hb is in g/dL and Hct is %

The hemoglobin calculation is an estimation based on a normal MCHC of 33.3%. The EasyStat hemoglobin estimation from samples with red cell dyscrasia or hemoglobinopathies may vary significantly from hemoglobin measured by the cyanmethemoglobin method.

HCO_3^-

The following equation is used to calculate the bicarbonate concentration[1]:

where: $\log [HCO_3^-] = pH - 7.608 + \log PCO_2$

HCO_3^- is expressed in mmol/L

BE_b

The base excess of blood, or *in vitro* base excess, is calculated using the following equation[1]. This parameter is defined as the titratable base of blood which may be determined by titration with strong acid or base to (plasma) pH = 7.400 and PCO_2 = 40 mmHg at 37.0°C.

$$BE_b = (1 - 0.014 [Hb]) ([HCO_3^-] - 25 + (1.43 [Hb] + 7.7) (pH - 7.4))$$

where: Hb is expressed in g/dL

HCO_3^- is expressed in mmol/L

BE_b is expressed in mmol/L

The hemoglobin value used is either preset (14.5 g/dL), entered or calculated. When entered, the value is input from the PATIENT INFORMATION screen.

BE_{ecf}

The base excess of the extracellular fluid, or *in vivo* base excess, or standard base excess, is calculated using the following equation[1]. The patient's acid-base interbalance metabolic component is measured by the BE_{ecf}. This parameter may be determined by titration of an extracellular fluid model to pH = 7.400 and PCO_2 = 40 mmHg at 37.0°C.

$$BE_{ecf} = [HCO_3^-] - 25 + 16.2\ (pH - 7.4)$$

where: BE_{ecf} is expressed in mmol/L
HCO_3^- is expressed in mmol/L

SBC

The bicarbonate concentration in plasma from a blood sample that is equilibrated to 37.0°C with PCO_2 = 40 mmHg and PO_2 greater than 100 mmHg is known as the standard bicarbonate of blood. The EasyStat analyzer uses the following equation[1]:

$$SBC = 25 + 0.78\ BE_b + 0.002\ [Hb]\ (\%SO_2c - 100)$$

where: SBC is expressed in mmol/L
$\%SO_2c$ is expressed as a percentage

The hemoglobin value used is either preset (14.5 g/dL), entered or calculated. When entered, the value is input from the PATIENT INFORMATION screen.

$\%SO_{2c}$

The EasyStat analyzer estimates the calculated oxygen saturation (at normal P50) of available hemoglobin from the measured value of PO_2, pH and PCO_2 according to the equation[1]:

$$\%SO_{2c} = \frac{(PO_2^*)^3 + 150\ PO_2^*}{(PO_2^*)^3 + 150\ PO_2^* + 23400}\ (100)$$

where: $PO_2^* = PO_2$ antilog {0.48 (pH - 7.4) - 0.0013 ([HCO_3^-]-25)}

ctO_2

The total oxygen content of blood is expressed as the volume of oxygen (mL per 100 mL or dL of blood. The oxygen content is the sum of the amount of oxygen bound to hemoglobin and the amount of dissolved oxygen. The following equation is used:

$$ctO_2 = \left(\frac{\%SO_{2c}}{100}\right)(1.39\ [Hb]) + (0.00314\ PO_2)$$

where: ctO_2 is expressed in mL/dL
1.39 is theoretical amount of oxygen bound to hemoglobin in mL/g Hb is expressed in g/dL
0.00314 is the amount of dissolved oxygen in blood as mL/(dL mmHg)
PO_2 is expressed in mmHg

$Ca^{++}(7.4)$

$Ca^{++}(7.4) = Ca^{++}$ (pH=x) * 10 exp - 0.24 * (7.4-x)

where: x is the measured pH

$A\text{-}aDO_2$

The EasyStat analyzer calculates the alveolar-arterial oxygen gradient according to the following equation[1]:

$$A\text{-}aDO_2 = PAO_{2(TC)} - PaO_{2(TC)}$$

Alveolar oxygen partial pressure ($PAO_{2(TC)}$) and arterial oxygen partial pressure ($PaO_{2(TC)} = PO_2(T)$) are expressed at the patient corrected temperature.

$$PAO_{2(TC)} = (FIO_2)\,(BP_{(TC)}) - (PaCO_{2(TC)})\,(FIO_2 + \frac{1 - FIO_2}{R})$$

where: $A\text{-}aDO_2$ is expressed in mmHg

$BP_{(TC)}$ = Barometric Pressure - Vapor Pressure of water in mmHg

Vapor Pressure of water = 0.4 + antilog (0.0244T + 0.7659)

T = temperature in °C

FIO_2 = fraction of inspired oxygen

R = 0.8 = respiratory quotient

$PaO_{2(TC)} = PO_2(T)$

The FIO_2 value used is either the preset 21% or when entered, the value input from the PATIENT INFORMATION screen.

RI

The EasyStat analyzer calculates the respiratory index according to the following equation[1]:

$$RI = \frac{A\text{-}aDO_2}{PaO_2}$$

Anion Gap

The EasyStat (chloride mode) analyzer calculates the Anion Gap according to the following equation[3]:

$$([Na^+] + [K]) - ([HCO_3^-] + [Cl^-])$$

[1] NCCLS: Tentative standard "Definition of quantities and conversions related to blood pH and gas analysis" Vol. 2, No. 10, pages 329-361 (1982) (National Committee for Clinical Laboratory Standards - Villanova, Pennsylvania, U.S.A.)
[2] B.F. Rodak, MS, MT (ASCP) SH: Diagnostic Hematology, W.B. Saunders Co., 1995, pg. 138
[3] Tietz, Fundamentals of Clinical Chemistry, 4th ed. 1996

7. Specifications

CLIA Classification: Moderate complexity

Sample Type: Whole blood

Sample Size: 120 µL Syringe mode/95 µL Capillary mode

Measured Parameters and Limits*

PO_2	5 - 700 mmHg	PCO_2	5.0 - 150.0 mmHg	pH	6.500 - 8.000 pH units	Hct	10-70%
Na^+	80-200 mmol/L	K^+	1.0-20.0 mmol/L	Ca^{++}	0.25-5.00 mmol/L (Ca^{++} mode)	Cl^-	50.0-150.0 (Cl^- mode) mmol/L

Calculated Parameters

THb (Total Hemoglobin)	3.3-23.3 g/dL
pH (T) (pH temperature corrected)	
PCO_2 (T) (PCO_2 temperature corrected)	
PO_2 (T) (PO_2 temperature corrected)	
TCO_2 (Total Carbon dioxide)	0-50 mmol/L
HCO_3^- (Bicarbonate)	0-50 mmol/L
BE_b (Base Excess in blood)	-25.0 to 25.0 mmol/L
BE_{ecf} (Base Excess in extra cellular fluid)	-25.0 to 25.0 mmol/L
SBC (Standard Bicarbonate)	0-50 mmol/L
$\%SO_{2c}$ (Oxygen Saturation)	40.0 - 100.0% (calculated at normal P50)
CtO_2 (Oxygen Content)	3.0 - 30.0 mL/dL
A-aDO_2 (Alveolar arterial oxygen gradient)	0-700 mmHg
RI (Respiratory Index)	0.0 - 70.0
Ca^{++} (7.4) (for $7.2 \leq pH \leq 7.6$) (Ca^{++} mode)	0.22 - 5.58 mmol/L
Anion Gap (Cl^- mode)	10-75 mEq/L

Input Parameters

Patient Temperature	(20 - 45°C)	Time Drawn	(00:00)
Hemoglobin	(3.0 - 30.0 g/dL)	Sample Source	(arterial, mixed venous, venous)
FIO_2 (Fraction Inspired Oxygen)	(10 - 100%)	Sample Type	(radial, brachial, femoral, arterial line, cord)
Patient ID	(14 digits)		
Operator ID	(14 digits)		

Sample Temperature Control: 37.0°C ± 0.2°C

Environmental Conditions: Indoor Use
15–30°C (59-86°F), 500–800 mmHg (max 15 PSI)
Altitude up to 2000m
5–85% relative humidity, non-condensing
atmospheric air environment (21% O_2)
Overvoltage category II, Pollution Degree 2

Analysis Time: <120 seconds

Data Storage: 64 Patient results with Operator ID, Patient ID, Date and Time
QC—up to 93 results for each Level (Blood Gas/Electrolytes 1, 2, 3, Hct 1, 2)

Calibration: Automatic or On-Demand

Input/Output: Numeric keypad, graphic display, 27 column thermal line printer, barcode reader port, RS-232 computer interface port

Power: 100/115~VAC, 50-60 Hz, 0.8 A or 220~VAC, 50-60 Hz, 0.4 A
Refer to the chassis serial number label for the voltage that has been factory set on your analyzer, and for proper fuse replacement.

Size & Weight: 14.5"W x 12.5"H x 7.0"D (37cmW x 32cmH x 18cmD), 17lbs (7.7kg) with reagent module

*Limits are using default correlations. Refer to CORRELATION for more information.

Typical performance data: Syringe Mode

Within-run precision using whole blood (for PO_2, PCO_2, pH, Cl^- and Hct) and serum (for Na^+, K^+ and Ca^{++})

	PO_2	PCO_2	pH	Na^+	K^+	Ca^{++}	Hct	Cl^-
N	80	80	25	80	80	80	40	20
Mean	71	37.0	7.362	146.0	4.13	0.97	40	102.8
SD	0.6	0.34	0.004	0.53	0.010	0.005	0.4	0.77
CV	0.8	0.9		0.4	0.2	0.5	0.9	0.8

Within-run precision of duplicates (NCCLS, EP-5) using EasyQC Blood Gas/Electrolyte controls

Level 1

	PO_2	PCO_2	pH	Na^+	K^+	Ca^{++}	Cl^-
N	80	80	80	80	80	80	80
Mean	64	73.5	7.171	114.6	1.96	1.35	71.1
SD	1.8	0.82	0.003	0.3	0.02	0.004	0.49
CV	2.8	1.1		0.3	0.8	0.3	0.7

Level 2

	PO_2	PCO_2	pH	Na^+	K^+	Ca^{++}	Cl^-
N	80	80	80	80	80	80	80
Mean	103	47.6	7.418	137.4	4.27	0.99	96.0
SD	1.2	0.39	0.002	0.21	0.027	0.004	0.2
CV	1.2	0.8		0.2	0.6	0.4	0.2

Level 3

	PO_2	PCO_2	pH	Na^+	K^+	Ca^{++}	Cl^-
N	80	80	80	80	80	80	80
Mean	142	21.5	7.631	163.0	6.15	0.48	124.6
SD	1.1	0.48	0.004	0.21	0.010	0.005	0.29
CV	0.8	2.2		0.1	0.2	1.0	0.2

Within-run precision of duplicates (NCCLS, EP-5) using EasyQC Hematocrit controls

Level 1

	Hct
N	80
Mean	32
SD	0.4
CV	1.1

Level 2

	Hct
N	80
Mean	51
SD	0.3
CV	0.5

Day-to-Day precision of duplicates (NCCLS, EP-5) using EasyQC Blood Gas/Electrolyte controls

Level 1

	PO_2	PCO_2	pH	Na^+	K^+	Ca^{++}	Cl^-
N	80	80	80	80	80	80	80
Mean	64	73.5	7.171	114.6	1.96	1.35	71.1
SD	2.2	0.82	0.010	0.35	0.020	0.011	0.52
CV	3.4	1.1		0.3	1.0	0.8	0.7

Level 2

	PO_2	PCO_2	pH	Na^+	K^+	Ca^{++}	Cl^-
N	80	80	80	80	80	80	80
Mean	103	47.6	7.418	137.4	4.27	0.99	96.0
SD	1.2	0.39	0.003	0.41	0.027	0.005	0.16
CV	1.2	0.8		0.3	0.6	0.5	0.2

Level 3

	PO_2	PCO_2	pH	Na^+	K^+	Ca^{++}	Cl^-
N	80	80	80	80	80	80	80
Mean	142	21.5	7.631	163.0	6.15	0.48	124.6
SD	1.1	0.48	0.011	0.95	0.057	0.005	0.29
CV	0.8	2.2		0.6	0.9	1.0	0.2

Day-to-Day precision of duplicates (NCCLS, EP-5) using EasyQC Hematocrit controls

Level 1

	Hct
N	80
Mean	32
SD	0.5
CV	1.6

Level 2

	Hct
N	80
Mean	51
SD	0.3
CV	0.6

Method comparison

	vs.	sample	N	R^2	Slope	Intercept	Range
pH	IL 1620	blood/pH buffer	448	0.997	1.02	-0.122	6.500-8.000
PO_2	EasyBloodGas	blood	412	0.998	1.04	-4.3	5.0-700.0 mmHg
PCO_2	EasyBloodGas	blood	412	0.995	0.97	0.5	5.0-150.0 mmHg
Na^+	EasyElectrolyte	blood/serum	1163	0.997	0.993	0.5	80.0-200.0 mmol/L
K^+	EasyElectrolyte	blood/serum	1108	0.999	1.00	-0.02	1.00-20.00 mol/L
Ca^{++}	EasyLyte Calcium	blood/serum	1168	0.997	1.03	0.06	0.25-5.00 mmol/L
Hct	Critspin	blood	370	0.994	0.984	0.3	10-70%
Cl^-	EasyElectrolyte	blood	204	0.99	1.006	-0.483	50.0-150.0 mmol/L

Typical performance data: Capillary Mode

Within-run precision of duplicates (NCCLS EP-5) using whole blood and serum

	PO_2	PCO_2	pH	Na^+	K^+	Ca^{++}	Cl^-
N	20	20	20	20	20	20	20
Mean	102	37.1	7.423	142.6	4.23	1.37	102.0
SD	0.9	0.57	0.008	0.67	0.020	0.010	1.00
CV	0.9	1.5		0.5	0.5	0.7	1.0

All tables: pH is in pH units, PCO_2 and PO_2 are in mmHg, CV are in %.

8. EasyStat Setup Defaults

For reference, the following tables show the settings of the EasyStat analyzer at initial startup. All listed settings may be adjusted by the user, refer to Operating the Analyzer/SETUP MENU.

Correlation	Off (when turned on, the correlation is 1.00x + 0.000 for all analytes)		
Reported Patient Data	On		
Barometric Pressure	(measured, user adjustable)		
Security Code	Off		
Calibration Frequency	8 hours		
Auto Standby	Off		
Printer	On		
Calculated Values	On		
Printouts	1		
PO_2/PCO_2/BP units	mmHg		
Na^+/K^+/Ca^{++}/Cl^-	mmol/L		
Temperature units	°C		
Hct	**%**		
Hb	g/dL, calculated		
QC reference limits	pH	0.000	0.000
	K^+	0.00	0.00
	PCO_2	0.0	0.0
	Ca^{++}	0.00	0.00
	PO_2	0.0	0.0
	Na^+	0.0	0.0
	Hct	0	0
	Cl^-	0.0	0.0
Normal reference limits	Refer to Stored Information in Chapter 4		
Critical reference limits	Refer to Stored Information in Chapter 4		
Patient information	Patient ID	Off	
	Patient Temp	Off	
	Hb	Off	
	FIO_2	Off	
	Time Drawn	Off	
	Sample Type	Off	
	Sample Site	Off	
	Operator ID	Off	

9. Troubleshooting

Introduction

To ensure trouble-free operation of the EasyStat analyzer, it is necessary to follow the Replacement Schedule shown in Replace Components and in Chapter 11.

When the EasyStat analyzer detects problems during operation, an ERROR message is displayed and printed. Refer to the error messages for an explanation, and the recommended corrective actions in this chapter.

Biohazard: Human body fluid specimens may be contaminated with HIV or other pathogens. Treat all specimens, collection devices, and analyzer components that may come in contact with specimens as biohazardous.

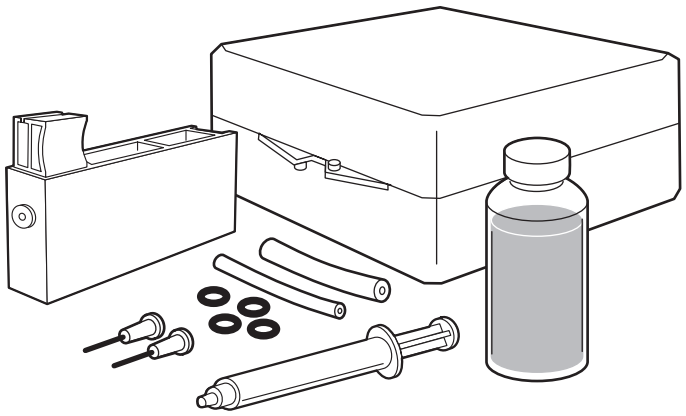
For Help

When the troubleshooting procedures do not correct the observed error, contact your EasyStat dealer.

Troubleshooting Kit

Tools to help diagnose and correct problems:

- Syringe
- Tubing Segments
- Electrode O-rings
- Red Test Dye Solution 50mL [0.1 mmol/L amaranth dye in electrolyte solution]
- Blunt Needles
- Test Block



Troubleshooting is outlined in the order that problems are most likely to occur. Approach troubleshooting as a logical sequence of events. Isolate the problem area to avoid unnecessary component replacement and downtime.

EasyStat error messages are grouped by type. Solutions for each are outlined in this chapter. The EasyStat DIAGNOSTICS software menu contains several component, hardware and fluidic tests to address many of the error messages listed below. For more information, refer to Diagnostics in Operating the Analyzer.

PROBLEM AREA	ERROR MESSAGES	
ELECTRODES	SLOPE ↑/↓	mV OUT OF RANGE
	CALIBRATION DRIFT	CAL mV OUT OF RANGE
	NOISE	QC DATA ↑/↓
	1 POINT DRIFT	<LIMIT ↓↓ >LIMIT ↑↑
	*****	
FLOW	PUMP CAL FAIL	BD FAIL
	AIR IN CALIBRANT A	AIR IN SAMPLE
	AIR IN CALIBRANT B	AIR IN CONTROL
	AIR IN CALIBRANT C	AIR IN CLEANER
	MOVEMENT OF CALIBRANT A	MOVEMENT OF SAMPLE
	MOVEMENT OF CALIBRANT B	MOVEMENT OF CONTROL
	MOVEMENT OF CALIBRANT C	
REAGENT MODULE	RGNT MODULE EMPTY	RGNT MODULE EXPIRED
	RGNT MODULE INVALID	RGNT MODULE OUT
SENSOR MODULE	SAMPLER UP	WARMING UP
	SENSOR TEMPERATURE	DOOR OPEN
VALVE MODULE	VALVE ERROR	VALVE TEMPERATURE
PRINTER	PRINTER ERROR	
HARDWARE	A/D ERROR	EEPROM ERROR
	DS NOT UPDATED	TEMP/BP ↑/↓
	MISMATCH ERROR	CLOCK ERROR
QUALITY CONTROL		QC ERROR!

To conserve reagents, remove and reinstall the reagent module only when necessary. ▲

When removing any EasyStat components, follow the procedures under Replace Components in Operating the Analyzer for the component being removed, to ensure that all reagents are purged from the sample flow path before component removal. ▲

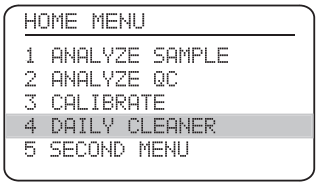
It is critical that the EasyStat sensor module surfaces and electrode exterior surfaces are completely dry before reassembly. The presence of moisture in these areas will interfere with normal calibration and sample analysis. ▲

It is recommended that quality control material be analyzed after troubleshooting to verify performance. ▲

ELECTRODES	SLOPE ↑/↓	mV OUT OF RANGE
	CALIBRATION DRIFT	CAL mV OUT OF RANGE
	NOISE	1 POINT DRIFT

To remove or replace any EasyStat electrodes, follow the instructions under Components in Operating the Analyzer. ▲

Random or single PO_2 or PCO_2 electrode error messages



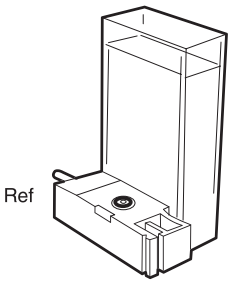
- Perform DAILY CLEANER **twice** and repeat calibration.
- If the error persists, replace the electrode.

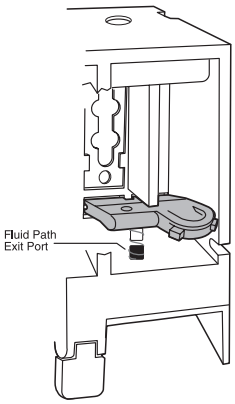
Random 1 POINT DRIFT errors

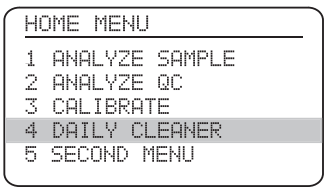
- Analyze the sample a second time.
- If the error persists, recalibrate.
- If the error persists, proceed to the Troubleshooting instructions for Sample Probe/Sensor Module Obstructions and clean the flow path with dilute bleach as instructed.
- Replace the electrode. If the error persists, replace the electrode.

Random or single Na^+, K^+, Ca^{++}/Cl^- or pH electrode error messages

The EasyStat electrodes operate with the reference electrode. (The PO_2 and PCO_2 electrodes operate independently of the reference electrode.) Error messages that are specific to the electrode can be caused by a faulty electrode or a faulty reference electrode.





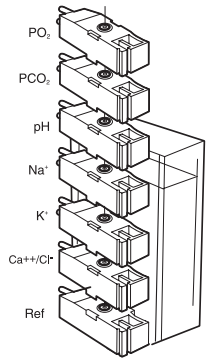


- Perform DAILY CLEANER twice and repeat calibration.
- If the error persists, remove and examine the exterior surface of the reference electrode for fill solution leakage and salt deposits. Replace if it has been installed longer than six months or the red ball is not floating.
- If leakage is observed, replace the reference electrode.
- If no leakage is observed, examine the reference electrode pin for corrosion. Clean the pin with warm water if necessary.
- Inspect inside the sensor module for liquid and/or salt deposits.
- Inspect the compression plate surfaces and the area around the fluid path exit port. Remove any salt deposits with a wet cloth.
- Make sure all sensor module and electrode surfaces are dry. Reinstall the electrodes.
- Perform DAILY CLEANER and repeat calibration.
- If electrode failure continues, replace the electrode.

For continued random or single electrode error messages, inspect all electrode pin contacts (gold coated) at the rear of the sensor module. Wipe dry all contacts. These contacts are spring loaded. Make sure the contacts are clean. If they are dirty or corroded, clean them gently with a pencil eraser, being careful not to remove the gold coating. Push in each contact, then release. The contact will *spring back*. If any contact does not *spring back*, contact your EasyStat dealer.

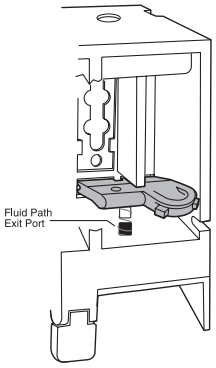
Random or single Hct Sensor error messages

- If the error occurred during calibration, re-calibrate the analyzer.
- If the error occurred during sample analysis, run the sample again.
- If the error remains, perform DAILY CLEANER twice and repeat calibration/analysis.
- If the error remains, remove the sensor module from the analyzer and examine the exterior surface of the sensor module and Hct sensor for liquid or salt deposits.
- Examine the sensor module's electronic connector for corrosion.
- Inspect inside the sensor module for liquid and/or salt deposits.
- Make sure all sensor module and electrode surfaces are dry.
- Re-install the sensor module, perform DAILY CLEANER and repeat calibration.
- If failure continues, replace the sensor module.

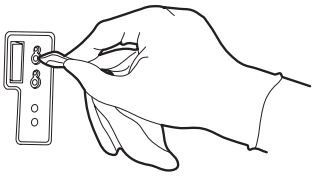


Electrode error messages for more than one electrode may indicate a flow problem.

- Remove the electrodes from the sensor module.
- Inspect the O-ring connections, and replace any cracked O-rings.

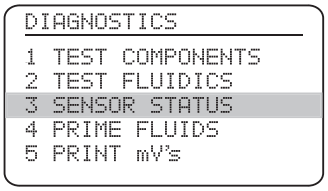


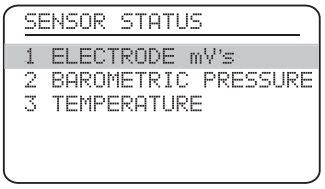
- Inspect the sensor module surfaces that surround the electrodes for salt deposits and/or liquid.
- Inspect above and below the compression plate, and the area around the fluid path exit port.



- Clean and dry all sensor module surfaces and electrode pin receptacles.
- Replace reference electrode if it has been installed longer than six months or the red ball is not floating.
- Wipe dry all electrodes before reinstallation.
- Reinstall the electrodes and confirm that they are correctly aligned. Each electrode is keyed to assist with correct placement. Release the compression plate. 
- Close the access door.
- Calibrate.

A WARMING UP message may appear for up to 30 minutes. During this time, the EasyStat will not calibrate or analyze samples. ▲





Continued electrode error messages may indicate electrode failure.

- Check the electrode millivolt readings by selecting SENSOR STATUS, then ELECTRODE mV's from the DIAGNOSTICS menu.

- Check both Calibrant A, B and C mV's. Wait 20 seconds for the displayed mV's to stabilize. Compare the readings to the Millivolt Range Guidelines listed below.

MILLIVOLT RANGE GUIDELINES:

	Calibrant A	Calibrant B	Calibrant C
pH (mV)	-350 - 350	-320 - 380	
PCO_2 (mV)	-150 - 150	-135 - 165	
PO_2 (mV)	150 - 800	less than 60	
Hct	100 - 250		300 - 600
Na^+ (mV)	100 - 200	85 - 185	
K^+ (mV)	100 - 200	115 - 215	
Ca^{++} (mV)	30 - 130	40-140	40 - 140
Cl^- (mV)	30 - 80		90 - 190

- Replace any electrode with mV's out of range.

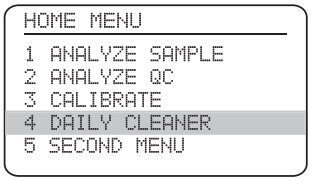
▲ The Na^+, K^+, Ca^{++}, Cl^-, and pH electrodes are dependent on the reference electrode mV readings. If the electrode mV readings are out of range, first verify that the reference electrode is within its use period (refer to the Replacement Schedule in Chapter 11).

- In the case of multiple electrode mV failures, contact your EasyStat dealer.

ELECTRODES	QC DATA ↑/↓

Quality control result is out of range.

When quality control data is out of range, review the quality control information under Analyze QC in Operating the Analyzer.



- Perform DAILY CLEANER twice.
- Recalibrate.
- Condition the electrodes by twice analyzing a serum or blood sample, ignore the results.
- Repeat analysis of control.
- Replace an electrode if it's quality control data remains out of range.

For electrode replacement instructions, refer to Replace Components/ Electrodes in Operating the Analyzer.

ELECTRODES	*****

Quality control or patient sample result is not reported.

- The electrode is not calibrated.
- An error occurred during sample analysis. Repeat sample analysis.
- If the error persists, recalibrate.

ELECTRODES	<LIMIT ↑↑ >LIMIT ↓↓

Quality control or patient sample result is not reported.

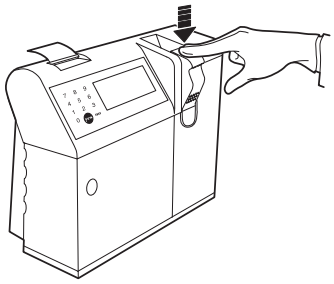
- The result is not within the operating limits of the analyzer.

FLOW	PUMP CAL FAIL BUBBLE DETECTOR!

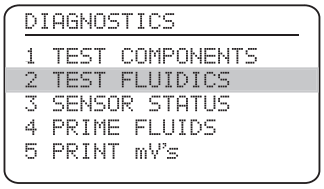
To remove or replace the EasyStat sensor module, pump tubing or valve module, follow the instructions under Replace Components in Operating the Analyzer.

▲

Pump Cal failures (PUMP CAL FAIL)

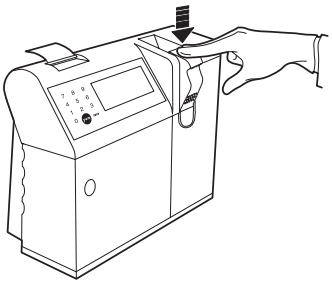


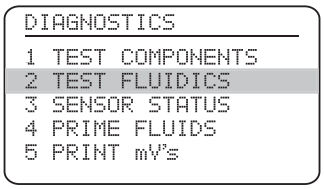
- Verify that all EasyStat components (electrodes, valve module, pump tubing and reagent module) are installed correctly.
- Confirm that the sampler is down.



- Open the access door.
- Perform the PUMP CAL test under TEST FLUIDICS in the DIAGNOSTICS menu. Look for liquid to flow through the pump tubing.
- If PUMP CAL fails, but flow is present, the pump tubing may be defective. Install a new pump tube and retest.
- If the error persists, replace the probe wiper.
- If flow is not present during the PUMP CAL test, proceed to the troubleshooting instructions for **FLOW**/ "AIR" messages.

Bubble detector failures (BD FAIL)

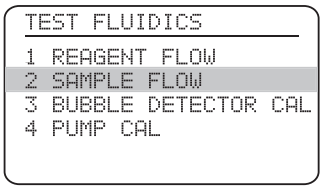




- Verify that all EasyStat components (electrodes, valve module, pump tubing and reagent module) are installed correctly.
- Confirm that the sampler is down.
- Open the access door.
- Perform the BUBBLE DETECTOR CAL test under TEST FLUIDICS in the DIAGNOSTICS menu. Look for liquid to flow through the electrode stack and pump tubing.
- If the test fails, but flow is present, the bubble detector circuit is defective, or the bubble detectors require cleaning. Proceed to the troubleshooting instructions Sample Probe/ Sensor Module obstructions and clean the flow path with dilute bleach as instructed.
- Perform the BUBBLE DETECTOR CAL test under TEST FLUIDICS in the DIAGNOSTICS menu. Look for liquid to flow through the pump tubing. If the test fails, but flow is present, install a new sensor module or replace the bubble detector in the existing sensor module.
- If flow is not present during the BUBBLE DETECTOR CAL test, proceed to the troubleshooting instructions for **FLOW**/ "AIR" messages.

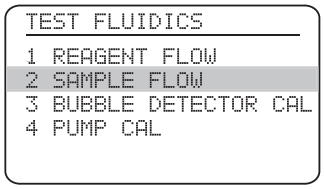
FLOW	AIR IN CALIBRANT A	AIR IN CALIBRANT B
	AIR IN CALIBRANT C	AIR IN SAMPLE
	AIR IN CONTROL	AIR IN CLEANER

Air messages for one reagent (Calibrant A, Calibrant B or Rinse)

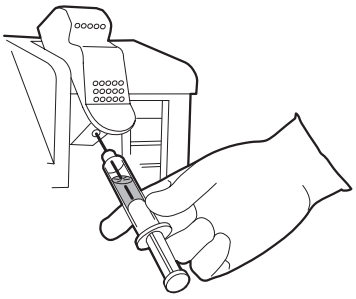


- Perform the REAGENT FLOW test under TEST FLUIDICS in DIAGNOSTICS with the sampler in the closed position. If all reagents pass, recalibrate.
- If any reagent fails, remove then reinstall the reagent module.
- Repeat the REAGENT FLOW test.
- If any reagent fails, remove the valve module and flush with water as described under VALVE MODULE/VALVE ERROR. Repeat the REGAGENT FLOW test (sampler closed).
- If failure continues, install a new reagent module.

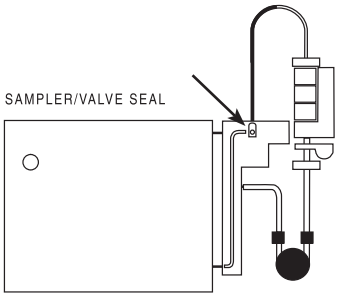
Air messages for two or more reagents (Calibrant A, Calibrant B and Calibrant C)

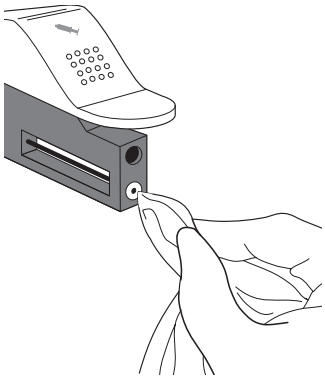


- Perform the SAMPLE FLOW test under TEST FLUIDICS in DIAGNOSTICS.
- Fill the troubleshooting kit syringe with red test dye solution.



- Lift the sampler into the syringe mode and use the red test dye as a sample.

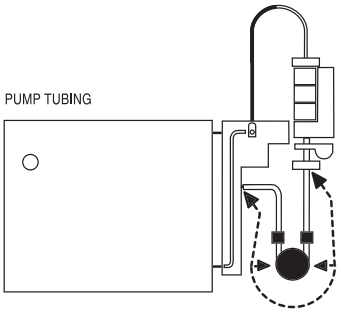




- Look for red dye movement through the pump tubing. If the red test dye does not move, proceed to the instructions for "No red dye movement during FLOW test".
- If there is fluid movement, this indicates a poor sampler/valve module seal.
- Inspect the sampler/valve module interface.
- Move the sampler to the capillary position.
- Inspect the seal on the sampler and the top of the valve module for debris. Clean these areas with a 10% bleach (0.4-0.6% NaClO) solution on a damp cloth, then repeat the SAMPLE FLOW test.
- If the error persists, replace the probe wiper and retest.
- If failure continues, the valve module or the reagent module may be defective.
- Reinstall the reagent module and repeat the REAGENT FLOW test (sampler closed).
- If successful, resume operation.
- If failure continues, remove the valve module and flush with water as described under VALVE MODULE/VALVE ERROR. Repeat the REAGENT FLOW test (sampler closed).
- If failure continues, install a new reagent module.

No red test dye movement during SAMPLE FLOW test

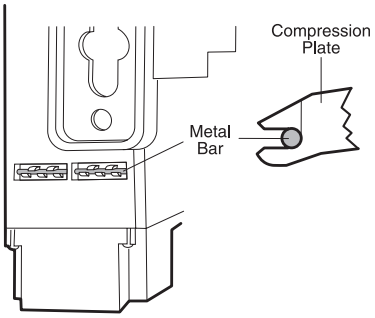
- If the red test dye is not moving through the pump tubing during the SAMPLE FLOW test, inspect the electrode alignment in the sensor module.



- Confirm that the electrodes are installed in the correct order and correctly seated.

- Confirm that the compression plate is closed, and verify that the bar at the rear of the sensor module is snapped inside the compression plate hinge tabs. If not, snap the bar inside the hinge tabs, then gently push down on the compression plate to engage the spring around the fluid path exit port.

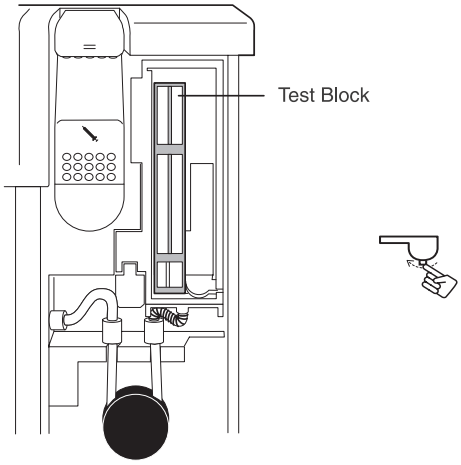


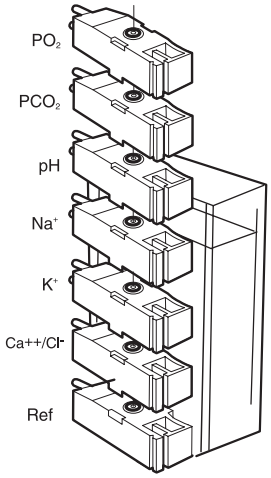


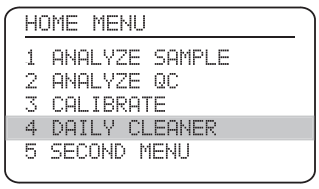
  Release the compression plate.

- Remove and inspect the pump tubing for poor connections, collapsed walls or obstructions.

- Replace the tubing when any of these conditions are evident, then repeat the SAMPLE FLOW test with the red test dye (syringe mode).







- If failure continues, remove the pump tube from the valve module and loosen the pump so that it is attached only to the Sensor Module and not stretched around the pump. Remove the electrodes and replace with the test block. Take a syringe filled with water and attach with small tubing segment to the sampler in the syringe mode. Gently press on the plunger of the syringe. Water should flow from the pump tube.

- Successful flow with the test block installed indicates poor electrode alignment poor sealing, or an electrode obstruction.

- Examine the electrodes for worn or cracked O-rings.

- Replace O-rings if necessary.

- If an elecrode appears to be obstructed, replace that electrode.

- DO NOT attempt to remove an obstruction from an electrode.

- If you cannot push fluid through the flow path with the test block installed, there is an obstruction in the bubble detector. Placing a warm, damp paper towel at its outlet for a period of time usually loosens material blocking the flow path. It can then be flushed out. Remove the paper towelling, resintall the test block and again attemp to purge warm water through the Sensor Module.

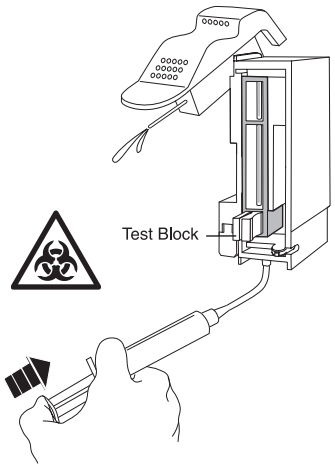
- If ther water purge is successful, reinstall the electrodes and test. Otherwise the Sensor Module will reqiure service or replacement.

- Reassemble the analyzer and perform DAILY CLEANER before calibration.

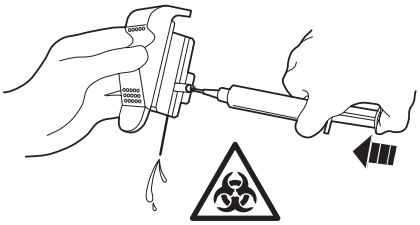
Sample probe/sensor module obstructions

To remove a persistent flow obstruction, or as preventive maintenance, perform the following steps.

- Remove the electrodes from the sensor module. Refer to Replace Components/Electrodes in Operating the Analyzer.
- Install the test block from the troubleshooting kit into the sensor module. Release the compression plate.
- Disconnect the pump tubing from the bottom of the sensor module.
- Lift the sampler to the syringe mode position.
- Attach the large tubing segment to the syringe from the troubleshooting kit. Fill the syringe with a 10% bleach (0.4-0.6% NaClO) solution.
- Connect the tubing segment to the bottom of the sensor module.
- Hold a container below the sampler.
- Flush the flow path by gently pushing on the syringe.
- Allow the bleach to remain in the flow path for 2 minutes.



- Remove the syringe and tubing from the sensor module.
- Discard any unused bleach from the syringe and fill the syringe with water.
- Flush the flow path with water. Repeat 4 times using a syringe full of water each time.
- Install the sensor module and reconnect the pump tubing.
- Confirm a successful SAMPLE FLOW test with the test block installed.
- If an obstruction remains, remove the sampler from the sensor module (refer to Replace Components/Sensor Module in Operating the Analyzer)



- Take a syringe filled with water and attach with small tubing segment to the sampler in the syringe mode and flush the flow path.
- Install a new sampler if the obstruction cannot be removed
- Confirm a successful SAMPLE FLOW test with the test block installed. Remove the test block and reinstall the EasyStat electrodes.
- Release the compression plate and close the sampler.
- Perform the SAMPLE FLOW test. If successful, resume normal operation.
- If the failure continues, it is the bubble detector that is obstructed. Placing a warm damp paper towel at its outlet for a period of time usually loosens the material blocking the flow path and it can then be flushed. Perform the SAMPLE FLOW test. If successful, resume normal operation.
- If an obstruction remains, replace the sensor module.

FLOW	AIR IN SAMPLE

Air was detected in the sample.

- Confirm that sample volume is sufficient (syringe mode - 120 µL, capillary mode - 95 µL).
- There may be air bubbles in the sample itself (sample was shaken). Anlyze a sample without air bubbles.
- If the error continues, refer to FLOW in this chapter.

FLOW	MOVEMENT OF CALIBRANT A	MOVEMENT OF CALIBRANT B
	MOVEMENT OF SAMPLE	MOVEMENT OF CONTROL
		MOVEMENT OF CALIBRANT C

These messages indicate a small movement of calibrant, patient sample, or quality control material during the measurement period of a calibration or analysis cycle.

- When any of these messages appear, repeat the calibration or sample analysis to confirm reproducibility.

Continued MOVEMENT messages could indicate damaged electrode O-ring seals, or a partial obstruction in the sample flow path. Obstructions are most common in the sample probe, sensor module, or electrodes. Follow the instructions for obstruction removal described earlier in this section under FLOW/Sample probe/sensor module obstructions.

REAGENT MODULE	RGNT MODULE EMPTY RGNT MODULE EXPIRED

▲ When removing or replacing the EasyStat reagent module, follow the Replace Components/Reagent Module procedure in Operating the Analyzer.

- The installed reagent module is consumed or has exceeded its expiration date or usage period.
- Install a new reagent module.

REAGENT MODULE	RGNT MODULE INVALID 1 RGNT MODULE INVALID 2 RGNT MODULE INVALID 3

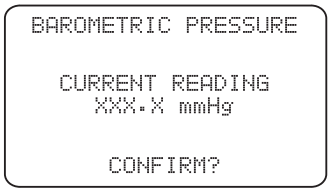
Analyzer/reagent module incompatibility

- Print out a copy of the Reagent Module Status Report if possible.
- Contact your EasyStat dealer.

REAGENT MODULE RGNT MODULE INVALID 4

During a calibration cycle, the PO_2 level of Calibrant A was determined to be substantially different from the assigned value.

This error indicates that the reagent module is defective, the measured barometric pressure is incorrect, or the analyzer is not in an environment of atmospheric air (21% O_2).



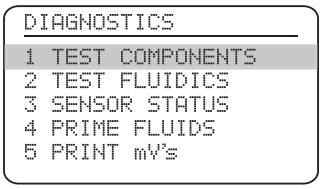
- Verify the barometric pressure under USER OPTIONS in the SETUP MENU.
- Recalibrate.
- If necessary, move the EasyStat to an atmospheric air environment (21% O_2) and recalibrate.
- If the error continues, install a new reagent module and recalibrate.
- If the error continues, contact your EasyStat dealer.

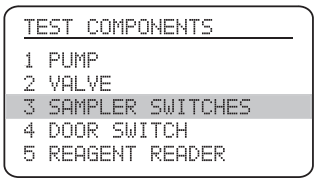
REAGENT MODULE RGNT MODULE OUT

The reagent module is not installed correctly or the reagent reader is defective.

- Remove and reinstall the reagent module. Make certain that the reagent module is properly positioned against the valve module.
- There are two small metal contacts on the analyzer which are mounted behind the reagent module and make contact with the round metal tag on the reagent module. Make sure these metal contacts are clean and spring out. If they are loose, contact your EasyStat dealer.
- If the RGNT MODULE OUT message continues, contact your EasyStat dealer.

SENSOR MODULE SAMPLER UP



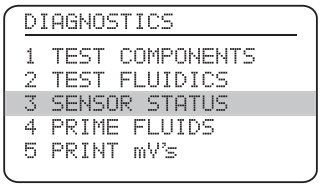


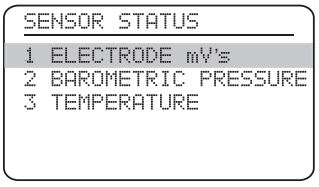
This error message appears when sampler is not completely down.

- Push the sampler down into the closed position.
- If the error continues, select TEST COMPONENTS from the DIAGNOSTICS menu.
- Verify that the valve module and sensor module are pushed in completely.
- Perform the SAMPLER SWITCHES test. Follow the display instructions.
- Remove the sensor module. Check the tightness of the thumb screw on the sampler. DO NOT overtighten (refer to Replace Components/Sampler in Operating the Analyzer).
- Repeat the SAMPLER SWITCHES test.
- If any of these position tests fail, the sensor module circuitry is defective.
- Install a new sensor module as described under Replace Components in Operating the Analyzer.

SENSOR MODULE WARMING UP

This error message appears when the sensor module has not stabilized at 37°C.

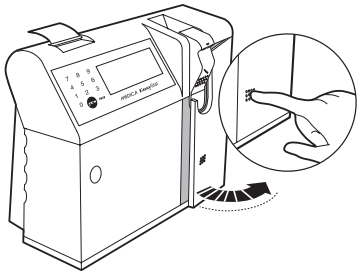




- Make sure the door is closed. The heating circuits will not function with the door open.
- Select SENSOR STATUS from the DIAGNOSTICS menu.
- Select TEMPERATURE to observe the real time sensor and valve temperatures.
- Close the access door and wait up to 30 minutes for WARMING UP to disappear.
- If WARMING UP remains displayed after 30 minutes, remove the sensor module, check and clean the contacts, reinstall and wait up to 30 minutes.
- If WARMING UP remains displayed after 30 minutes, install a new sensor module, and wait up to 30 minutes.
- If the temperature remains out of range, contact your EasyStat dealer.

SENSOR MODULE SENSOR TEMPERATURE

This error indicates an abnormally high temperature in the sensor module.

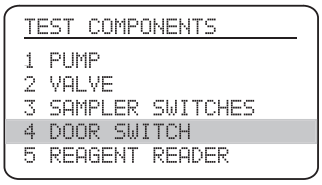


- Open the access door and carefully touch the sensor module. Note if it feels unusually warm or hot. Wait a few minutes for this message to disappear.
- Close the access door.
- If the SENSOR TEMPERATURE display remains, power the analyzer off and then on.

SENSOR MODULE	DOOR OPEN

This message indicates that the access door is not closed.

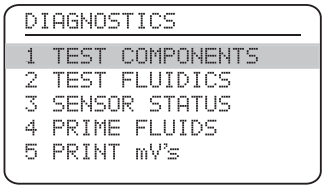
▲ The access door must be closed during EasyStat operation.



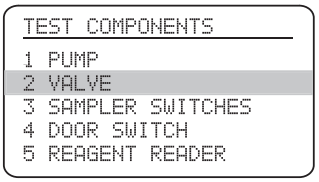
- Verify that all electrodes are installed properly. If any electrode is not pushed in completely, the door will not close properly.
- Perform the DOOR SWITCH test. When closing the door, press against the raised dots and listen for a click.
- If the DOOR SWITCH test fails, contact your EasyStat dealer.

VALVE MODULE VALVE ERROR

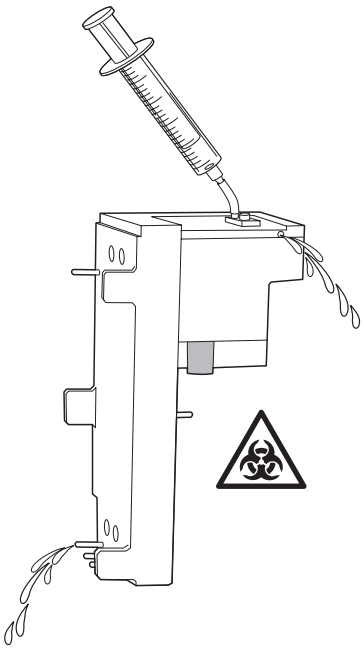
This error indicates a valve malfunction.



- Select TEST COMPONENTS from the DIAGNOSTICS menu.

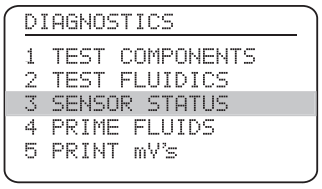


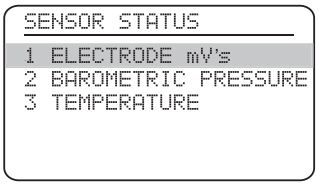
- Perform the VALVE test.
- When the test passes, proceed with EasyStat operation.
- If the test fails, remove the valve module as described under Replace Components in Operating the Analyzer.
- If the valve is not rotating freely, (usually due to the analyzer being turned off with fluids in the flow path that dry up leaving solids), try and rotate the valve manually with a pair of pliers.
- Fill the syringe from the troubleshooting kit with 3mL of warm water. Attach the blunt needle and the large tubing segment.
- Connect the syringe assembly to the fluid port on the top surface of the valve module.
- Begin to flush the water through the valve module. The water may exit through the air port (near the top surface or one of the reagent tubes.
- If there is no flow from any port, slowly turn the valve knob while maintaining pressure on the syringe.
- After successful flow through one port, refill the syringe with 3mL of warm water and slowly turn the knob until flow comes from another port.



- Continue by flushing the other two ports with warm water.
- If flow from any port cannot be established, install a new valve module.
- Flush each port with air by filling the syringe with air and following the above instructions.
- Remove the syringe from the valve module.
- Dry off all valve module surfaces, reinstall the valve module and reassemble the analyzer.
- If the valve error remains, remove the valve module from the analyzer and tap it several times on a counter. Tap on all six major sides of the valve module and then finally tap the valve module on the bottom with the top oriented up. This process may dislodge any minor salt contamination that is interfering with the optical sensor of the valve module. Retest.
- If these steps returned the valve module to operation, it is strongly advised that a replacement valve module be obtained as the valve errors recently cured may return permanently.
- For repeated valve failure, contact your EasyStat dealer.

VALVE MODULE — VALVE TEMPERATURE

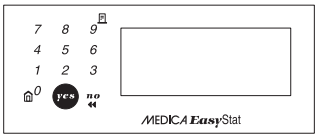




The valve temperature is not in the range 36-41°C.

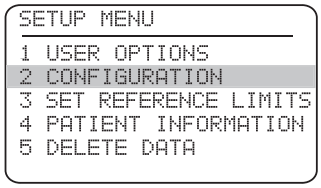
- Make sure door is closed. The heating circuits will not function with the door open.
- Select SENSOR STATUS from the DIAGNOSTICS menu.
- Select TEMPERATURE under SENSOR STATUS. If the valve temperature is not within this range, verify that the valve module is completely installed.
- If Valve Temperature remains displayed after 30 minutes, remove the valve module, check and clean the contacts, reinstall and wait up to 30 minutes.
- If Valve Temperature remains displayed after 30 minutes, install a new valve module and wait up to 30 minutes.
- Contact your EasyStat dealer if the error persists.

PRINTER	PRINTER ERROR



Printer failure

- Press the paper advance button . The paper should advance.



- If the paper does not advance, proceed to SETUP MENU and select CONFIGURATION. Turn the printer on.
- If printer failure continues, carefully inspect the printer mechanism for paper obstructions. Remove any obstructions using caution not to damage the printer assembly.
- If the printer continues to fail, note the failure mode (paper does not advance, printhead does not move, printhead moves but poor or no printing), and contact your EasyStat dealer.

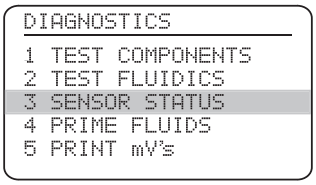
HARDWARE	A/D ERROR	DS NOT UPDATED
	EEPROM ERROR	MISMATCH ERROR
	CLOCK ERROR	

Electronic failure messages

- Power the analyzer off and then on. If the error continues, retain the printouts with the errors and contact your EasyStat dealer.

HARDWARE	TEMP/BP↑/↓

Room temperature or barometric pressure not within the operating specifications (15-30°C, 500-800 mmHg)



- Check the room temperature or barometric pressure by proceeding to DIAGNOSTICS and selecting SENSOR STATUS.
- Move the analyzer to a location where the temperature and barometric pressure fall within the operating limits.
- If the error continues, contact your EasyStat dealer.

QUALITY CONTROL	QC ERROR 1

Incorrect values for EasyStat.

- Only occurs when using barcode.
- Scan correct barcode. If problem continues, contact your EasyStat dealer.

10. Computer Connection

Interface the EasyStat analyzer with an external computer by means of the RS-232 serial interface, using the following specifications.

EasyStat RS-232 Protocol:

Transmission Rate	2400 bits per second
Bit Configuration	8 data bits, 1 stop bit, no parity

Interface requires the EasyStat serial cable. A telephone-style connector at one end of the cable plugs into the receptacle labeled on the back of the analyzer. The other end of the cable is a 9 pin connector with the following signals:

Pin #2	TxD
Pin #3	RxD
Pin #7	CTS
Pin #8	RTS
Pin #5	Signal Ground

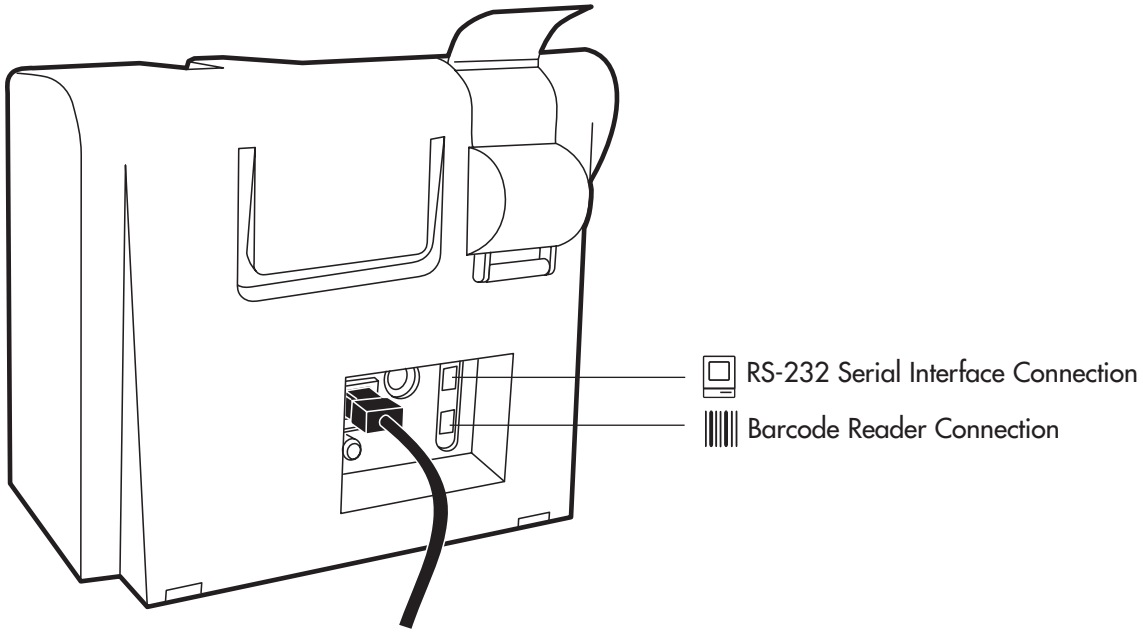
Data control characters such as ETX, STX, etc. are not present. All text lines end with CRLF (0DH, 0AH).

For computers running:

- Windows 95, select *Hypertrm* from *Accessories/Hyperterminal*
- Windows 98 and above, select *HyperTrm* from *Accessories/ Communications/HyperTerminal*

Choose any name and "Direct to Com1" under *Connect using:*. Use the RS-232 protocol stated above. Under *Flow control* use the "Hardware" setting. From the *File/Properties* menu selection, choose *Settings*. Under the *ASCII Setup*, choose "Append line feeds to incoming line ends" under *ASCII Receiving*.

If running Windows 3.1, select Terminal from Accessories. Select Communications under Settings, and use the RS-232 protocol as stated above.



11. Replacement Schedule

PUMP TUBING	Replace every 6 months	(Warranty – 3 months use)
VALVE MODULE	Replace as required	(Warranty – 12 months use)
SENSOR MODULE	Replace as required	(Warranty – 12 months use)
SAMPLER	Replace as required	(Warranty – 6 months use)
pH ELECTRODE	Replace as required	(Warranty – 12 months use)
PCO_2 ELECTRODE	Replace as required	(Warranty – 4 months use)
PO_2 ELECTRODE	Replace as required	(Warranty – 4 months use)
Na^+ ELECTRODE	Replace as required	(Warranty – 6 months use)
K^+ ELECTRODE	Replace as required	(Warranty – 6 months use)
Ca^{++} ELECTRODE	Replace as required	(Warranty – 6 months use)
Cl^- ELECTRODE	Replace as required	(Warranty – 6 months use)
▲ REFERENCE ELECTRODE	Replace every 6 months	(Warranty – 6 months use)
REAGENT MODULE	Replace when empty or expired	
PRINTER PAPER	Replace as required	
PROBE WIPERS	Replace every 3 months	(Warranty – 3 months use)

Appendix A

Warranty

Medica warrants the EasyStat analyzer will be free of defects in material and workmanship for a period of twelve months from the date of purchase excepting only those parts which are consumed or expended in normal use. In the case of consumables or expendables, the warranty time period shall be the usage time, providing such consumable or expendable is used prior to any "install by" or expiration date. The warranty is only applicable when the EasyStat analyzer is used under normal operating conditions and maintained in accordance with the instructions in the operator's manual and if the EasyStat analyzer has not been subjected to accident, alteration, or misuse. In the event of failure within the warranty period, Medica will repair or replace any Analyzer returned and not conforming to the above warranty or, at its option, refund the purchase price.

THE WARRANTY DESCRIBED ABOVE IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES WHETHER STATUTORY, EXPRESS, OR IMPLIED (INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND ALL WARRANTIES ARISING FROM THE COURSE OF DEALING OR USAGE OF TRADE). THE BUYER'S SOLE AND EXCLUSIVE REMEDY IS FOR REPAIR OR REPLACEMENT OF THE DEFECTIVE ANALYZER OR PART THEREOF, OR REFUND OF THE PURCHASE PRICE OF SUCH PRODUCT; BUT IN NO EVENT SHALL MEDICA BE LIABLE TO THE BUYER OR ANY PERSON FOR ANY SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OR OTHERWISE WITH RESPECT TO, OR ARISING OUT OF, THE PRODUCT FURNISHED THEREUNDER.

Representations and warranties made by any person, including Dealers, representatives and employees, which are inconsistent or in conflict with, or in addition to, the terms of this warranty shall not be binding upon Medica unless in writing and signed by one of its officers.

For warranty service in the USA or Canada, please call our Customer Service Department, 1-800-777-5983. Outside the United States and Canada, please contact your local distributor.

Appendix B

Understanding the Symbols

Symbol	Definition
IVD	**In vitro** diagnostic device
	Consult operating instructions
	Attention, see instructions for use
	Temperature limitation
	Do not freeze
LOT	Batch code
	Use by
REF	Catalog Number
	Manufacturer
EC REP	Authorized Representative
CE	CE Mark
	Biohazard
SN	Serial Number
c UL us LISTED Laboratory Equipment 73LN	UL

Symbol	Definition
	Fuse
	Barcode connection
	Battery port connection
	RS-232 serial interface connection
~	Alternating current
	Date Installed
	Install by

003770-001 R1

For Service or Technical Assistance:

800 777 5983 In Continental US
781 275 4892 International
781 275 2731 Fax

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Medica Corporation 5 Oak Park Drive Bedford, MA 01730-1413 USA

MEDICA