

IRMA
TruPoint[®]
Blood Analysis System

User Manual

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Section 1

The IRMA TruPoint[®] Blood Analysis System

INTRODUCTION

This section outlines general information about the IRMA TruPoint Blood Analysis System, and describes the installation process.

INTENDED USE

The IRMA TruPoint Blood Analysis System is intended for use with IRMA TruPoint cartridges for the in vitro measurement of various critical care analytes in human whole blood. See Appendix B, Table B-6 for a list of the analytes that may be measured with the IRMA TruPoint system.

SYSTEM OVERVIEW

The major components of the IRMA TruPoint system are a portable, battery-operated analyzer, and disposable cartridges that contain sensors and a calibrant. Cartridges come in a variety of analyte configurations.

Cartridges calibrate with every test using the self-contained calibrant. Instructions displayed on the interactive touchscreen guide the user through all steps of the testing process. Patient and sample information can be entered during analysis. Test results are displayed within approximately 90 seconds after sample injection. Test results and associated information can be automatically printed via the on-board printer. Test results and associated information can be transmitted via serial, LAN10/100, or modem port to the Integrated Data Management System (*idms*) or other connected system capable of accepting ASTM output.

CLIA COMPLEXITY CLASSIFICATION

The IRMA TruPoint Blood Analysis System has a “moderate complexity” CLIA classification. The optional SureStep[®]Pro Glucose Module has a “waived status” CLIA classification (see SureStep[®]Pro Glucose Module User Manual).

IMPLEMENTATION

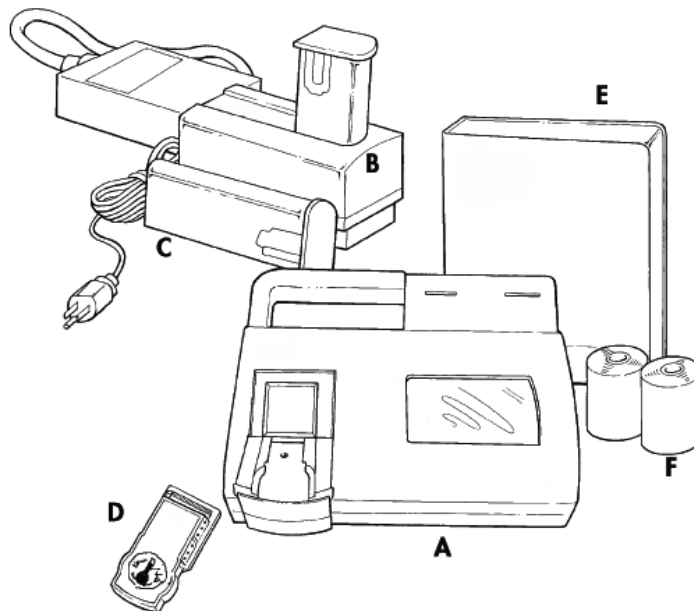
An implementation protocol is available from your service provider upon request.

SYSTEM COMPONENTS

SYSTEM - MAJOR COMPONENTS

Figure 1-1

- A. IRMA TruPoint analyzer
- B. Battery charger (PN 442900) and power supply (PN 573400)
- C. Two rechargeable batteries (PN 448700)
- D. Temperature card
- E. User manual
- F. Two rolls of thermal printer paper (PN 403800)
- G. AC Adapter (PN 440100)-Not Pictured

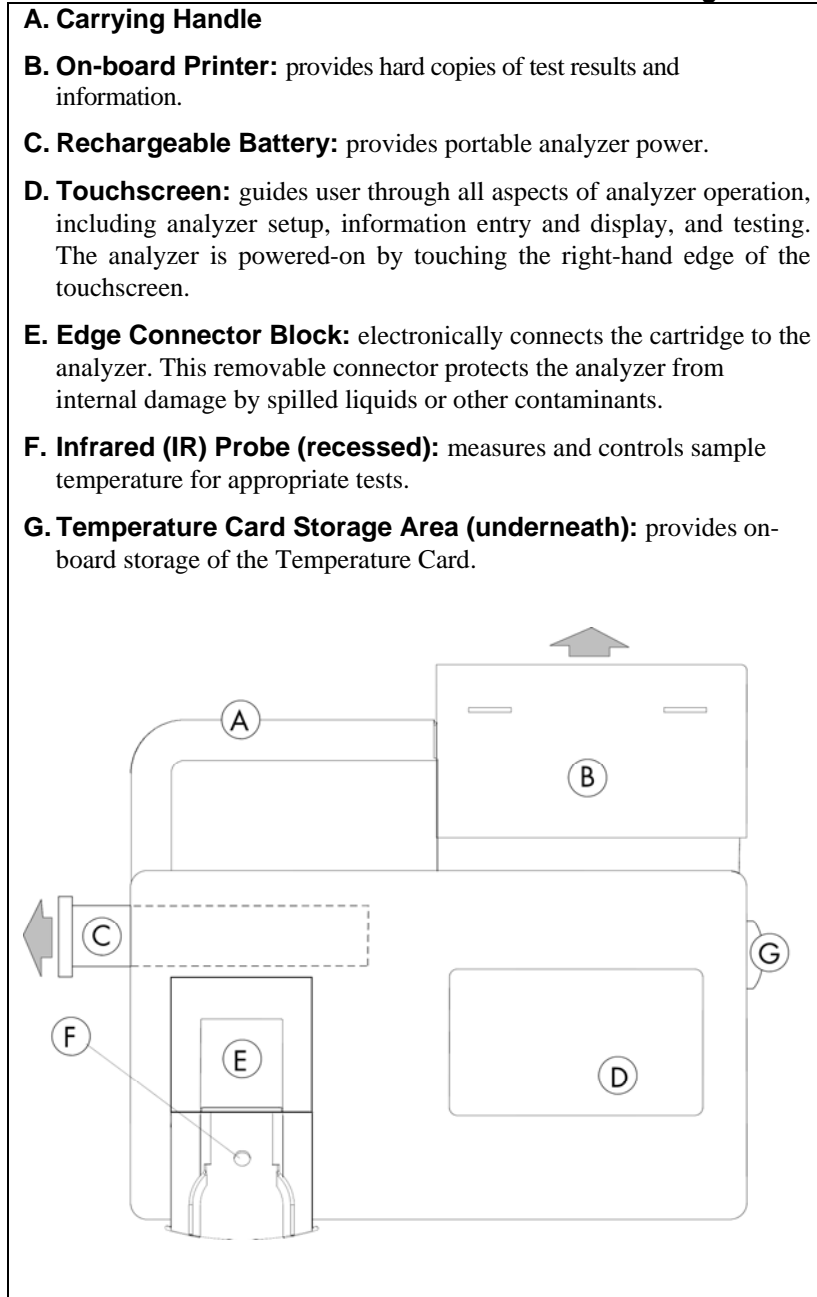


IRMA TruPoint cartridges (not pictured) are ordered, packaged, and shipped under separate cover.

Additional system components are available for use with the IRMA TruPoint system, including the Integrated Data Management System (*idms*), the SureStepPro Glucose Module (PN 444100), an AC power adapter (PN 440100), and a bar code reader (PN 463120). Contact your service provider for information on these and other IRMA TruPoint products.

IRMA TRUPOINT BLOOD ANALYZER

Figure 1-2

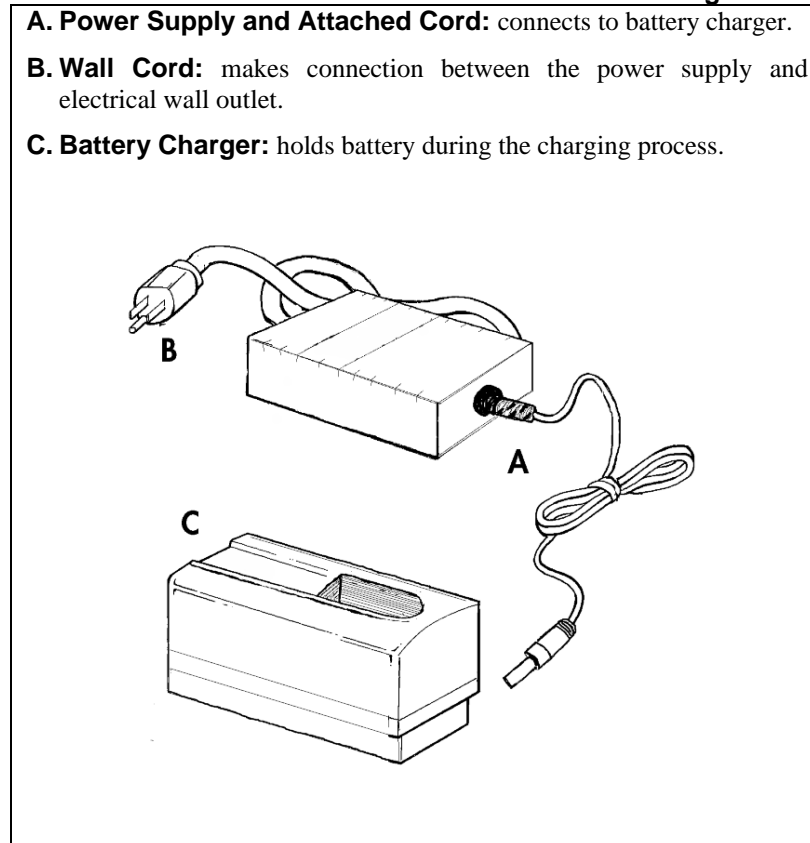


IRMA TRUPOINT BATTERY CHARGER AND POWER SUPPLY

The IRMA TruPoint analyzer can be operated on battery or AC power. The IRMA TruPoint battery power system consists of two rechargeable nickel metal hydride (NiMH) batteries and an external battery charger and power supply.

- NiMH batteries take approximately 5.5 hours (battery empty when placed in charger) to 10 hours (battery full when placed in charger) to charge. A fully charged batter will yield approximately 30-40 tests when fully charged. Test yield will depend on other factors (e.g., cartridge type, amount of printing, etc.)

Figure 1-3



Caution: Battery charger with power supply is not intended for use within a 1.5 meter radius of patient.

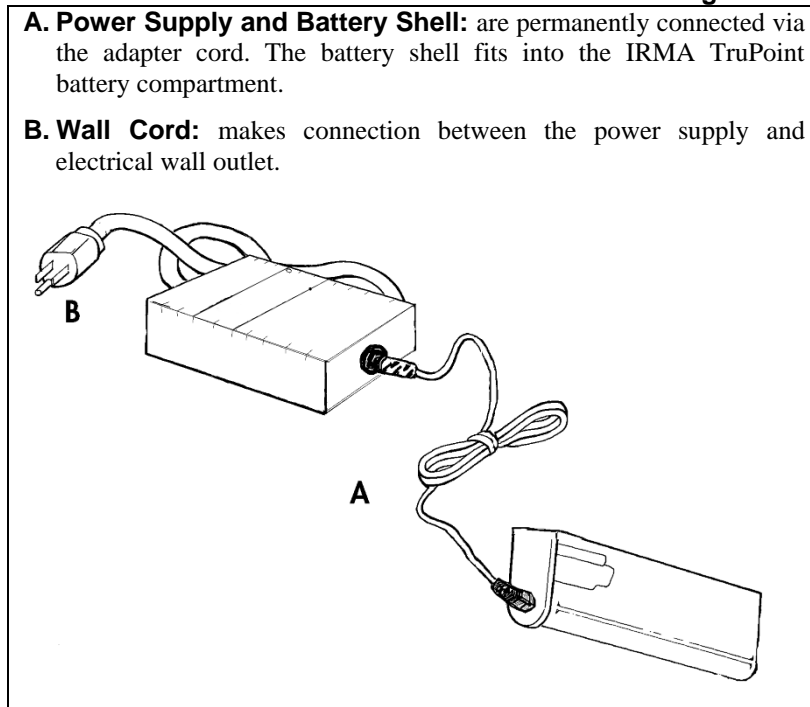
IRMA TRUPOINT AC POWER ADAPTER



The IRMA TruPoint analyzer can be operated on AC power using the IRMA TruPoint AC power adapter.

- The analyzer will not automatically shut off when the AC adapter is in use, and can be left on indefinitely.
- After two minutes of inactivity, the analyzer will enter into “sleep mode” (screen goes dark). The user can return to the last screen displayed by touching the right side of the screen at anytime during sleep mode.
- If the user ID feature is enabled, then the user ID screen will be displayed before the analyzer can be accessed again.
- The analyzer power can be left on indefinitely
- The analyzer can be shut off via the **quit** button on the main MENU.

Figure 1-4

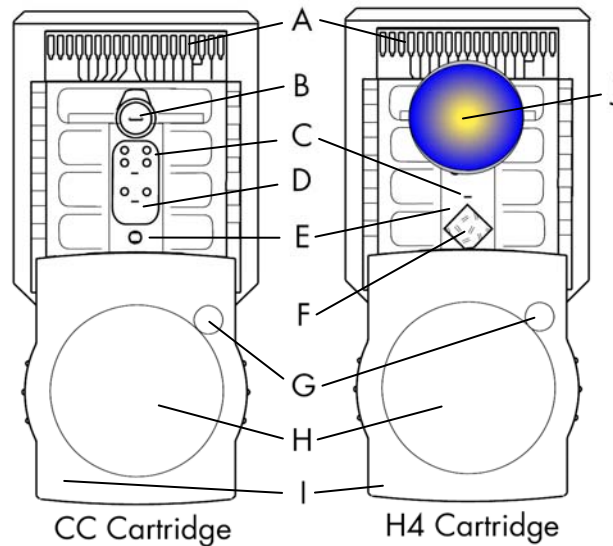


IRMA TRUPOINT CARTRIDGES

Each IRMA TruPoint cartridge contains a sensor array and self-contained calibrant. One patient or liquid QC test is performed on each cartridge.

Figure 1-5

- A. Cartridge Leads: electronically connect the cartridge to the analyzer.
- B. Luer Injection Port: where the sample collection device attaches to the cartridge.
- C. Sensors: measure analyte concentrations.
- D. Calibrant Gel: covers the sensors and is used to calibrate the sensors.
- E. Temperature Monitoring Site (Internal): where IRMA TruPoint IR probe measures and controls sample temperature.
- F. Enzyme Pad: may be present on cartridges that employ enzymatic methodologies.
- G. Overflow Indicator: alerts user that the maximum sample volume (5 mL) that the cartridge can hold has been reached.
- H. Waste Reservoir: holds a maximum sample volume of 5 mL.
- I. Air Vent: located on the bottom, left side of the waste reservoir.
- J. Cal Cap: contains calibrant for cartridges with enzymatic sensors.



GETTING STARTED

UNPACK AND INSPECT THE SYSTEM

- Verify that all components have been received, and inspect components for shipping damage. Immediately report any shipping damage to your service provider.
- Retain one set of packaging materials. Analyzers requiring service by the manufacturer must be returned in the original packaging materials. If the original packaging materials are not available, contact your service provider to order a replacement.

BRING THE ANALYZER TO ROOM TEMPERATURE

- The IRMA TruPoint temperature operating range is **12-30°C (54-86°F)**. If the analyzer is exposed to a temperature outside of that range for a significant period of time, an instrument temperature error message may display. The analyzer must equilibrate at a temperature within the temperature operating range for a minimum of 30 minutes before testing may resume.

ASSEMBLE THE CHARGER

- Connect the power supply to the IRMA TruPoint charger.
- Connect the wall cord to the power supply.
- Plug the wall cord into an electrical wall outlet (110 VAC/60Hz or 220 VAC/50 Hz).

CHARGE THE BATTERY

Conditioning Charge:

Prior to initial use, condition each battery as follows:

- Insert a battery into the battery charger. The battery should ‘click’ into the charger when properly inserted. The yellow light indicates that the battery is charging. Charge the battery for **24** hours.
- After 24 hours, remove the battery from the charger, then reinsert the battery into the charger. Leave the battery in the charger until the green light flashes continuously, indicating that the battery is fully charged. The battery should remain in the charger until it is needed for use in the analyzer.

Routine Charge:

See Section 6-Charging the Battery - Routine for routine battery charging instructions.

UNPACK THE IRMA TRUPOINT CARTRIDGES

IRMA TruPoint cartridges are shipped in an insulated shipping container. The shipping temperature range is **0-50°C**.

- Check the shipping temperature indicators that are enclosed with each shipping container. Instructions accompany the indicators. If the temperature indicators show that the shipping temperature range has been exceeded, do not use the cartridges. Call your service provider for replacement cartridges.

CARTRIDGE STORAGE AND EQUILIBRATION PROCEDURE

Most cartridges are stored at room temperature. Some cartridges, however, require refrigeration. Refer to *Appendix B, Table B-7* for cartridge storage temperature information for all cartridge types.

Room Temperature Cartridge Storage and Equilibration Procedure

- IRMA TruPoint cartridges that require storage at room temperature (**15-30°C/59-86°F**), must be removed from their shipping container and equilibrated to room temperature prior to use. Equilibration times depend on the product type. Refer to *Appendix B, Table B-7* for equilibration times.

Equilibrate cartridges as follows:

- Remove cartridges from their shipping container upon receipt.
- Place cartridges in the area where they will be stored. The storage area must have a stable temperature between 15-30°C (59-86°F). The cartridge storage temperature must not fluctuate more than 8°C (14.4°F). If it does, the cartridges must go through an additional equilibration period before they can be used.
- Proper storage conditions should be documented daily by recording the minimum and maximum storage area temperatures.

Refrigerated Cartridge Storage Procedure

- The CR cartridges are stable through the expiration date indicated on the package label. CR Cartridges must be removed prior to use from the refrigerator and sit at room temperature (15-30°C) for a minimum of 15 minutes.
- CR cartridges **must be used within 8 hours** of removal from the refrigerator.
- CR Cartridges that are not used within 8 hours should be discarded. **Do not place unused cartridges back into the refrigerator.**

CARTRIDGE TEMPERATURE OPERATING RANGE

The IRMA TruPoint temperature operating range is 12-30°C (54-86°F).

- Room temperature cartridges that are used in environments below the cartridge storage temperature range (e.g., CVORs below 15°C/59°F) must be used within 4 hours of transfer from the 15-30°C storage area to the colder area. Cartridges that were not used within the 4 hour time limit must be returned to the 15-30°C storage area, and go through an additional equilibration period before they can be used. Refer to *Appendix B, Table B-7* for equilibration times.
- Refrigerated cartridges may be used until their out-of-refrigerator outdate.

INSERT CHARGED BATTERY OR AC ADAPTER INTO IRMA TRUPOINT ANALYZER

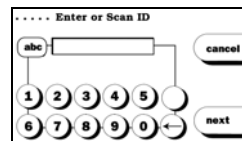
- Insert a charged battery or AC Adapter into the IRMA TruPoint analyzer. The insertion area is located on the left side, below the carrying handle.

SYSTEM FEATURES AND SETUP

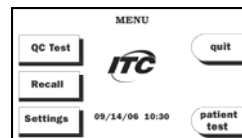
MAIN MENU ACCESS

All IRMA TruPoint test, setup, and recall options are accessed via the main MENU. To access the main MENU:

1. Touch the right-hand edge of the screen to turn the analyzer “on.”
 - a. If the User ID option has not been activated, the main MENU automatically appears at start-up.
 - b. If the User ID option has been activated, the *Enter ID* screen appears. This option requires the entry of a valid User ID code before the analyzer can be used. Following entry of a User ID, the main MENU displays.



The main MENU also appears following completion of a test by pressing the **done** button or the **Menu** button from other screens.

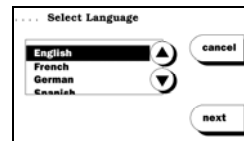
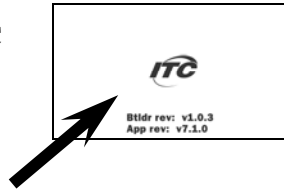


ALTERNATE LANGUAGES

The IRMA TruPoint analyzer software is available in multiple languages. All available languages are automatically loaded into the analyzer during the software installation process.



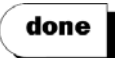




To select an alternate IRMA TruPoint analyzer software language:

1. Touch the right-hand edge of the screen to start power-up. Press down and hold the ITC logo that appears in the center of the screen during power-up. Continue to press down (logo will flash off) until the *Select Language* screen appears.
2. The *Select Language* screen displays a picklist containing all available analyzer languages. Highlight the desired language and press **next**. The main MENU displays in the language selected.



IRMA TRUPOINT TOUCHSCREEN INTERFACE

The IRMA TruPoint touchscreen guides the user through each procedure using screens containing simple directions, buttons, and graphics. Most IRMA TruPoint screens have a title at the top of the screen that describes the on-screen display. IRMA TruPoint uses the following conventions and screen icons:

- | | |
|---|--|
|  | Does not save entries on the current screen and returns to the previous screen. |
|  | Returns to the beginning of the procedure and does not save entries made throughout the procedure. |
|  | Completes the current procedure and returns to the appropriate menu. |
|  | Allows a displayed or highlighted screen item or setting to be changed. |
|  | Proceeds to the next step in the procedure. |
|  | Test Information Button displays on screens where patient test information can be added to test result record, and initiates patient test information entry. |
|  | Oxygen Therapy Button displays on screens where patient oxygen therapy information can be added to test result record, and initiates patient oxygen therapy information entry. |



Bypass Status Button displays on the *Calibrating and Analyzing* screens when available. When “On Bypass” option is selected, *Bypass Correlation* hematocrit results are reported.



Temperature Test Button displays on the QC TEST OPTIONS screen, and initiates an IRMA TruPoint temperature test.



QC Lockout Icon may be displayed on the *Select Product Type* screen during a patient test. Product types that are locked out will have the padlock icon over their selection button, and may not be selected until QC lockout requirements have been met.



Pressing this key erases the last character in the display.



Patient Temperature Icon displays with patient temperature in both °F and °C in upper-right corner of a blood gas test results screen.



Battery Icon displays in the upper-right corner of all screens except the *patient test* and *QC test* screens. A dark meter bar in the battery icon represents the battery capacity. See Section 6-Battery Maintenance for details.

- Alpha-numeric keyboard entry: Allows entry of information from an alpha-numeric keypad that automatically appears when a keypad entry is required.

SYSTEM SECURITY

The IRMA TruPoint analyzer offers 3 user security levels:

- **QA User(s)** have access to all IRMA TruPoint test, recall, and setting options. QA Users have sole access to barometer calibration, communications configuration, results transfer, VueLink, and setup of QC Lockout, User ID, and QC.
- **General Users** have access to all IRMA TruPoint test and recall options, and limited setting options. These setting options include enabling or disabling the beeper and printer, and setting the time, date format, and screen contrast.
- **Gluc Strip Users** may perform and recall only glucose strip, EQC, and temperature tests, and have limited access to setting options. These setting options include enabling or disabling the beeper and printer, and setting the time, date format, and screen contrast.

Note:

- The **Gluc Strip User** privilege is available for users that have purchased the SureStep®Pro Glucose Module, an optional side attachment to the IRMA TruPoint analyzer. Refer to the SureStep®Pro Glucose Module User Manual for details.
- The **General User** privilege allows both IRMA TruPoint cartridge and glucose strip testing (if glucose module is present).

SYSTEM SETUP

Prior to initial testing, complete the following activities:

- Identify QA User(s) to supervise IRMA TruPoint setup and monitoring.
- Use the factory default QA User ID “**123456**” to access the USER ID SETTINGS menu. New QA User ID(s) may be added, and the default QA User ID deleted if desired.
- Review the factory default analyzer settings in Appendix E, and make any necessary adjustments. Refer to Section 7-System Settings for instructions on changing default settings.
- Perform an EQC test (Section 3-Performing an EQC Test). When the test is complete, access the barometer setting, and check the reading against the barometer in your facility. If necessary, change the barometric pressure value in the analyzer (Section 7-Calibrate Barometer).

Note:

- The IRMA TruPoint barometer was calibrated at the factory, and should read within ± 5 mmHg of a NIST-calibrated barometer. Use of a non-NIST-calibrated barometer to adjust the IRMA TruPoint barometer reading is not recommended.

- Enter appropriate User IDs if the User ID feature is enabled.
- Establish quality control procedures and set-up liquid controls (control type, lot, level, and limits).

SYSTEM FEATURES

The IRMA TruPoint analyzer provides many optional software features that can be activated from the main MENU via the *Settings* Option. The following is a summary of these features. Please refer to Section 7-**System Settings** for additional detailed information.

- **Auto-Print:** Enables automatic printing of results immediately upon completion of analysis, or delayed auto-printing after sample and/or oxygen therapy information entry is complete. If this feature is “off”, a printout can still be obtained via the print key on the touchscreen.
- **Bar Code Reader:** A bar code reader is available for IRMA TruPoint analyzers equipped with an accessory port on the back of the analyzer. Please refer to Section 1-Bar Code Reader for additional bar code reader information.
- **Beeper:** When enabled, an audible beep alerts the user that an action is required or that a message is displayed.
- **Correlation:** Allows optional entry of slope and intercept values for each analyte to correlate IRMA TruPoint analyzer results to a reference method.
- **Correlation for Cardiopulmonary Bypass (Pump) Hematocrits:** Allows optional entry of hematocrit slope and intercept values specifically for samples from patients on cardiopulmonary bypass to correlate IRMA TruPoint hematocrit results to a reference method.
- **Date Format:** Date may be displayed in the following formats: MM/DD/YY; YY/MM/DD; or DD/MM/YY.
- **Date and Time:** Allows the definition of the correct date and time. The default analyzer date and time is U.S. Central Standard Time.
- **Electronic QC (EQC):** Quality control is performed through a comprehensive diagnostic check of the IRMA TruPoint edge connector, internal electronics, and analyte circuitry. EQC minimizes the use of reagents and disposable cartridges required for liquid QC testing. EQC can be configured to run automatically when the analyzer is powered by the AC adapter.
- **Oxygen Therapy Information:** Allows optional entry of patient oxygen therapy information to be associated with a patient blood gas test record.
- **Patient ID:** Allows optional or required entry of a patient ID when performing a patient test. ID lengths (number of characters) may also be defined.
- **Patient Hemoglobin:** Allows optional entry of a hemoglobin value, or use of the calculated tHb value derived from an IRMA TruPoint hematocrit result for the associated patient, to be used in the BEb calculation when running a blood gas test.
- **Patient Notes:** Allows optional entry of up to 3 pre-defined patient notes to be associated with a patient test record.

- **QC Notes:** Allows optional entry of up to 3 pre-defined QC notes to be associated with a QC test record.
- **QC Limits:** Allows optional definition of an upper and lower limit for each control lot, level, and analyte. The limits are reported on the analyzer printout with each associated test, available through result recall, and can be transferred via the ASTM output to the *idms*.
- **QC Lockout:** Allows optional definition of requirements (number of tests per level per shift) for both electronic and liquid QC that must be met before the analyzer can be used for patient testing.
- **Reference Ranges:** Allows ability to define reference ranges and provide an optional entry of an upper and lower reference limit for each analyte by sample type, and a reference range title. When activated, patient test results that fall outside of the defined limits will be flagged “H” (High) or “L” (Low). The ranges are reported on the analyzer printout with each associated test and sample type. Reference ranges are stored with the results at the time the test is performed; therefore, changes can be made to the limits without affecting previous results.
- **Reportable Ranges:** Allows optional entry of user-defined upper and lower reportable range limits for each analyte. User-defined reportable range limits must be within the default IRMA TruPoint reportable range limits.
- **Results Transfer:** Enables transfer of new or previously-transferred results via the serial port, LAN 10/100 port, or the internal or external modem utilizing ASTM standard format and communication protocols.
- **Sample Type/Site:** Allows optional selection of a sample type and site (from pre-defined list) to be associated with a patient test record.
- **Screen Contrast:** Allows touchscreen backlight to be adjusted to one of nine settings for optimal viewing in all ambient light conditions.
- **Sleep Mode:** When the analyzer is “on” and has not been used for two minutes, the analyzer goes into a 2 minute sleep mode (screen goes dark) to conserve battery power. The user can return to the last screen displayed by touching the right side of the screen at anytime during sleep mode. When powered by battery, the analyzer powers down if the 2 minute sleep mode period passes without any activity. When powered by AC adapter, the analyzer will not shut down after 2 minutes of inactivity in sleep mode. Entry of a User ID is required (if the User ID feature is enabled) to exit sleep mode. During the two minute sleep mode, the beeper (if enabled) will beep every 15 seconds, unless the screen is on the main MENU or Enter ID screens.

- **User ID:** Requires entry of a valid User ID prior to performing select functions.
- **VueLink:** Allows IRMA TruPoint patient test results to be transmitted to the Philips/Agilent patient monitor for display.

BAR CODE READER

Description

A high performance linear imaging bar code reader is available for use with IRMA TruPoint analyzers that are equipped with an accessory port. The bar code reader is connected to the round accessory port located on the back of the IRMA TruPoint analyzer, next to the RJ45 serial port.

Intended Use

The bar code reader can be used to scan the following information:

- **Cartridge information:** Cartridge type, lot code, and cal code are all encoded in a single bar code found on the cartridge package label. The cartridge package may be scanned with each test instead of manually selecting *Product Type* and verifying the information on the *Verify Information* screen.
- **Glucose test strip information:** Lot code and Ctl code are encoded in separate bar codes found on the SureStepPro test strip bottle. The bottle label may be scanned with each test instead of manually selecting *Product Type* and verifying the information on the *Verify Information* screen.
- **User IDs:** User ID bar codes may be scanned, replacing manual entry of IDs via the touchscreen keyboard.
- **Patient IDs:** Patient ID bar codes may be scanned, replacing manual entry of IDs via the touchscreen keyboard.
- **QC Expected Values:** Expected values for Liquid Quality Control and Calibration Verification Control materials can be scanned from the expected values chart, replacing the manual entry of values via the touchscreen keyboard.

During power-up, the IRMA TruPoint analyzer determines whether or not a bar code reader is connected to the analyzer, and will display the appropriate screen prompts. The bar code reader will only be activated on the entry screens for cartridge information, User ID, Patient ID and QC control settings.

Bar Code Scan Symbologies

The bar code reader is factory programmed to read the following bar code symbologies:

Code 11	EAN/JAN	Plessey
Code 39	Interleaved 2 of 5	Telepen
Code 128	Matrix 2 of 5	UPC
Codabar	MSI	

Scanner Specifications

Refer to the User's Guide that came with the bar code reader for detailed specifications and regulatory compliance statements.

Note:

- The Welch Allyn bar code reader uses a non-laser, red LED light source.

Connecting the Bar Code Reader

1. Ensure that the IRMA TruPoint analyzer is turned "off".
2. Connect the bar code reader cable to the round keyboard port on the back of the analyzer.
3. The reader will be ready for use when the analyzer is powered back "on".

Caution:

- The IRMA TruPoint analyzer can only determine the presence or absence of a bar code reader during analyzer power-up. Do not connect or disconnect the reader when the analyzer is "on". Doing so may result in damage to the reader or analyzer, or the display of incorrect screen prompts.

Disconnecting the Bar Code Reader

1. Ensure that the IRMA TruPoint analyzer is turned "off".
2. Disconnect the bar code reader cable from the keyboard port on the back of the analyzer.

Mounting the Bar Code Reader

The bar code reader may be attached to the IRMA TruPoint analyzer using the mounting clip that came with the reader.

1. Attach the clip to the IRMA TruPoint handle as shown. (Figure 1-6).

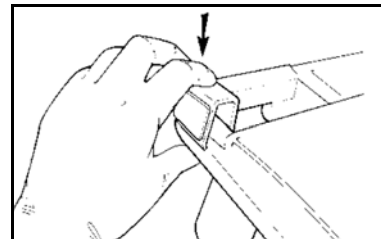
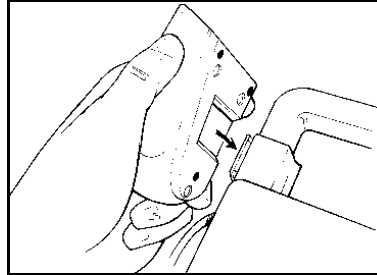


Figure 1-6

2. Connect the bar code reader to the clip. (Figure 1-7)

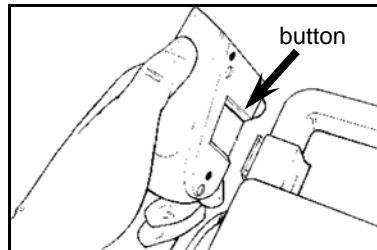
Figure 1-7



Operating the Bar Code Reader-General

To scan a bar code, position the bar code 3-6 inches (7-15 cm) from the reader light source window. Press and hold the button on the bottom of the reader and align the red light line with the bar code. The red light line will turn off and the IRMA TruPoint screen will advance when the scan is complete. (Figure 1-8)

Figure 1-8

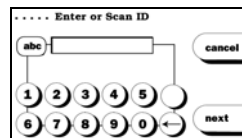


Operating the Bar Code Reader-Patient Sample Analysis and QC Testing

If a bar code reader is connected to the IRMA TruPoint analyzer, the appropriate screen prompts will display upon initiation of a patient test or liquid QC test. The bar code scanner can be used to scan the following items:

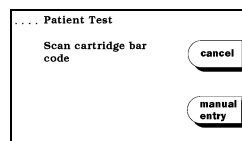
- **User ID**
- **Patient ID**
- **Cartridge Information:** Product Type, Lot Code, and Cal Code are encoded in the single bar code found on each cartridge package label.
- **Glucose Test Strip Information:** Product Type, Strip Lot, and Ctl Code are encoded in the two bar codes found on each test strip bottle label.
- **QC and Calibration Controls:** QC product, level, lot number, expiration date, and expected values are encoded in the series of bar codes located on the ITC expected values sheet. These sheets are located at www.itcmed.com.

1. Enter User ID (optional). If the User ID option is activated, the Enter or Scan ID screen will display. The User ID may be entered using either the alpha/numeric keypads or the bar code scanner.



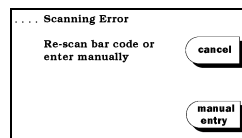
- a. Entry via touchscreen keypads - enter your User ID and press next.
- b. Entry via bar code scanner - scan your User ID. The IRMA TruPoint display will automatically advance to the next screen.

2. Scan cartridge bar code. A screen instructing you to *Scan cartridge bar code* will display at the appropriate time. Scan the cartridge package label for the cartridge to be used. Note: To manually enter and/or verify cartridge information, press **manual entry**.



- a. Successful scan - cartridge product type, Lot Code, and Cal Code will be accepted. The IRMA TruPoint display will automatically advance to the next screen (the *Select Product Type and Verify Information* screens will not be displayed).

- b. Scanning Error - the Scanning Error message will be displayed. The cartridge bar code may be re-scanned, or the user may press manual entry to manually enter and/or verify product type, Lot Code, and Cal Code.



VUELINK

Please contact your local representative regarding the current availability of Vuelink.

Description

The Philips/Agilent VueLink module is a component for Philips/Agilent patient monitors. VueLink allows IRMA TruPoint patient test results to be transmitted to the Philips/Agilent patient monitor for display.

VueLink Setup

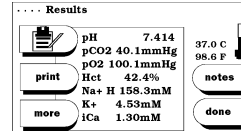
Refer to Section 7-VueLink for IRMA TruPoint VueLink setup instructions.

Patient ID should be configured “Required”.

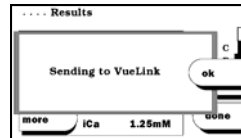
Refer to the appropriate Philips/Agilent document for monitor operating instructions and other information related to the Philips/Agilent patient monitoring system and VueLink.

Transmitting Results to VueLink

1. The patient test results displayed on the Results screen are transmitted to VueLink when **done** is pressed, only under the following conditions:



- The VueLink option in DEVICE SETTINGS is “on”, and;
 - The IRMA TruPoint analyzer is connected to a VueLink module residing in a patient monitor or monitor rack. If there is no connection between IRMA TruPoint and VueLink, pressing **done** will end the test and advance IRMA TruPoint to the appropriate screen.
2. The *Sending to VueLink* screen displays once a connection has been established. The user has 15 seconds to verify that the patient ID from the test record transmitted matches the patient ID entered into the patient monitor.

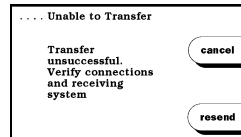


- a. **Patient ID verified within allotted time** - test results display on the patient monitor and the IRMA TruPoint advances to the appropriate screen, depending on setup.
- b. **Patient ID not verified within allotted time** - test results do not display on the patient monitor and the IRMA TruPoint advances to the appropriate screen, depending on setup.

Transmission Errors

If a connection is made, but the transmission is unsuccessful, an error message will display.

- a. **Resend** - verify connections and receiving system and press **resend** button.
- b. **Cancel transmission** - press **cancel** button.



Transmitting Recalled Results

All IRMA TruPoint patient test results can be recalled and transmitted to VueLink.

- A result can be transmitted multiple times.
- A result cannot be edited in IRMA TruPoint once it has been transmitted to VueLink.
- Transmitting a result to VueLink does not affect its sent/unsent status for transmission to *idms* or a host system.

DEVICE COMMUNICATION UTILITY (DEVICECOM)

Description

DeviceCom is a PC software application that handles all communications between the IRMA TruPoint device and other software programs such as *idms*.

DeviceCom Setup

There is no specific DeviceCom setup required in IRMA TruPoint. See the *Device Communication Utility User Manual for DeviceCom* setup instructions.

DEVICASET

Description

DeviceSet is a PC software tool that provides an easy and efficient way to create, modify, restore and manage configuration settings on all IRMA TruPoint instruments at a site. Settings profiles are established in DeviceSet and then a profile is assigned to one or more IRMA TruPoint analyzers. A profile is a collection of IRMA TruPoint settings that includes most of the IRMA TruPoint settings that may be manually established via the IRMA TruPoint SETTINGS OPTIONS menu.

QA Users can configure IRMA TruPoint to automatically receive settings profile updates, or updates may be sent manually.

- **Automatic Device Updates:** available settings profile updates, as well as available software and/or language updates are automatically transferred to IRMA TruPoint when downloading test results to *idms*. Following IRMA TruPoint software upgrades, DeviceSet automatically restores settings in the IRMA TruPoint that would otherwise revert to factory default settings.
- **Manual Device Updates:** QA Users can manually request updates from DeviceSet via the IRMA TruPoint SETTING OPTIONS menu.

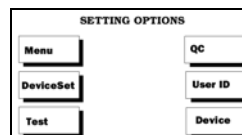
DeviceSet Setup

Refer to Section 7-DeviceSet for automatic update setup instructions. Refer to the *DeviceSet User Manual* for DeviceSet instructions.

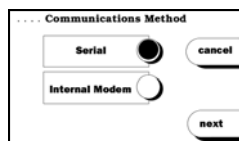
Initiating a Manual Device Update

QA Users may initiate a manual device update as follows:

1. Upload any unsent results to *idms* or a host system.
2. Press the **DeviceSet** button on the SETTING OPTIONS menu.

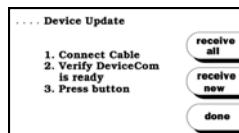


3. a. If the Communications Method setting is User Selects, highlight the button next to the appropriate method and press **next** and go to step 4.



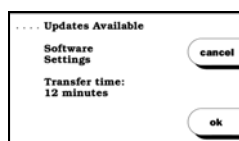
- b. If the Communications Method setting is not User Selects, go to step 4.

4. Connect cable to computer and verify that DeviceCom is running. Select an option on the Device Update screen:



- a. “receive all” - All profile settings will be sent to the analyzer, overwriting the existing settings. If new software or language updates are available, they will be also be sent.
 - b. “receive new” - Only profile settings that have changed since the last analyzer update will be sent to the analyzer. If new software or language updates are available, they will be also be sent.

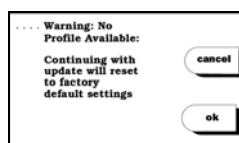
5. The available updates (i.e., Languages, Software, Settings, None), and the estimated time it will take to complete the update will display. If there is a profile associated with the analyzer and there are no unsent records in the analyzer, pressing **ok** will continue the update until completion.



If the update cannot proceed for one of the following reasons, a message screen will be displayed:

a. The analyzer is not associated with a profile.

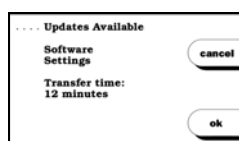
- > Press **ok** to continue update. Factory default IRMA TruPoint settings will overwrite existing analyzer settings. If new software or language updates are available, they will be also be sent.



- > Press **cancel** to cancel update and return to the SETTING OPTIONS menu.

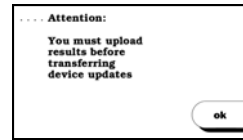
b. Result Transfer setting is “idms” and there are unsent results.

- > Unsent results will automatically be transferred when **ok** is pressed from the Updates Available screen.



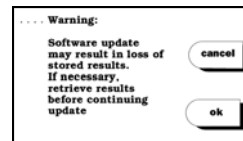
c. Result Transfer setting is “host” and there are unsent results.

- > Results must be manually transferred to the host system before the update can be initiated. Press **ok** to return to the main MENU.



d. Result Transfer setting is “off” and there are unsent results.

- > The unsent stored results may be deleted during the software update. Press **ok** to continue update if stored results have already been retrieved or if it is acceptable that they may be deleted.



- > Press **cancel** to cancel update and retrieve results.

- 6. When the update is complete, THE SETTING OPTIONS menu will display.

Section 2

Patient Sample Analysis

OVERVIEW

This section describes the procedure for performing a whole blood patient sample analysis on the IRMA TruPoint analyzer, including sample requirements, sample collection, and sample handling guidelines.

SAMPLE REQUIREMENTS

ACCEPTABLE SPECIMENS

- Fresh arterial or venous whole blood collected in a 1, 2, or 3 mL lithium heparin syringe. Balanced or low-volume heparin is recommended for ionized calcium testing; sodium heparin may be used, but sodium values may be elevated 1-2 mmol/L.
- Fresh capillary whole blood collected in the IRMA TruPoint Capillary Collection Device, which contains balanced lithium heparin.
- Fresh venous whole blood collected in a lithium heparin collection tube. Balanced or low-volume heparin is recommended for ionized calcium testing; sodium heparin may be used, but sodium values may be elevated 1-2 mmol/L. The sample should be transferred to a non-heparinized 1, 2, or 3 mL syringe for injection into a cartridge.

SYRINGE REQUIREMENTS

Most standard ABG syringes are compatible with IRMA TruPoint cartridges. The following general types of syringes **should not** be used with IRMA TruPoint cartridges:

- Frictionless or “pulsating” syringes. These syringes have plungers that will continue to travel downward after the user has stopped injecting. This may result in a sensor error.
- Syringes that contain a mixing ball or non-dissolving disk impregnated with heparin. The ball or disk may become lodged in the tip of the syringe, and the sample may hemolyze when it is forced through or around the plug during injection.
- Syringes that have a non-standard Luer hub that does not fit the IRMA TruPoint cartridge Luer injection port.

CAPILLARY REQUIREMENTS

Capillary samples must be collected in the IRMA TruPoint Capillary Collection Device. See Appendix F for detailed Capillary Collection Device instructions.

SAMPLE SIZE

The minimum whole blood sample volumes that must be injected into a single-use cartridge for a patient sample analysis are:

- **200 uL** if sample collected in a syringe
- **125 uL** if sample collected in an IRMA TruPoint Capillary Collection Device.
- Ensure that sufficient sample is collected to meet the minimum volumes required for injection into the cartridge.

GENERAL SAMPLE COLLECTION GUIDELINES

- Time sample collection to minimize delays between collection and analysis.
- Avoid drawing samples above an IV line to prevent dilution of the sample with IV fluid.
- When drawing a sample from an indwelling line, back-flush and clear the line of IV fluids prior to sampling to remove anticoagulants or medications which might interfere with the test.
- Allow the blood collection site to dry after being cleansed with alcohol to prevent hemolysis.
- Fill the collection device to the appropriate capacity. Incomplete filling may cause high heparin to blood ratios which may lower ionized calcium results and may affect other results.
- Thoroughly mix samples collected in syringes.

BLOOD GAS SAMPLE HANDLING

- Expel any air present in the syringe immediately after collection and **before** the sample is mixed. If a portion of the sample must be separated for other testing, do not expose sample to air.
- If a sample cannot be tested within 5 minutes of collection:
 - > Expel all air from the syringe.
 - > Cap or seal-off the end of the collection device.
 - > Store the blood gas sample in an ice slurry.
 - > Thoroughly mix the sample while the cartridge is calibrating.

- Capillary samples must be free-flowing from an “arterialized” site. Avoid excessive squeezing of the puncture site to prevent erroneous results that could result from dilution of analytes or hemolysis.

ELECTROLYTE/GLUCOSE/LACTATE SAMPLE HANDLING

- If a blood sample cannot be tested within 20 minutes of collection, keep the collection device capped to minimize pH changes that could affect the ionized calcium concentration.
- Do not ice samples that are to be analyzed for potassium; iced samples may hemolyze.
- Analyze samples that are to be tested for glucose immediately; glucose will decrease 5-10 mg/dL/hour as a result of glycolysis.
- Samples for lactate should be analyzed immediately on drawing as lactate increases by as much as 70% within 30 minutes at 25° C as a result of glycolysis.¹

PREPARING THE SAMPLE FOR INJECTION

- Remove any entrapped air from the syringe sample by pointing the syringe at an upward angle to allow air bubbles to rise to the surface; expel the air, along with a small amount of blood, onto an absorbent surface.
- Mix the sample thoroughly using the following technique:
 - > Roll the syringe between the palms of both hands with the syringe tip pointing up.
 - > Invert the syringe (i.e., tip down) after 15-30 seconds. Continue to roll the sample, alternating syringe orientation, until thoroughly mixed.
- Check the expelled sample for blood clots. A clot usually indicates inadequate sample anticoagulation (e.g., the sample and heparin were not well mixed). If a clot is injected near or over the cartridge sensors, erroneous test results or sensor errors could occur. Do not use clotted samples.
- When using the IRMA TruPoint Capillary Collection Device, analyze the sample immediately, or place a luer cap on the tip of the device and analyze within 5 minutes.

SAMPLE INJECTION

With each test, the cartridge automatically calibrates before the sample is injected into the cartridge. Following calibration, the calibrant that is present in the sample path must be completely displaced by the blood sample that is being analyzed. The sample path is the area of the cartridge that houses the sensors and must be completely filled with blood (see Figures 2-2 and 2-3). Proper sample injection technique will ensure that the calibrant is completely displaced, and that no air bubbles are introduced during the injection step. If calibrant or bubbles are present in the sample path following the initial sample injection from a syringe, the user can displace them by injecting additional sample from the same syringe. This prevents sensor errors and sample loss.

INJECTING A SYRINGE SAMPLE

The following injection technique should be used for all syringe samples, regardless of syringe size or sample volume:

1. Firmly attach the syringe to the cartridge luer injection port. If the syringe does not have a luer lock tip, place the syringe tip in the injection port and give the syringe a slight twist to firmly seat it in the port.
2. Place your fingers around the syringe so that your thumb rests on top of the plunger (Figure 2-1). Inject the sample by depressing the syringe plunger in a single, quick, controlled motion, similar to the motion used to press a stopwatch button. This initial injection should be done forcefully enough to eject the calibrant from the sample path (Figure 2-2).
3. Stop injecting when you feel the sample eject the calibrant from the sample path. If you can see the sample pushing the calibrant out of the sample path, you are injecting too slowly.

Figure 2-1

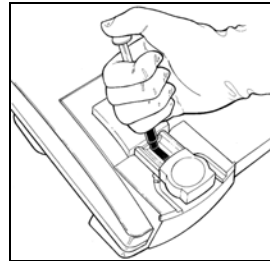
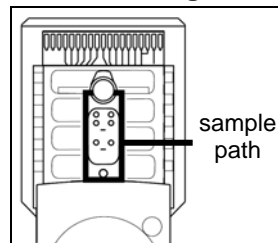


Figure 2-2



Note:

- Do not inject the entire syringe contents (i.e., do not push the syringe plunger all the way down until it bottoms out) during the initial sample injection. Doing so may hemolyze the sample.
4. Following initial sample injection, confirm that the sample path is completely filled with sample, and that no bubbles or calibrant are

present (Figure 2-3). Bubbles or calibrant should rarely be seen if proper injection technique is being used.

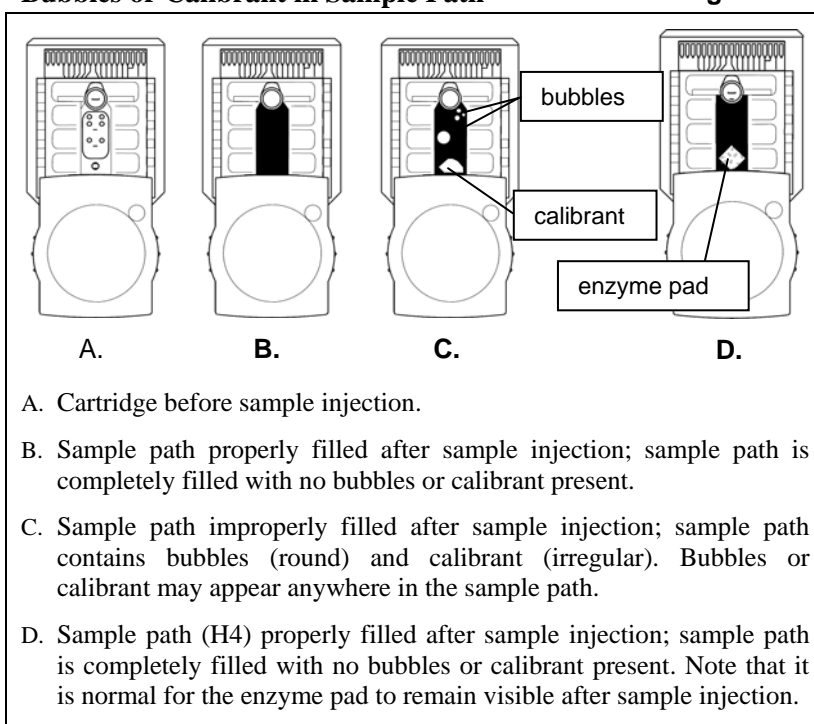
The sample path was designed to be easily viewed. If bubbles or calibrant are present in the sample path, slowly inject additional sample to push them out of the sample path and into the waste area.

Note:

- Do not pull sample from the waste area back into the sample path. Doing so may cause inaccurate results.

Bubbles or Calibrant in Sample Path

Figure 2-3



If bubbles or calibrant do not move when additional sample is injected, tap the top of the plunger to dislodge them, then inject additional sample from the same syringe to push them into the waste area. The entire contents of the syringe may be injected if necessary, to either reach the minimum sample volume injection requirement (200uL) or to displace bubbles or calibrant. Do not inject more than 5 mL of blood into the cartridge.

If air bubbles or calibrant gel cannot be displaced from the sample path, press **cancel** to stop the test, discard the single-use cartridge, and begin again with a new cartridge.

- Once the sample path is completely filled with a minimum of 200 uL of sample, press **test** to begin sample analysis. Leave the syringe attached to the cartridge until the analysis is complete.

INJECTING A CAPILLARY SAMPLE

The IRMA TruPoint Capillary Collection Device must be used to collect and inject samples into IRMA TruPoint cartridges. Refer to Appendix F of this manual, or the IRMA TruPoint Capillary Collection Device package insert for instructions.

PATIENT TEST PROCEDURE

PERFORMING A PATIENT TEST

Initiate a Patient Test

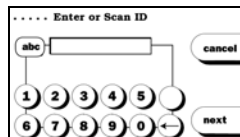
There are two ways to begin a patient test:

- Touch the right-hand edge of the screen to turn the analyzer “on”; or
- With the analyzer “off”, insert a cartridge to turn the analyzer “on” and automatically initiate a patient test (see steps 7-10 for cartridge insertion instructions).

Enter User ID (optional)

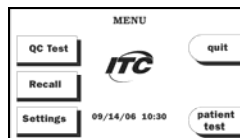
- If the User ID option has not been activated, go to step 5.

- If the User ID option is activated, the *Enter or Scan ID* screen will display. The User ID may be entered using either the alpha/numeric keypads or the bar code scanner.



- Entry via touchscreen keypads - enter your User ID and press **next**.
- Entry via bar code scanner - scan your User ID. The IRMA TruPoint will automatically advance to the next screen.

- a. If the analyzer was powered “on” by touching the screen, the main menu will display. Press **patient test**.



- If no bar code reader connected the *Select Product Type* screen displays. Go to step 6
- If bar code reader connected - the *Scan cartridge bar code* screen displays. Scan the cartridge package label for the cartridge to be used. The cartridge product type, Lot Code, and Cal Code are encoded in the single bar code on the cartridge label. The IRMA TruPoint will automatically advance to the next screen (the *Select Product Type* and *Verify Information* screens will not be

displayed). Go to step 7 if cartridge not yet inserted or step 13 if cartridge has been inserted.

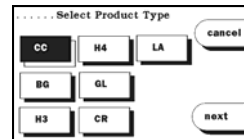
5. b. If the analyzer was powered “on” by cartridge insertion, the *Select Product Type* or *Scan cartridge bar code* screen appears following insertion.

Note:

- If the QC Lockout option is “on”, and lockout requirements have not been met, a lockout message will display. Refer to Section 2- QC Lockout for details.

Select Product Type

6. Highlight the desired product type and press **next**. The *Insert Cartridge* screen displays. If a cartridge was already inserted to initiate the test, go to step 11.



Note:

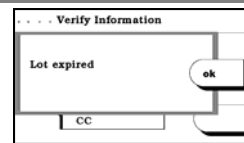
- If only one product type was established in TEST SETTINGS/Product Setup, the *Product Type* screen will not be displayed. The analyzer will assume that the product is the same type as was established in TEST SETTINGS/Product Setup. See Section 7-Product Setup.

Open Cartridge Package

7. Check the expiration date on the cartridge package. The analyzer will not allow testing with expired cartridges.

Note:

- If an expired cartridge is inserted into IRMA TruPoint, the *Lot expired* message will display, and the test cannot proceed. Remove expired cartridge, and initiate a new test with an in-date cartridge. If the wrong lot was selected on the *Verify Information* screen, press **ok** to return to the *Verify Information* screen and press **edit** to enter or select the correct cartridge lot.



8. Remove the cartridge from the package and retain the package until cartridge information is verified.

Remove Tape and Insert Cartridge into Analyzer

9. Remove the protective tape from the cartridge leads (if applicable).

Figure 2-4

Do not touch the cartridge leads after the tape has been removed. Do NOT remove the luer cap from the cartridge. (Figure 2-4).

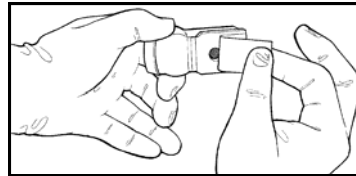
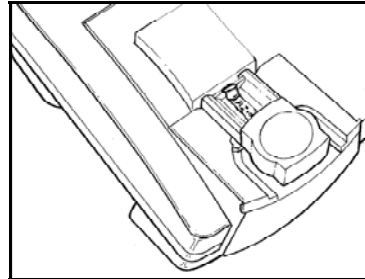


Figure 2-5

10. Fully insert the cartridge into the analyzer within 15 minutes of opening the package. (Figure 2-5)

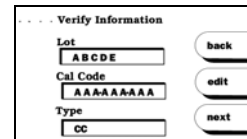
Note:

- Do not use a cartridge if it has been out of the package longer than 15 minutes; do not reuse a single-use cartridge once it has been inserted into the analyzer.

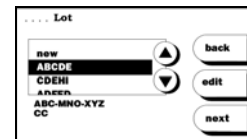


Verify/Enter Cartridge Information

11. Ensure that the product type (Type) displayed on the *Verify Information* screen is correct. If the product type displayed does not match the type of the cartridge inserted into the analyzer, press **back** to return to the *Select Product Type* screen.



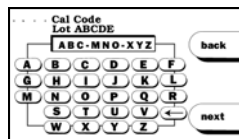
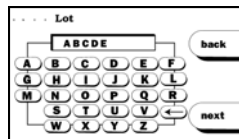
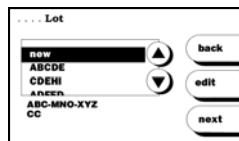
12. The Verify Information screen displays the cartridge Lot and Cal Code from the most recent test performed on the same product type.
 - a. If the Lot displayed **matches** the Lot of the cartridge inserted into the analyzer, press **next**. Proceed to step 13.
 - b. If the Lot displayed **does not match** the Lot of the cartridge inserted into the analyzer, press **edit** to choose a different previously-entered Lot, or enter a new Lot for the first time.
 - i. To choose a previously-entered Lot, highlight the correct cartridge Lot from the picklist. Press **next** to return to the *Verify Information* screen. If the information is correct, press **next** to continue patient test. If the information is incorrect, press **edit** to re-enter the Lot and Cal Code.



b2. To enter a new cartridge Lot for the first time, highlight **new** from the picklist and press **edit**.

› Enter the cartridge Lot using the alpha keypad. Press **next**.

› Enter the Cal Code using the alpha keypad. Press **next** to return to the *Verify Information* screen. If the information is correct, press **next** to continue patient test. If the information is incorrect, press **edit** to re-enter the Lot and Cal Code.



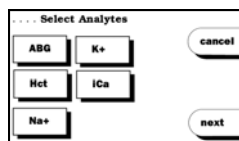
Note:

- IRMA TruPoint generates an error if the calibration code is not verified within approximately 2 minutes of cartridge insertion.

Select Analytes

13. If the QA User set up the analyzer to always automatically report results for a specified group of analytes, the *Select Analytes* screen will not appear; the analytes defined in the setup will always automatically be reported. Proceed to step 16.

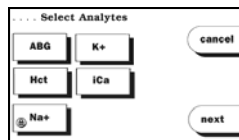
14. If the QA User set up the User Selects option for the product being run, the *Select Analytes* screen will appear with each test.



15. Select the analytes or analyte groups to be tested by highlighting the appropriate button(s). Press **next** when all desired analytes have been selected.

Note:

- Analytes that are locked-out will have a padlock over the selection button, preventing selection of that analyte until QC Lockout requirements have been satisfied.

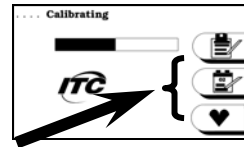


Calibration

16. Once the required data has been entered or verified, the calibration process begins.

- a. **For cartridges that have calibrant gel packaged over the sensors (CC, BG, H3):** calibration begins automatically. Proceed to step 17.
- b. **For cartridges that have a Cal Cap (H4, GL, CR, LA):** when the *Dispense Calibrant* screen displays (with countdown timer at bottom), follow the on-screen instructions for dispensing the calibrant over the sensors. Depress the Cal Cap firmly and quickly to dispense the calibrant, and press **next**. The calibrant must be dispensed within **1** minute or the test is terminated and an Error message appears.

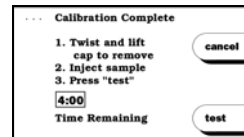
17. If the QA User enabled the test information, oxygen therapy information, and/or bypass status features, buttons will appear on the *Calibrating* and *Analyzing* screens.



Information may be entered during calibration. Refer to Section 2- Test Information Entry for instructions.

Remove Luer/Cal Cap, Inject Blood Sample, and Press “test”

18. The Calibration Complete screen displays when calibration is complete. Twist and lift the luer or Cal cap to remove it from the injection port. The sample must be injected within **4** minutes of completing calibration.



A timer displayed at the bottom of the screen counts down from 4 minutes. If more than 4 minutes elapse, the test is terminated and an Error message appears.

Note:

- If an Error screen appears during calibration, refer to **Section 5- Troubleshooting** for assistance.

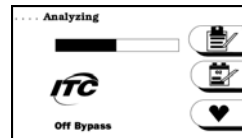
19. Inject 0.125 mL (IRMA TruPoint Capillary Collection Device) or 0.2 - 5.0 mL (syringe) of blood into the cartridge within **4** minutes after the cartridge is calibrated. Leave the collection device attached to the cartridge. Refer to Section 2-Injecting a Syringe Sample or Section 2-Injecting a Capillary Sample for sample injection details.

Note:

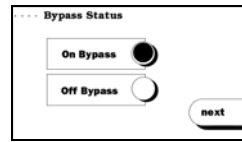
- If air bubbles or calibration gel are present in the sample path after the initial sample injection, remove them by injecting additional sample from the same syringe, or by lightly tapping the top of the syringe plunger and then injecting additional sample from the same syringe.
- If air bubbles or calibration gel cannot be removed from the sample path, press cancel to stop the test, discard the cartridge, and begin again with a new cartridge. Proper injection technique will prevent air bubbles or calibration gel from being present in the sample path after initial sample injection.

20. Ensure that no air bubbles or calibration gel are present in the sample path, then immediately press **test** to continue sample analysis.

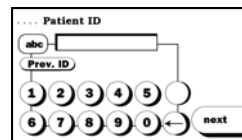
a. The *Analyzing* screen displays if there is no required patient bypass status or patient ID information to be entered.



b. If patient bypass status or patient ID information entry is required, but not yet entered, the *Bypass Status* screen or *Patient ID* screen will display when **test** is pressed. The required information must be entered



before results will display or print. Refer to Section 2-Entering Test Information and Section 2-Patient Bypass Status for details. Enter the required information and press **next** to advance to the *Analyzing* (or *Results*) screen.

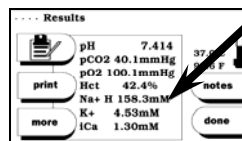


21. When the test is complete, remove the cartridge with the collection device attached. Dispose of both in accordance with established guidelines for your facility.

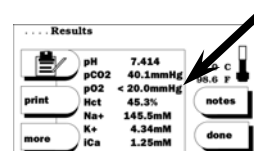
View Test Results

22. Results automatically appear on the IRMA TruPoint touchscreen when the analysis is complete. Press **more** to view additional measured or calculated results if all the results do not appear on the screen.

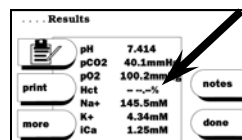
a. **Result outside of reference range:** If reference ranges were established by the QA User, and a patient test result falls outside of the defined limits, the result will be flagged “H” (High) or “L” (Low).



b. **Result outside of reportable range:** If a measured result is outside of the IRMA TruPoint reportable range, that result, and any corresponding calculated results, will be flagged “<” (less than) or “>” (greater than).



c. **Result suppressed:** If a sensor errors during the analysis phase of a patient test, the result for that sensor, any sensors dependent on that sensor, and any corresponding calculated values, will be suppressed. Suppressed results will be dashed-out on both the screen and printout.



Note:

- pH Normalized iCa results will be reported only for pH values within the range of 7.2 - 7.6; if pH values fall outside of this range, pH Normalized iCa results will be suppressed.

**Complete Test Information Entry (optional);
Document Patient Notes (optional)**

23. Refer to Section 2-Test Information Entry and Section 2-Patient Notes for details.

Obtain a Printout (optional)

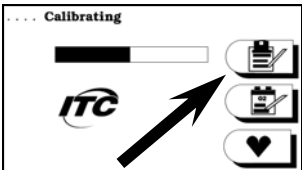
24. a. If the Auto-print setting is “immediate”, test results will automatically print when the analysis is complete.
- b. If the Auto-print setting is “delayed”, test results will automatically print when the **done** button is pressed from the *Results* screen.
- c. If the Auto-print setting is “off”, a printout may be obtained by pressing the **print** button.

TEST INFORMATION ENTRY

The **Test Information** feature allows the user to enter information into the IRMA TruPoint for each patient test. The entry options that are available for selection with each test have been established by the QA User, and may include any combination of the following: patient ID, patient temperature, patient hemoglobin, sample type, sample site, MDRD GFR calculation and FIO₂. When entered, this information becomes a permanent part of the patient test record, and may be transferred to the *idms*.

ENTERING TEST INFORMATION

- Press the **Test Information** button that appears on the *Calibrating*, *Analyzing*, *Results*, or *Patient Recall/Last Results* screens. If this button is not present, the QA User has not enabled this feature or none of the options apply to the associated test record.

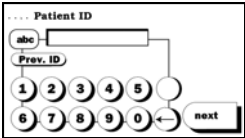


- The first test information entry screen will display. Enter information, or press next to advance to the next entry screen.

Patient ID

Patient ID is the only test information item that may require entry. When Patient ID was enabled by the QA User, two options were available for selection:

- **Optional Patient ID Entry:** enter a one-to-twelve character ID to identify the sample, or press **next** to leave the Patient ID blank.
- **Required Patient ID Entry:** enter a one-to-twelve character ID to identify the sample. Results will not display or print until a Patient ID is entered and **next** is pressed. This screen cannot be bypassed; the only way to exit this screen is to enter a Patient ID.
- To automatically display the Patient ID from the last patient test performed, press **Prev. ID**.
- If the ID entered or displayed exists in the stored results, the remainder of the Test Information fields are assigned the same values as the most recent result for the same product type. If the previous values are correct, press **next** to accept the values displayed, or change values as necessary.



Note:

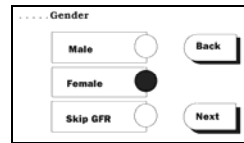
- If Patient ID entry is “Required”, and a patient ID was not entered during the Calibrating phase, the Patient ID screen will display instead of the Analyzing screen after sample injection. A patient ID must be entered before results will display or print. Enter a patient ID and press **next** to advance to the *Analyzing* (or *Results*) screen.
- If the analysis completes before the patient ID is entered, a flashing “ANALYSIS COMPLETE” message displays in the upper right corner of the Patient ID screen. Results will not display or print until a Patient ID is entered and **next** is pressed. This screen cannot be bypassed; the only way to exit this screen is to enter a Patient ID.
- If a Patient ID has not been entered (no results were displayed or printed), and IRMA TruPoint powers-down, the test results may be viewed and printed by recalling the result. If the test being recalled was the last patient test performed on the analyzer, a patient ID can be entered upon recall. Refer to Section 4-Recall Patient Results for instructions on recalling last test result.
- If the test being recalled was not the last patient test performed on the analyzer, the results can be viewed or printed, but a patient ID cannot be entered. Refer to Section 4-Recall Patient Results for instructions on recalling test results.
- A configuration option may have been selected by the QA User which defines the minimum and maximum number of characters that must be entered for a valid Patient ID. If the ID entered does not conform to the defined ID length, an Invalid Length message will display. Enter a Patient ID of acceptable length.

MDRD GFR

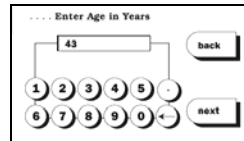
- If a CR test is being performed and the QA User has selected the GFR calculation settings, the user can enter information to obtain the GFR or they can skip the GFR.

- Enter the following information when the Gender screen appears:

> Select Male, Female or skip the GFR.
Press **next**.



> If a gender is selected then enter age in years.
Press **next**.



Patient Temperature

- The *Patient Temperature* option allows entry of a patient temperature when performing a blood gas test. A default temperature of 37°C automatically displays if a patient ID is not entered, or no previous blood gas results exist for a patient ID. Press **next** to accept the temperature displayed or enter a new temperature and press **next**.

The screenshot shows a screen titled "Patient Temperature". At the top, it displays "37.0 °C". To the right of the display is a "back" button. Below the display is a numeric keypad with buttons for digits 1-9, 0, and a left arrow. To the right of the keypad is a "next" button.

Patient Hemoglobin

- The *Patient Hemoglobin* (manual entry) feature allows entry of a hemoglobin value to be used in the BEb calculation when running a blood gas test. Press **next** to accept the hemoglobin value displayed or enter a new value and press **next**.

The screenshot shows a screen titled "Patient Hemoglobin". At the top, it displays "15 g/dL". To the right of the display is a "back" button. Below the display is a numeric keypad with buttons for digits 1-9, 0, and a left arrow. To the right of the keypad is a "next" button.

Reference Range

- The *Reference Range* feature allows documentation of the reference range group selected. Select the reference range group and press **next**.

The screenshot shows a screen titled "Select Reference Range Group". It has three radio button options: "ADULT", "PEDIATRIC", and "NEWBORN". To the right of each option is a button: "cancel" for ADULT, "edit" for PEDIATRIC, and "done" for NEWBORN.

Sample Type

- The *Sample Type* feature allows documentation of the sample type collected. Press **next** to accept the sample type displayed or enter a new type and press **next**.

The screenshot shows a screen titled "Sample Type". It has six radio button options: "Arterial", "Venous", "Cord", "Mixed Venous", "Capillary", and "Neonate". To the right of the options are "back" and "next" buttons.

Sample Site

- The *Sample Site* feature allows documentation of the sample site. Press **next** to accept the sample site displayed, enter a new site, or select other to enter a one-to-twelve character free-text sample site. Press **next**.
- If the sample site selected is Brachial, Femoral, or Radial, highlight "right" or "left" and press next.

The screenshot shows a screen titled "Sample Site". It has six radio button options: "Radial", "Brachial", "Femoral", "Arterial Line", "Cord", and "Other". To the right of the options are "back" and "next" buttons.

FIO₂

- If a blood gas test is being performed, and the QA User has selected the Oxygen Therapy setting *FIO₂ only*, an FIO₂ value may be entered. Press **next** to accept the FIO₂ displayed, or enter a new FIO₂ value. Press **next**.

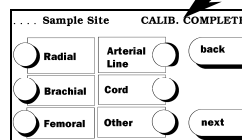
The screenshot shows a screen titled "FIO2". At the top, it displays a blank field followed by a "%" symbol. To the right of the field is a "back" button. Below the field is a numeric keypad with buttons for digits 1-9, 0, and a left arrow. To the right of the keypad is a "next" button.

TEST INFORMATION ENTRY – MISCELLANEOUS

If test information entry is completed before calibration is complete, the operator is automatically returned to the *Calibrating* screen.

If calibration completes at any time during test information entry, the **CALIB. COMPLETE** message appears in the upper right corner of the test information screen. Complete information entry, or press **next** through each remaining screen

to save entries and return to the *Calibration Complete, Inject Sample* screen. None of the information screen entries will be saved until **next** is pressed on the last entry screen. Pressing **back** to return to the *Calibration, Calibration Complete, or Analyzing* screens will not save test information entries. Test information entry can be resumed and completed during the *Analyzing* phase, after the test is complete (*Results* screen), or upon recalling the last patient test result.

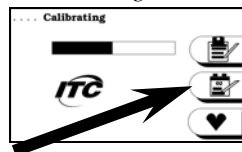


OXYGEN THERAPY INFORMATION ENTRY

The **Oxygen Therapy** feature allows the user to enter oxygen therapy information into the IRMA TruPoint for each patient blood gas test. Information available for entry includes mode of oxygen therapy and the relevant settings for each mode. When entered, this information becomes a permanent part of the patient test record, and may be transferred to *idms*.

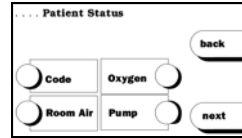
ENTERING OXYGEN THERAPY INFORMATION

- Press the **Oxygen Therapy** button that appears on the *Calibrating* or *Analyzing* screens. If this button is not present, the QA User has not enabled this feature or none of the options apply to the associated test record. Oxygen Therapy information can also be entered by pressing the Test Information button that appears on the *Results* screen following a test or upon recalling the last patient test result.
- The first oxygen therapy entry screen will display. Enter information, or press **next** to advance to the next entry screen.



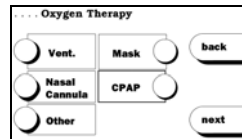
Patient Status

- Highlight the appropriate *Patient Status* setting.
 - › If **Code** or **Room Air** status is selected, press **next** to accept the selected oxygen status and complete entry.
 - › If **Pump** status is selected, press **next** to access the FIO₂ screen. Enter FIO₂ value and press **next** to access *Comments* screen. Enter a one- to twelve-character comment (optional) and press **next** to complete entry.
 - › If the **Oxygen** status is selected, press **next** to access the *Oxygen Therapy* screen.



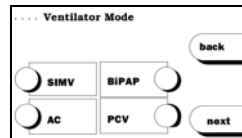
Oxygen Therapy

- Highlight the appropriate Oxygen Therapy mode. Press **next**.
- The entry options displayed depend on the relevant settings for the selected oxygen therapy mode.



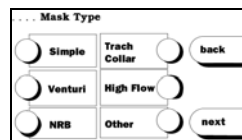
Ventilator Mode

- The *Ventilator Mode* screen appears following selection of **Vent.** from the *Oxygen Therapy* screen. Highlight the appropriate mode and press **next**.
- The following information may be entered, depending upon the ventilation mode selected:
 - › **Tidal Volume** (mL)
 - › **Rate or Frequency** (B/min.)
 - › **FIO₂** (%)
 - › **PEEP** (cm H₂O)
 - › **IPAP** (cm H₂O)
 - › **EPAP** (cm H₂O)
 - › **Comments** (up to twelve alpha-numeric characters)



Mask Type

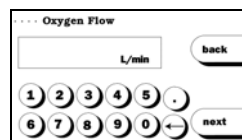
- The *Mask Type* screen appears following selection of **Mask** from the *Oxygen Therapy* screen. Highlight the appropriate mask type and press **next**.



- The following information may be entered:
 - › If **Venturi**, **Trach Collar**, or **High Flow** is selected, enter the FIO₂ (%) and press **next**.
 - › If **Simple** or **NRB** is selected, enter the oxygen flow (L/min.) and press **next**.
 - › If **Other** is selected, enter mask type (up to twelve characters); enter the oxygen flow (L/min.) and press **next**.

Nasal Cannula Mode

- The *Oxygen Flow* screen appears following selection of **Nasal Cannula** from the *Oxygen Therapy* screen. Enter the oxygen flow (L/min.) and press **next**.

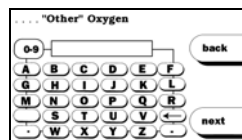


CPAP Mode

- The *CPAP* screen appears following selection of **CPAP** from the *Oxygen Therapy* screen. Enter the CPAP (cm H₂O) delivery pressure and press **next**.
- Enter the FIO₂ (%) and press **next**.

Other Mode

- The “*Other*” *Oxygen* screen appears following selection of **Other** from the *Oxygen Therapy* screen. Enter the form of oxygen therapy (up to twelve characters). Press **next**.



- Enter associated comments (up to twelve characters). Press **next**.

OXYGEN THERAPY ENTRY – MISCELLANEOUS

If oxygen therapy information entry is completed before calibration is complete, the operator is automatically returned to the *Calibrating* screen.

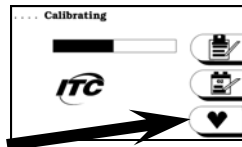
If calibration completes at any time during oxygen therapy information entry, the “CALIB. COMPLETE” message appears in the upper right corner of the information screen. Complete information entry, or press **next** through each remaining screen to save entries and return to the *Calibration Complete, Inject Sample* screen. None of the information screen entries will be saved until **next** is pressed on the last entry screen. Pressing **back** to return to the *Calibration, Calibration Complete*, or *Analyzing* screens will not save test information entries. Oxygen therapy information entry can be resumed and completed during the *Analyzing* phase of the test. After the test is complete (*Results* screen displayed) or upon recalling the last patient test result, oxygen therapy information may be entered via the **Test Information** button.

PATIENT BYPASS STATUS

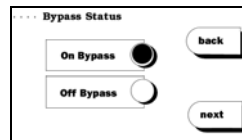
The **Bypass Status** feature, when established by the QA User, requires the user to select a patient bypass status (“On Bypass” or “Off Bypass”) for each patient test. When “On Bypass” is selected, the bypass correlation factors established by the QA User will be used to determine the hematocrit results. This information becomes a permanent part of the patient test record, and may be transferred to *idms*. See Section 7-Bypass Correlation.

SELECTING PATIENT BYPASS STATUS

- Press the patient **Bypass Status** button (heart icon) that appears on the *Calibrating* or *Analyzing* screens. If this button is not present, the QA User has not enabled this feature or none of the options apply to the associated test record. Bypass status can also be selected by pressing the **Test Information** button that appears on the *Results* screen following a test or upon recalling the last patient test result. Highlight the correct patient bypass status and press **next**.



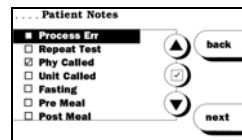
- Bypass status must be selected for each test that includes hematocrit when this feature has been established by the QA User. If a patient bypass status was not selected during the *Calibrating* phase, the *Bypass Status* screen will display instead of the *Analyzing* screen after sample injection. A patient bypass status must be selected before results will display or print. Select the patient bypass status and press **next** to advance to the *Analyzing* (or *Results*) screen.



PATIENT NOTES

ENTERING PATIENT NOTES

- The **Patient Notes** feature allows pre-defined notes to be permanently associated with individual patient test records. Up to 3 notes can be attached to an individual patient record. If the QA User enabled Patient Notes, a **notes** button will be present on the *Results* screen. Press the **notes** button to access the pre-defined notes available for selection. Use the up and down arrows to highlight the desired note and press the **check box** button. Repeat for additional notes, and press **next** when complete.



QC LOCKOUT

The **QC Lockout** feature allows the QA User to define the number of successful QC tests (EQC and/or liquid) required to support patient testing. When activated, either 1, 2, or 3 successful quality control tests must be run during a shift or the analyzer will deny access to the patient test screen, or in the case of a partial lockout condition, limit access to the tests available. Shifts can be specified as 8-, 12-, or 24- hours in length.

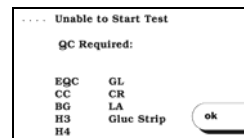
SATISFYING QC LOCKOUT - GENERAL RULES

- QC Lockout can be configured separately for EQC, and for each product type (liquid).
- When EQC Lockout is on, an EQC test failure at any time (i.e., even if EQC passed earlier on a shift) will lockout patient testing. Following an EQC test failure, a passed EQC test is required to resume patient testing.
- When liquid QC limits have been established, results must fall within the established QC limits to be considered a successful test and satisfy QC lockout requirements.
- When no liquid QC limits have been established, running the designated number of controls will satisfy QC lockout requirements for all non-suppressed results.
- Result Suppression during an liquid QC test: If an individual sensor on a cartridge errors during the analysis phase of an liquid QC test, the result for that sensor and any other sensors that are dependent on that sensor will be suppressed. Suppressed results will be dashed-out on both the screen and printout, and will not satisfy QC lockout requirements for the associated analyte group (with or without QC limits established).
- If a patient test is initiated and QC Lockout is “on” and Lockout requirements have not been met, a QC lockout screen displays.

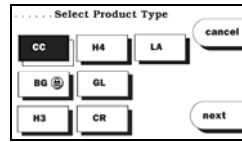
QC LOCKOUT SCREENS

If a patient test is initiated and QC Lockout is on and Lockout requirements have not been met, one of the following lockout information screen displays:

- **All Analyte Groups and Product Types are locked out** (none of the QC lockout requirements for the current shift have been satisfied).
 - > Press **ok** to return to main.

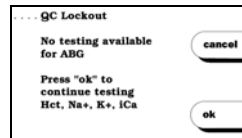


- **Some, but not all, Product Types are completely locked-out for all analyte groups available on that product.** A padlock will display over the selection button, preventing selection of that product type until QC lockout requirements have been satisfied.



- › Select a product type that is not locked out and press **next** to continue test; or
 - › Press **cancel** to return to main.

- **Product types that are partially locked-out** (some, but not all, analyte groups available) will not show a padlock icon over the selection button. When selected, a screen detailing the analyte groups not available for testing will display.



- › Press **ok** to continue testing for available analyte groups; or
 - › Press **cancel** to return to main.

REFERENCES

1. Tietz, N. Clinical Guide to Laboratory Tests, Fourth Edition. Philadelphia: W.B. Saunders, 1995: 4th Ed.

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Section 3

Quality Control Testing

OVERVIEW

Quality Assurance (QA) can be defined as the required systems and actions to provide adequate confidence that a service, such as a point of care diagnostics program, satisfies the medical needs of the patient.¹ Quality Control (QC) is a major component of a QA program, and can be defined as the systematic process of assessing and documenting the analytical performance of an analysis system.

By design, a point of care (POC) system is intended to be used by non-laboratory clinical staff who typically do not have a background in the quality control, analyzer maintenance, and calibration procedures that are inherent components of traditional laboratory analyzer QA programs. Traditional laboratory analyzer QC programs are designed to detect system problems primarily through the use of liquid controls. System problems are typically related to calibration or maintenance problems that result from the exposure of the system and sensors to multiple samples. The IRMA TruPoint system was designed to eliminate problems related to calibration and maintenance.

Single-Use Cartridges

The IRMA TruPoint system utilizes single-use cartridges, also referred to as unit-use or disposable cartridges. Each cartridge houses miniaturized electrochemical sensors and a pre-packaged calibrant. A single-use cartridge is used to perform analysis on one sample, then is discarded.

Cartridge Calibration

Prior to sample introduction, the sensors on each IRMA TruPoint cartridge are automatically calibrated using a pre-packaged calibrant. The calibrant is manufactured and tested with NIST traceable gases and standards. Calibration of the cartridge is completed when information determined at the factory for each lot of cartridges (the Cal Code) is combined with measurements taken during the calibration process. The factory derived Cal Code information is stored in the analyzer memory following initial entry of a new cartridge lot, or can be entered via the bar code reader.

IRMA TRUPOINT QUALITY CONTROL

The IRMA TruPoint Quality Control program consists of the following four elements:

1. **Comprehensive, automatic, on-line quality and procedural checks** that continuously monitor sensor response and instrument response. The IRMA TruPoint software monitors responses throughout both the calibration and sample analysis phases of a test. If an uncharacteristic response is detected during the calibration phase, the system rejects the cartridge and does not allow that cartridge to be used for sample analysis. Since sample introduction occurs after calibration, rejected cartridges do not result in the loss of the sample. If an uncharacteristic sensor response is detected during the sample analysis phase, the system suppresses that sensor and does not report an analyte result for that sensor.
2. **Electronic Quality Control (EQC)** is performed through a comprehensive diagnostic check of the edge connector, internal electronics, and analyte circuitry. An EQC test simulates the electronic signals that are produced by IRMA TruPoint sensors during a cartridge test. During an EQC test, an isolated region of the internal circuit board sends a range of simulated sensor signals through the cartridge measurement channels. The range of signals generated encompasses the entire linear range expected from blood analysis. This measurement is followed sequentially by measurements of conductivity out to the connector pins, insuring that no contamination is present in the edge connector which would interfere with test results. Signal measurements must fall within strict predetermined thresholds for the test to pass. IRMA TruPoint EQC is an internal method, and does not require the use of an external EQC card. Analyzers powered by AC adapter can be configured to automatically run EQC tests per a preconfigured schedule.
3. **Liquid Quality Control (LQC)** is performed to verify proper shipping and cartridge storage conditions using various liquid control solutions of known analyte concentration. Control materials are commercially available in levels corresponding to normal and abnormal clinical conditions.
4. **Temperature Test** is performed using the IRMA TruPoint Temperature Card to verify proper operation of the IRMA TruPoint temperature control system. Although the temperature is monitored continuously during patient testing, the Temperature Card allow for easy external verification.

QUALITY CONTROL RECOMMENDATION

Following method verification and establishment of liquid quality control limits, ITC recommends EQC as the primary method of assessing system accuracy and precision. Since each test site may have unique requirements, each site should select and verify a quality control system that meets their needs. ITC recommends that QC be performed as follows:

RUN AN EQC TEST:

- Once per shift of patient testing on each analyzer;
- When the analyzer experiences a significant change in storage temperature, (e.g., movement from a cold to a hot environment);
- Whenever the performance of the analyzer requires verification, according to facility or regulatory agency protocol.

RUN TWO LEVELS OF LIQUID CONTROL:

- Before a new cartridge lot or shipment is put into use, (following the required equilibration period) to verify proper shipping and equilibration conditions. Cartridge lot verification is not required for each analyzer in use.

ADDITIONAL LIQUID CONTROL TESTING:

- Is required only if cartridges are required to go through an additional equilibration period due to temperature fluctuations of greater than 8°C (14.4°F) in the cartridge storage area. Refer to Section 1-Cartridge Equilibration Procedure for additional equilibration information.
- If cartridges are required to go through an additional equilibration period, run two levels of liquid control before putting the cartridge lot back into use.

RUN A TEMPERATURE TEST:

- Monthly to verify that the IRMA TruPoint temperature control system is operating properly.

ELECTRONIC QUALITY CONTROL

Electronic Quality Control tests may be performed two ways:

1. **Manual EQC Test:** initiated by user by pressing the **EQC** button on the *QC Test Options* screen.
2. **Automatic EQC Test:** runs automatically per a pre-configured schedule. This feature requires the use of an AC adapter to power the IRMA TruPoint.

PERFORMING A MANUAL EQC TEST

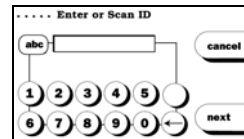
Turn IRMA TruPoint Analyzer On

1. Touch the right-hand edge of the screen to turn the analyzer “on”.

Enter User ID (optional)

2. If the User ID option has not been activated, go to step 4.

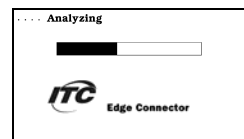
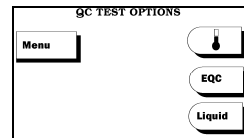
3. If the User ID option is activated, the *Enter or Scan ID* screen will display. The User ID may be entered using either the alpha/numeric keypads or the bar code scanner.



- a. Entry via touchscreen keypads - enter your User ID and press **next**.
- b. Entry via bar code scanner - scan your User ID. The IRMA TruPoint will automatically advance to the next screen.

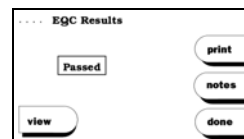
Initiate an EQC Test

4. Press **QC Test** on the main MENU. The QC TEST OPTIONS menu displays.
5. Press **EQC** on the QC TEST OPTIONS menu to initiate the EQC test.
6. The *Analyzing* screen appears, indicating that the diagnostic tests are in progress.



Review Results

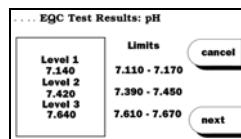
7. Once the EQC test is complete, the analyzer displays the *EQC Results* status screen. The initial result for an EQC test is either “Passed” or “Failed”.



a. Passed EQC Test:

Manual

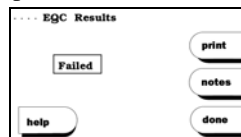
- a1. Press **view** to view quantitative results (optional). Press **next** from each screen to proceed through results for all analytes.



- a2. Press **notes** to select QC notes to attach to the QC record (optional).
- a3. Press **print** to obtain a printout. (Results may automatically print, depending on auto-print setup).
- a4. Press **done** to return to the QC TEST OPTIONS menu.

Automatic

- a5. Results will print (if the printer is configured to print) and the analyzer will display the main menu or user ID screen (if required).
- a6. If printer is not configured to print, there will be no print out. The main MENU will be displayed.



b. Failed EQC Test:

Manual

- b1. Press **help** for assistance in resolving the problem that caused the failure (optional).
- b2. Press **notes** to select QC notes to attach to the record (optional).
- b3. Press **print** to obtain a printout. (Results may automatically print, depending on auto-print setup).
- b4. Press **done** to return to the QC TEST OPTIONS menu.

Automatic

- b5. If printer is configured to print, "EQC failed" will print and the "EQC Results failed" screen will display.
- b6. Press **done** to return to the main MENU or the User ID entry screen (if required). Another auto-EQC test will initiate following the next inactivity period, or a manual EQC test can be performed.

Note:

- When EQC Lockout is on, an EQC test failure at any time (i.e., even if EQC passed earlier on a shift) will lockout patient testing. Following an EQC test failure, a passed EQC test is required to resume patient testing.

AUTOMATIC EQC TEST

Refer to Section 7- *QC Lockout* for configuration instructions.

LIQUID QUALITY CONTROL

This section of the manual describes the liquid quality control test procedure following set up of the control parameters (control type, lot number, level, and limits) by the QA User. If controls have not been established, the *Unable to run QC Test, No Controls Defined* message will appear when an liquid QC test is attempted.

Before the test is started, review the control sample preparation recommendations described in steps 15-17 on page 3.10.

LIQUID QC MATERIAL REQUIREMENTS

- The IRMA TruPoint system requires liquid controls to verify cartridge shipping and equilibration conditions. Control, linearity, and proficiency testing material recommendations and ranges are available on the ITC website (www.itcmed.com) or from your service provider or ITC Technical Services.
- IRMA TruPoint BG, CC and LA cartridges require liquid blood gas control, linearity, and proficiency testing material. Do not use perfluorocarbon- based materials.
- The IRMA TruPoint cartridges require controls that contain physiologic concentrations of electrolytes (i.e., controls that have assayed values for electrolytes on the control package insert), even if electrolyte results will not be reported.
- The IRMA TruPoint system requires hematocrit controls that are intended for use with conductive hematocrit methodologies.

PERFORMING A LIQUID CONTROL TEST

Turn IRMA TruPoint Analyzer On

1. Touch the right-hand edge of the screen to turn the analyzer “on”.
Do NOT insert a cartridge to power-on the analyzer.

Note:

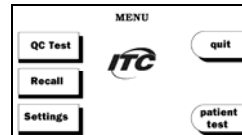
- All QC tests must be initiated via the main MENU, QC Test option. If a cartridge is inserted to power-on the analyzer, or inserted at the main MENU screen, the analyzer will automatically initiate a patient test, not a QC test.

Enter User ID (optional)

2. If the User ID option has not been activated, go to step 4.
3. If the User ID option is activated, the *Enter or Scan ID* screen will display. The User ID may be entered using either the alpha/numeric keypads or the bar code scanner.
 - a. Entry via touchscreen keypads - enter your User ID and press **next**.
 - b. Entry via bar code scanner - scan your User ID. The screen will automatically advance.

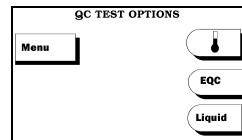
Initiate Liquid QC Test

4. Press **QC Test** on the main MENU. The QC TEST OPTIONS menu is displayed.



5. Press **Liquid** on the QC TEST OPTIONS menu.

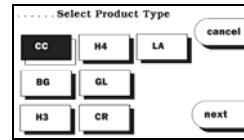
- a. If no bar code reader is connected - the Select Product Type screen will display. Go to step 6.



- b. If the bar code reader is connected - the Scan cartridge bar code screen will display. Scan the cartridge package label for the cartridge to be used. The cartridge product type, Lot Code, and Cal Code are encoded in the single bar code on the cartridge label. The IRMA TruPoint will automatically advance to the *Insert Cartridge* screen (the *Select Product Type* screen will not be displayed). Go to step 7.

Select Product Type

6. Highlight the desired product type and press **next**. The *Insert Cartridge* screen displays.



Note:

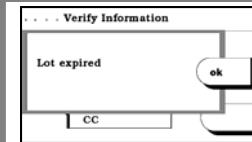
- If only one product type was established in TEST SETTINGS/Product Setup, the *Select Product Type* screen will not display. The analyzer will assume that the product is the same type as was established in TEST SETTINGS/Product Setup. See Section 7-Product Setup.

Open Cartridge Package

7. Check the expiration date on the cartridge package. The analyzer will not allow testing with expired cartridges.
8. Remove the cartridge from the package and retain the package until cartridge information is verified.

Note:

- If an expired cartridge is inserted into IRMA TruPoint, the *Lot expired* message will display, and the test cannot proceed. Remove expired cartridge, and initiate a new test with an in-date cartridge. If the wrong lot was selected on the *Verify Information* screen, press **ok** to return to the *Verify Information* screen and press **edit** to enter or select the correct cartridge lot.



Remove Tape and Insert Cartridge into Analyzer

9. Remove the protective tape (if applicable) from the cartridge leads. Do not touch the cartridge leads after the tape has been removed. Do NOT remove the luer cap from the cartridge. (Figure 3-1).
10. Fully insert the cartridge into the analyzer within 15 minutes of opening the package. (Figure 3-2)

Figure 3-1

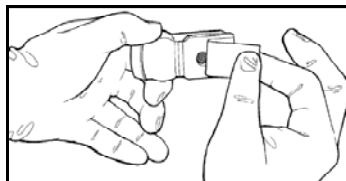
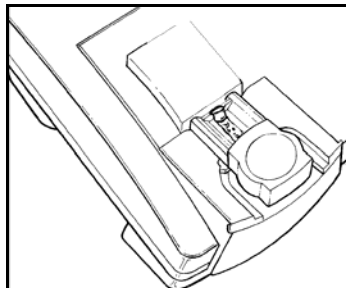


Figure 3-2



Note:

- Do not use a cartridge if it has been out of the package longer than 15 minutes.
- Do not reuse a cartridge once it has been inserted into the analyzer.

Verify/Enter Cartridge Information

11. a. If the cartridge package bar code was scanned, go to step 13.

- b. If manual entry, ensure that the product type (Type) displayed on the *Verify Information* screen is correct. If the product type displayed does not match the type of the cartridge inserted into the analyzer, press **back** to return to the *Select Product Type* screen.

12. The *Verify Information* screen displays the cartridge lot number (Lot) and Cal Code from the most recent test performed on the same product type.

- a. If the lot number displayed matches the lot number of the cartridge inserted into the analyzer, press **next**. Proceed to step 13.
- b. If the lot number displayed does not match the lot number of the cartridge inserted into the analyzer, press **edit** to choose a different previously-entered lot, or enter a new lot for the first time.

- b1. To choose a previously-entered lot, highlight the correct cartridge lot from the picklist. Press **next** to return to the *Verify Information* screen. If the information is correct, press **next** to continue QC test. If the information is incorrect, press **edit** to re-enter the lot number and Cal Code.

- b2. To enter a new cartridge lot for the first time, highlight **new** from the picklist and press **edit**.

- › Enter the cartridge lot number from the keypad. Press **next**.

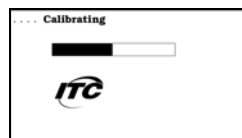
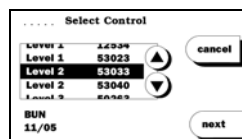
- › Enter the Cal Code from the keypad. Press **next** to return to the *Verify Information* screen. If the information is correct, press **next** to continue liquid QC test. If the information is incorrect, press **edit** to re-enter the lot number and Cal Code.

Dispense Calibrant (Cartridges with Cal Cap Only)

- For cartridges that have a Cal Cap (H4, GL, CR, LA) the *Dispense Calibrant* screen displays (with countdown timer at bottom). Follow the on-screen instructions for dispensing the calibrant over the sensors. Depress the Cal Cap firmly and quickly to dispense the calibrant, and press **next**. The calibrant must be dispensed within **1** minute or the test is terminated and an Error message appears.

Select Control Type, Lot, and Level to be Tested

- Scroll through the list of established controls using the arrow keys until the desired control for the test is highlighted. Press **next** to select the highlighted control. The *Calibrating* screen appears, indicating that calibration is in progress.



Note:

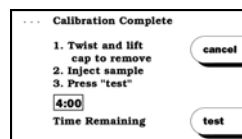
- IRMA TruPoint generates an error if the calibration code is not verified or the control is not selected within approximately 2 minutes of cartridge insertion.

Prepare Control Sample

- Shake the control sample to equilibrate the gas and liquid contents according to the manufacturer's recommendations. To ensure sample integrity, avoid warming the ampule in the palms of your hands, and do not open the ampule until calibration is complete.

Remove Luer/Cal Cap, Inject Control Sample, and press "test"

- The *Calibration Complete* screen displays when calibration is complete. Twist and lift the luer or Cal cap to remove it from the injection port. The sample must be injected within **4** minutes of completing calibration. A timer displayed at the bottom of the screen counts down from 4 minutes. If more than 4 minutes elapse, the test is terminated and an Error message appears.



Note:

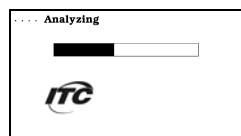
- If an Error screen appears during calibration, refer to **Section 5-Troubleshooting** for assistance.

17. After cartridge calibration is complete, open the ampule. Immediately draw the sample into a 1-3 mL non-heparinized syringe through an 18-20 gauge needle. Place the needle opening below the liquid surface when drawing the sample to minimize air contamination. Draw approximately 1 mL into a 1 mL syringe, or all but the last bit of ampule contents into a 2 mL or 3 mL syringe. When done, remove the needle from the syringe. Do not attempt to invert the syringe or to expel gas bubbles from the syringe.
18. Remove the luer/Cal cap from the injection port and firmly attach the syringe to the cartridge. Immediately inject the sample using the technique described in Section 2-Injecting a Syringe Sample. Inject all but the last bit of syringe contents into the cartridge, taking care not to inject an air bubble into the cartridge.

Note:

- If air bubbles or calibration gel are present in the sample path after the initial sample injection, remove them by injecting additional sample from the same syringe, or by lightly tapping the top of the syringe plunger and then injecting additional sample from the same syringe.
- If air bubbles or calibration gel cannot be removed from the sample path, press cancel to stop the test, discard the cartridge, and begin again with a new cartridge. Proper injection technique will prevent air bubbles or calibration gel from being present in the sample path after initial sample injection.

19. Ensure that no air bubbles or calibration gel are present in the sample path, then immediately press **test** to continue sample analysis. The *Analyzing* screen displays.



20. When the test is complete, remove the cartridge with the collection device attached. Dispose of both in accordance with established guidelines for your facility.

View Test Results

21. Verify that the quality control test results fall within accepted limits. If control limits have been established, results falling outside the limits will flash. An “H” (High) or “L” (Low) will appear on the printout next to values falling outside the limits. Press limits to view control limits (if established). If results are not within the limits, take corrective action in accordance with established guidelines for your facility.

The image shows a screen titled "QC Test Results" with the following data:

QC Test Results		CC, L1 Lot 12485	
pH	7.421		
pCO2	40.7	mmHg	
pO2	100.1	mmHg	
Hct	4.4	%	
Na+	140.3	mM	
K+	14.21	mM	
iCa	11.14	mM	

Buttons for "print", "limits", "notes", and "done" are visible at the bottom of the screen.

22. If a sensor errors during the analysis phase of a liquid QC test, the result for that sensor and any other sensors that are dependent on that sensor will be suppressed. Suppressed results will be dashed-out on both the screen and printout, and will not satisfy QC lockout requirements for the associated analyte group (with or without QC limits established).

Document QC Notes (optional)

23. The **QC Notes** feature allows pre-defined notes to be permanently associated with individual QC test records. Up to 3 notes can be attached to an individual QC test record. If the QA User enabled QC Notes, a notes button will be present on the *Results* screen. Press the **notes** button to access the pre-defined notes available for selection. Use the up and down arrows to highlight the desired note and press the check box button. Repeat for additional notes, and press **next** when complete.

Obtain a Printout (optional)

24.
 - a. If the Auto-print setting is “immediate”, test results will automatically print when the analysis is complete.
 - b. If the Auto-print setting is “delayed”, test results will automatically print when the **done** button is pressed from the *QC Test Results* screen.
 - c. If the Auto-print setting is “off”, a printout may be obtained by pressing the **print** button.

TEMPERATURE TEST

PERFORMING A TEMPERATURE TEST

Turn IRMA TruPoint Analyzer On

1. Touch the right-hand edge of the screen to turn the analyzer “on”.
Do NOT insert a cartridge to power-on the analyzer.

Note:

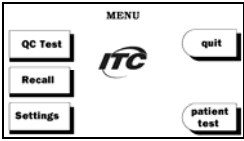
- All QC tests must be initiated via the main MENU, *QC Test* option. If a cartridge is inserted to power-on the analyzer, or inserted at the main MENU screen, the analyzer will automatically initiate a patient test, not a QC test.

Enter User ID (optional)

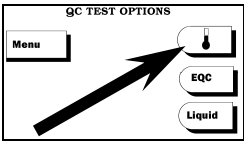
2. If the User ID option has not been activated, go to step 4.
3. If the User ID option is activated, the *Enter or Scan ID* screen will display. The User ID may be entered using either the alpha/numeric keypads or the bar code scanner.
 - a. Entry via touchscreen keypads - enter your User ID and press **next**.
 - b. Entry via bar code scanner - scan your User ID. The IRMA TruPoint will automatically advance to the next screen.

Initiate Temperature test

4. Press **QC Test** on the main MENU. The QC TEST OPTIONS menu is displayed.

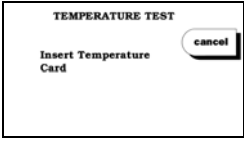


5. Press the **Thermometer** on the QC TEST OPTIONS menu to initiate a temperature test.



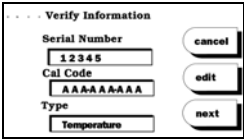
Insert Temperature Card

6. Fully insert the Temperature Card into the analyzer.



Verify Card Information

7. Verify that the Temperature Card Serial Number and Cal Code match the information displayed on the *Verify Information* screen.



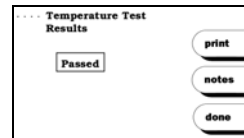
- a. If the information displayed **matches** the information on the Temperature Card, press **next**. Proceed to step 8.
 - b. If the information displayed **does not match** the information on the Temperature Card, press **edit** to enter or select the correct serial number and Cal Code. Verify the information and press **next**.
8. The *Analyzing* screen appears, indicating that the temperature test is in progress.

Review Results

9. Once the temperature test is complete, the analyzer displays the *Temperature Test Results status* screen. The result for a temperature test is either “Passed” or “Failed”.

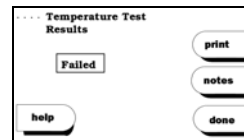
a. Passed Temperature Test:

- a1. Press **notes** to select QC notes to attach to the record (optional).
- a2. Press **print** to obtain a printout. (Results may automatically print, depending on the auto-print setup).
- a3. Press **done** to return to the QC TEST OPTIONS screen.



b. Failed Temperature Test:

- b1. Press **help** for assistance in resolving the problem that caused the failure (optional).
- b2. Press **notes** to select QC notes to attach to the record (optional).
- b3. Press **print** to obtain a printout. (Results may automatically print, depending on the auto-print setup).
- b4. Press **done** to return to the QC TEST OPTIONS screen.



REFERENCES

1. Elin RJ: Elements of cost management for quality assurance. College of American Pathologists, pp 182-183, April 1980.

Section 4

Data Access

OVERVIEW

This section describes the IRMA TruPoint data storage capabilities, the procedures for patient and QC test result recall, and result transfer to *idms* or other connected system.

DATA STORAGE

Results can be recalled, printed, and/or transferred to other systems. The analyzer stores the following number of test records even when powered-off or when the battery is removed:

- **200** patient test records
- **150** liquid QC records
- **100** EQC/Temperature Test results
- Error codes for the last **10** failed EQC/Temperature Tests

Access the RECALL menu by pressing the **Recall** button on the main MENU. The following options are presented:

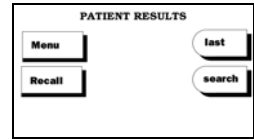
- Patient:** Search for patient test records by *patient ID* and/or *date range*, or recall results for the *last* test performed. Results and associated test information can be viewed and/or printed. Test information can be modified when recalled by the last result performed option if the record has not been sent to *idms*, VueLink, or an LIS/HIS.
- QC:** Search for QC test records by *QC type*, *product type*, *control lot/level*, and/or *date range*, or recall results for the *last* QC test performed. QC Notes can be modified when recalled by the *last* result performed option.
- Send:** When the results transfer option is “on”, new or previously transferred results can be sent via the *RS232 port*, *LAN 10/100*, or *modem* to another system capable of accepting the ASTM output (i.e., *idms* or other information systems capable of accepting ASTM formatted data).
- Status:** View the *battery information* and *About IRMA TruPoint* screens. This information may be requested by your service provider to help resolve operating problems.

Logs: The *error*, *usage*, and *transfer* logs can be printed. This information may be requested by your service provider to help resolve operating problems.

RECALLING RESULTS

PATIENT RESULTS

From the RECALL menu, press **Patient** to access the PATIENT RESULTS menu. This menu displays the following options:



Menu: Returns to main MENU.

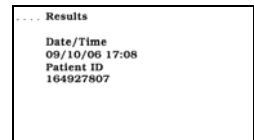
Recall: Returns to RECALL menu.


last: Displays results for the last patient test performed.

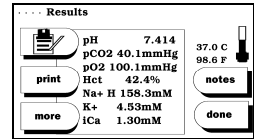
search: Allows search of results by date and/or patient ID.

Recalling “Last” Patient Test Results

1. Press **last** from the PATIENT RESULTS menu. Results display for the last patient test performed, regardless of product type. The options available are:



 Presents the Test Information/O₂ Therapy/Bypass Status screens that were enabled at the time of the patient test. This information may be added or edited on *last* result recall if the record has not been sent to *idms*, HIS/LIS, or another connected system.



print: Prints a hard copy of the patient test results displayed.

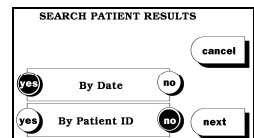
more: Displays additional results and/or associated calculated values from the same test that do not appear on the current screen.

notes: Displays up to 3 patient notes that were added following the test. Notes may be added or edited on last result recall.

done: Returns to the PATIENT RESULTS menu.

Recalling Patient Test results by “Search”

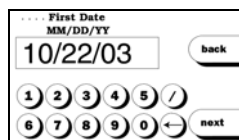
1. Press **search** from the PATIENT RESULTS menu. The *Search Patient Results* screen presents the By Date and By Patient ID search options. Select desired search criteria and press **next**.



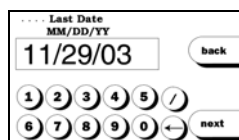
2. Screens that appear are based on search criteria selection:

a. Search by Date:

a1. The First Date from the previous search or the current date automatically displays. Accept displayed date or enter a new First Date (oldest date) for the search in the date format displayed at the top of the screen. Press **next**.

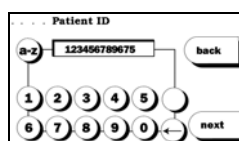


a2. The Last Date from the previous search or the current date automatically displays. Accept displayed date or enter a new Last Date (newest date) for the search in the date format displayed at the top of the screen. Press **next**.



b. Search by Patient ID:

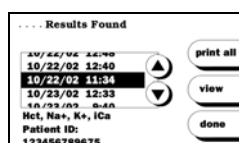
Enter a Patient ID and press **next**. Only results associated with that patient ID will display.



c. Search by Date and Patient ID:

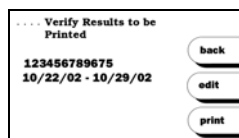
Enter both a date range and a Patient ID and press **next**. Only results associated with that date range and patient ID will display.

3. If there are results in memory for the search criteria entered, the *Results Found* screen displays a picklist with test dates and times. Use the up and down arrows to scroll through the list of results until the desired result is highlighted. The analytes reported for that record and patient ID (if applicable) are shown below the picklist for the highlighted result.

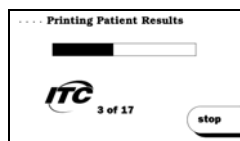


The options available from the *Results Found* screen are:

a. **print all:** Proceeds to the *Verify Results to be Printed* screen. The search criteria previously entered displays with the following options:



- a1. **print**: Presents the *Printing Patient Results* screen that displays the total number of patient results found and the number of the result currently printing. Printing can be stopped by pressing the **stop** button, and restarted by pressing **resume**. Upon completion of printing, the screen returns to the *Results Found* screen.

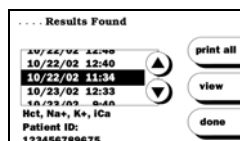


Note:

- The number of patient test results that can be printed at one time depends on the IRMA TruPoint power source at printing time:
 - › **AC Adapter** - an unlimited number of results can be printed.
 - › **Battery** - up to fifty test results can be printed. If there are >fifty results in the selection set, a message prints indicating that the maximum number of records that can be printed at once has been exceeded. Select **edit** to redefine the search dates or **cancel** to return to the PATIENT RESULTS menu.

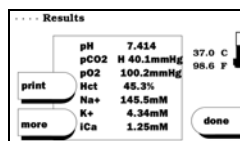
- a2. **edit**: Returns to the *Search Patient Results* screen.

- b. **view**: Results can be viewed from the *Results Found* screen by highlighting the desired result and pressing **view**.



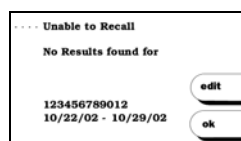
- b1. **print**: Prints a hard copy of the patient test results displayed.

- b2. **more**: Displays additional results and/or associated calculated values from same test that do not appear on current screen.



- b3. **done**: Returns to *Results Found* picklist.

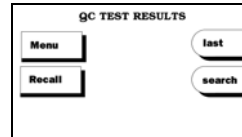
4. If no results for the criteria entered are found, the *Unable to Recall - No Results found for the dates entered or No Results found for the Patient ID entered* screen displays. Press **edit** to return to the *Search Patient Results* screen or **ok** to return to the PATIENT RESULTS menu.



QUALITY CONTROL RESULTS

From the RECALL menu, press **QC** to access the QC TEST RESULTS menu. This menu displays the following options:

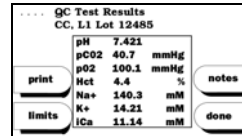
- Menu:** Returns to main MENU.
- Recall:** Returns to RECALL menu.
- last:** Displays results for the last QC test performed.
- search:** Allows search of results by *QC type*.



Recalling “Last” QC Test Results

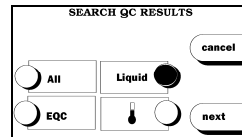
1. Press **last** from the QC TEST RESULTS menu. Results display for the last QC test performed, regardless of QC type. The options available from the last results display are:

- print:** Prints a hard copy of the QC test results displayed.
- limits:** Displays QC limits, if they have been established by the QA User.
- notes:** Displays up to 3 QC notes that were added following the QC test. Notes may be added or edited on last result recall.
- done:** Returns to the QC TEST RESULTS menu.



Recalling QC Test Results by “Search”

1. Press **search** from the QC TEST RESULTS menu. The *Search QC Results* screen presents the search options *All*, *EQC*, *Liquid*, and *Temperature* (icon). Select desired search criteria and press **next**.

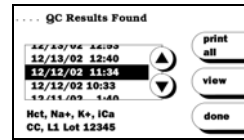


2. Screens that appear are based on search criteria selection:

a. Search “All”, “EQC”, or “Temperature”:

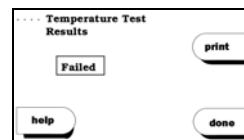
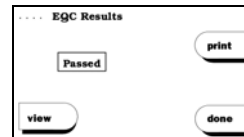
- a1. The First Date from the previous search or the current date automatically displays. Accept displayed date or enter a new First Date (oldest date) for the search in the date format displayed at the top of the screen. Press **next**.
- a2. The Last Date from the previous search or the current date automatically displays. Accept displayed date or enter a new Last Date (newest date) for the search in the date format displayed at the top of the screen. Press **next**.

- a3. The *QC Results Found* screen displays a picklist of all the QC tests that meet the search criteria, and the test dates and times. Scroll through the list of results until the desired result is highlighted. The product type, QC lot and level, and analytes are shown below the picklist for the highlighted result (if applicable). Press **print all** to print a detailed hard copy for all results found in the picklist. Press **view** to see the results for the highlighted result only. The options from the results screens vary with QC type:



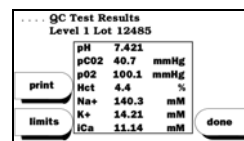
EQC or Temperature Test Result:

- › **print:** Prints a hard copy of the result selected.
- › **view:** Present only on Passed EQC. Displays quantitative results and limits. Press **next** from each results screen to view results for the next analyte.
- › **done:** Returns to the *QC Results Found* screen.
- › **help:** Present only on Failed EQC or Temperature test. Provides assistance in resolving the problem that caused the failure.



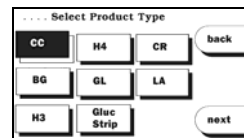
Liquid QC Test Result:

- › **print:** Prints a hard copy of the result selected.
- › **view:** Displays QC limits, if they have been established by the QA User.
- › **done:** Returns to the *QC Results Found* screen.

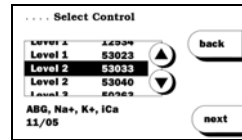


b. Search “Liquid” QC:

- b1. Highlight the desired Product Type on the *Select Product Type* screen and press **next**.

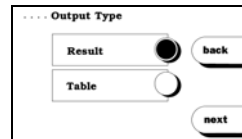


b2. The *Select Control* screen displays a picklist with the control lots and levels available for the selected Product Type. The analytes available and control expiration date are shown below the picklist for the highlighted control. Highlight the desired control and press **next**.



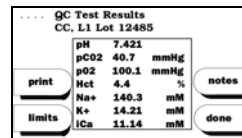
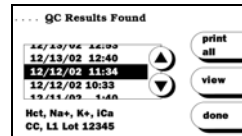
b3. Enter first and last search dates.

b4. The *Output Type* screen allows selection of **Result** (detailed report) or **Table** (summary report).



“Result” Output Selected:

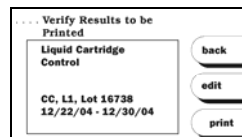
The *QC Results Found* screen displays a picklist with test dates and times. Scroll through the list of results until the desired result is highlighted. The product type and QC lot, level, and analytes are shown below the picklist for the highlighted result. Press **print all** to print a detailed hard copy for all results found in the picklist. Press **view** to see the results for the highlighted result only. The options from the *QC Results* screen are:



- › **print:** Prints a hard copy of the QC test results selected.
- › **limits:** Displays QC limits, if they have been established by the QA User.
- › **done:** Returns to QC RESULTS FOUND menu.

“Table” Output Selected:

The *Verify Results to be Printed* screen displays. The options from this screen are:



- › **print:** Sorts results and prints a table for all the results that meet the search criteria displayed. Printing can be stopped by pressing the **stop** button, and restarted by pressing **resume**. Upon successful completion of printing, the system returns to the SEARCH QC RESULTS menu.
- › **edit:** Returns to SEARCH QC RESULTS menu.

- › **back**: Returns to the *Output Type* screen.
3. If no results for the criteria entered are found, the *Unable to Recall - No Results found* for the search criteria entered screen displays. Press **edit** to return to the *Search QC Results* screen or **ok** to return to the QC RESULTS menu.

Note:

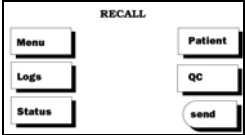
- Refer to Section 3-Quality Control of the SureStep®Pro Glucose Module User Manual for glucose QC test recall instructions.

RESULTS TRANSFER

The **Results Transfer** feature allows IRMA TruPoint patient and QC test results and associated test information to be transferred to *idms* or other connected system via the IRMA TruPoint serial port, LAN 10/100, internal modem (if present) or external modem. If the QA User has enabled Results Transfer, any IRMA TruPoint user can transfer results. IRMA TruPoint analyzers can also be configured to automatically transfer test results under certain conditions. See *Section 7-Communications* for Results Transfer and Automatic Results Transfer Setup instructions.

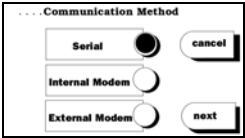
MANUAL TRANSFER OF IRMA TRUPOINT RESULTS

1. Press **send** from either the main MENU or RECALL menu. If a **send** button is not present, the QA User has not turned Results Transfer “on”.

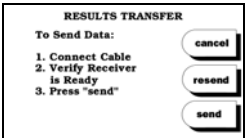


2. If the QA User selected either the *Serial*, *LAN 10/100*, *Internal Modem*, or *External Modem* transfer method option during Results Transfer setup, go to step 4.

3. If the QA User selected the *User Selects* transfer method option during Results Transfer setup, the *Communication Method* screen displays. Highlight the button next to the transfer method of choice and press **next**.



4. The RESULTS TRANSFER screen displays transfer instructions. Connect the appropriate cable (and adapter if required) to the IRMA TruPoint analyzer and the receiving system.



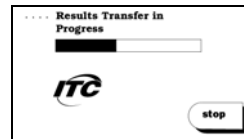
- a. **Serial Port transfer:** Connect one end of the RJ45 cable to the serial port on the back of the IRMA TruPoint (labeled “Computer”). Connect the other end to a receiving system serial port. Note: *idms* setup includes specifying which receiving system serial port will be used for data transfer. Ensure that the cable is connected to the correct serial port.
- b. **Internal Modem transfer:** Connect one end of the RJ11 cable to the modem port on the back of the IRMA TruPoint (labeled “Modem”). Connect the other end to an analog phone line.

- c. **IRMA TruPoint LAN 10/100 transfer:** Connect one end of a CAT5e patch cable to the LAN port on the back of the IRMA TruPoint (labeled “LAN 10/100”). Connect the other end to a network port.
- d. **External Modem transfer:** Connect one end of the RJ45 cable to the serial port on the back of the IRMA TruPoint (labeled “Computer”). Connect the other end to the external modem. Some modems will require a RJ45 to DB25 connector and others will require a RJ45 to DB9 connector.

Note:

- External serial servers connect to the IRMA TruPoint.

5. Verify that the receiving system is ready to receive IRMA TruPoint data, and press one of the following buttons:
 - a. **send:** Sends all stored results that have not been previously transferred.
 - b. **resend:** Sends all results in memory that were previously sent, along with a flag indicating their previous-transfer status.
 - c. **cancel:** Returns to the recall OPTIONS menu or main MENU.
6. Data transfer can be stopped while in progress by pressing **stop**; the screen will return to the RECALL OPTIONS menu or main menu.

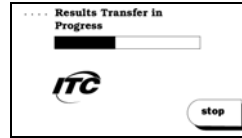


AUTOMATIC RESULTS TRANSFER

IRMA TruPoint analyzers may be configured to automatically transfer test results to *idms* or another connected system. IRMA TruPoint results will automatically be transferred to *idms* or other connected system when **ALL** of the following conditions are met:

1. The IRMA TruPoint Communications Method is configured to one of the following: serial, internal modem, LAN 10/100, or external modem. Automatic Results Transfer will not work when the Communications Method is configured to User Selects.

2. The *Automatic Results Transfer* option is configured “on”.
3. The IRMA TruPoint analyzer is operated with the AC adapter. Automatic Results Transfer will not initiate when the analyzer is powered by battery.
4. The IRMA TruPoint analyzer is connected to the receiving system via the appropriate cable.



After a four to six minute period of inactivity on the analyzer, the IRMA TruPoint will make a single attempt to transmit results. If all of the above criteria have been met, the IRMA TruPoint will begin to transfer results and the *Results Transfer in Progress* screen will display. Data transfer can be stopped while in progress by pressing **stop**; the screen will return to the main MENU or Enter ID screen.

Note:

- See the *idms* User Manual for *idms* setup instructions and cable and adapter information.
- See the DeviceCom User Manual for DeviceCom setup instructions.
- See the External Modem User Manual for setup instructions.

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Section 5

Troubleshooting

OVERVIEW

The IRMA TruPoint Blood Analysis System troubleshooting information is organized to address both general and specific operating problems.

General problems are those that cannot be detected by the analyzer's software (e.g., the analyzer does not turn "on" or the printer does not operate).

Specific problems are those identified by the software (e.g., low battery or faulty cartridge). A screen message signals the presence of a specific operational problem or condition, and guides the user through the resolution process.

TROUBLESHOOTING GENERAL OPERATIONAL PROBLEMS

Corrective actions are listed to help resolve each problem noted in this section. If necessary, call your service provider for service assistance.

PROBLEM

CORRECTIVE ACTION(S)

<u>PROBLEM</u>	<u>CORRECTIVE ACTION(S)</u>
ANALYZER DOES NOT POWER-ON	
<ul style="list-style-type: none"> • Analyzer does not turn “on” when right-hand edge of screen is pressed • Analyzer does not turn “on” when cartridge is inserted 	<ol style="list-style-type: none"> 1. Verify that the battery is installed, or that AC adapter is plugged into a working outlet. 2. Try again, pressing more firmly or longer on the screen. 3. Try a fully charged battery, or AC adapter. Verify that the battery is fully inserted into the analyzer. 4. Call your service provider. <ol style="list-style-type: none"> 1. Verify that a charged battery is installed, or that AC adapter is plugged into a working outlet. 2. Remove and re-insert the cartridge. Verify that the cartridge is fully inserted into the analyzer. 3. Try inserting a new cartridge. 4. Install new edge connector (if available). 5. Call your service provider.
BATTERY PROBLEMS	
<ul style="list-style-type: none"> • Battery does not charge • Fully charged battery is yielding fewer than expected tests, or the battery icon on the IRMA TruPoint screen does not display. 	<ol style="list-style-type: none"> 1. Verify that the battery charger is plugged into the power supply prior to battery insertion. 2. Verify that the battery is fully inserted (yellow indicator light comes on upon insertion of the battery into the charger). 3. Inspect battery and battery charger contacts for damage. 4. Clean the contacts on the battery, battery charger, and analyzer battery compartment. See Section 6-Maintenance for details. 5. Verify that a NiMH battery is being charged in a NiMH charger, not a NiCad charger. See Section 6-Maintenance for details. 6. Call your service provider. <ol style="list-style-type: none"> 1. Condition the battery. See Section 6-Maintenance for details.

PROBLEM

CORRECTIVE ACTION(S)

<u>PROBLEM</u>	<u>CORRECTIVE ACTION(S)</u>
PRINTER PROBLEMS	
<ul style="list-style-type: none">• Poor print quality	<ol style="list-style-type: none">1. Only use paper supplied by your service provider.2. Try a new roll of paper. Verify that paper rolls and printouts are not exposed to sunlight or fluorescent light for an extended time period.
<ul style="list-style-type: none">• Printer paper advances, but nothing is printed (printer sounds are audible)	<ol style="list-style-type: none">1. Only use paper supplied by your service provider.2. Verify that the paper roll unwinds in the proper direction, since printing is possible only on one side of the paper. See Section 6-Maintenance.
<ul style="list-style-type: none">• Paper does not advance during printing	<ol style="list-style-type: none">1. Remove the printer door. Check printer for a paper jam. See Section 6-Maintenance.
<ul style="list-style-type: none">• Printer does not operate	<ol style="list-style-type: none">1. Verify that the printer option is activated in instrument set-up. See Section 7-System Settings.2. Call your service provider.
INCONSISTENT TEST RESULTS	
<ul style="list-style-type: none">• General	<ol style="list-style-type: none">1. Verify that the cartridge has not been out of the package more than 15 minutes.2. Verify that the cartridges have equilibrated to room temperature for the recommended time following removal from shipping cartons. See Appendix B, Table B-7 for equilibration requirements.3. Run an EQC test to verify that the analyzer is operating properly.4. Verify that the barometric pressure reading is correct.
<ul style="list-style-type: none">• Patient Test Results	<ol style="list-style-type: none">1. Review the above corrective actions (general).2. Draw another sample and repeat patient test with a new cartridge. Rule out preanalytical errors. See Section 2-Sample Requirements.3. Verify that injection technique is correct. See Section 2-Sample Injection.4. Call your service provider.
<ul style="list-style-type: none">• Liquid QC Test Results	<ol style="list-style-type: none">1. Review the above corrective actions (general).2. Verify that the room temperature has not shifted (some analytes are temperature sensitive in liquid solutions).3. Verify that injection technique is correct. See Section 2-Sample Injection.4. Review QC sample handling recommendations (see Section 3-Liquid Quality Control) and repeat the test with a new control ampule.5. Call your service provider.

<u>PROBLEM</u>	<u>CORRECTIVE ACTION(S)</u>
EQC FAILURES	<ol style="list-style-type: none"> 1. Clean edge connector and IR probe. See Section 6-Maintenance. 2. Repeat EQC test. 3. Call your service provider.
TEMPERATURE TEST FAILURES	<ol style="list-style-type: none"> 1. Clean IR probe. See Section 6-Maintenance. 2. Verify that the correct Temperature Card cal code is used. 3. Verify that analyzer and Temperature Card have equilibrated to room temperature. If a temperature test fails, wait at least 1 minute before re-testing with the same Temperature Card. 4. Repeat temperature test using same Temperature Card; if temperature test fails again, use a different Temperature Card (if available). 5. Clean the Temperature Card. See Section 6-Maintenance. 6. Call your service provider.

TROUBLESHOOTING SPECIFIC OPERATING PROBLEMS

A screen message signals the presence of a specific operating, data entry, or screen selection problem or condition, explains its probable cause, and guides the user through the resolution process. If necessary, call your service provider for assistance.

<u>SCREEN MESSAGE</u>	<u>REASON FOR MESSAGE</u>	<u>CORRECTIVE ACTION</u>
SENSOR ERRORS “Sensor error- Use new cartridge” or SUPPRESSED RESULT Analyte value displays “_.._”	Displays upon receipt of a sensor error during testing.	<ol style="list-style-type: none"> 1. Remove and dispose of the cartridge; retest with a new cartridge. 2. Verify that cartridges are properly equilibrated. 3. Verify that test procedures are being followed. 4. If a high rate of sensor errors persists, clean the IR probe and edge connector (see Section 6-Maintenance). 5. If a high rate of sensor errors persists, run an EQC test and call your service provider for assistance.

<u>SCREEN MESSAGE</u>	<u>REASON FOR MESSAGE</u>	<u>CORRECTIVE ACTION</u>
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PROCEDURAL ERRORS		
“Cartridge removed prematurely”	Cartridge was removed during a test or was not completely inserted.	Dispose of the cartridge and retest with a new cartridge. Fully insert the cartridge, and do not remove cartridge during test.
“Time for data entry expired”	Data was not completely entered within the allotted time period following cartridge insertion.	Remove and dispose of the cartridge. Retest with a new cartridge, making required entries within allotted time period.
“Sample injection time expired”	Sample was not injected and/or test button was not pressed within 4 minutes of <i>Calibration Complete</i> message display.	Remove and dispose of the cartridge. Retest with a new cartridge. Inject sample and press test within required time period.
“Temperature Card removed prematurely”	Temperature Card was removed while a temperature test was in progress.	Press ok to return to the QC Test Options menu. Repeat temperature test without removing the Temperature Card during the test.

ENTRY ERRORS		
“Lot, Product Type mismatch”	Cartridge Lot was entered that cannot exist for specified product type.	Enter correct cartridge Lot and product type.
“Lot, Cal Code mismatch”	Cartridge Lot was entered that cannot exist for the Cal Code entered.	Enter correct cartridge Lot and Cal Code.
“Invalid Length- Enter X - XX characters”	The length of an entry was invalid (too many or too few characters). Some features, such as Patient ID, can be configured to require entry of a specific number of characters.	Note the entry length requirements displayed on the screen. Press ok and enter a valid number of characters.
“Invalid Format-Enter value in format X.XXX - X.XXX”	The format of an entry was invalid.	Note the entry format requirements displayed on the screen. Press ok and enter the value in a valid format.
“Value out of range- Enter a value from X.XXX - X.XXX”	The value entered was outside of the entry range.	Note the entry range requirements displayed on the screen. Press ok and enter a value within the entry range.

<u>SCREEN MESSAGE</u>	<u>REASON FOR MESSAGE</u>	<u>CORRECTIVE ACTION</u>
TEMPERATURE ERRORS		
“Cartridge out of temperature range”	Cartridge temperature was outside of the acceptable temperature operating range (12°-30°C / 54°-86°F).	Remove and dispose of the cartridge; re-test with a new cartridge within temperature operating range.
“Analyzer out of temperature range”	Analyzer temperature was outside of the acceptable temperature operating range (12°-30°C / 54°-86°F).	Press quit to power-off analyzer; allow analyzer to equilibrate at a temperature within the temperature operating range for at least 30 minutes before resuming testing.
ANALYZER PROBLEMS		
“Instrument Error - Error Code XXXX. Press quit and restart”	Self-test failed during power-on or the analyzer experienced a recoverable system failure.	Press quit to power-off analyzer; power analyzer back “on”.
“Instrument Error - Error Code XXXX. Press quit and call technical support”	Analyzer experienced an unrecoverable system failure.	Press quit to power-off analyzer. Call your service provider for assistance.
“Instrument Error - Record These Values. Call Technical Support”	Analyzer experienced an unrecoverable system failure.	Record values displayed, and press quit to power-off analyzer. Call your service provider for assistance.
“Attention! No functional printer”	Printer is not operational.	Press ok to acknowledge the message. Call your service provider for assistance.
“Loading Paper”	Displayed anytime that the printer door is removed.	Replace the printer door cover to return to previous screen.
ANALYZER POWER PROBLEMS		
“Low Battery”	Low battery condition was reached that will not allow continued analyzer operation.	Press quit to power-off analyzer; replace the battery with a freshly charged battery.
“WARNING! Remove damaged AC adapter”	AC adapter voltage was out of- range	Press quit to power-off analyzer. Call your service provider for assistance.

<u>SCREEN MESSAGE</u>	<u>REASON FOR MESSAGE</u>	<u>CORRECTIVE ACTION</u>
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ANALYZER MEMORY		
“Attention! Approaching result capacity”	<p>Patient, EQC, LQC, or Temperature Test was selected and the analyzer memory was within 20 records of being full. Message will display only if results transfer is “on”.</p> <p>If Auto-EQC is “on” the message will display when the analyzer exits sleep mode.</p>	<p>Press ok to continue test. Following completion of the test, transfer stored data if stored results should not be overwritten. See Section 4-Data Access. Once storage capacity is reached, analyzer will begin to overwrite stored results.</p> <p>A. Press cancel to abort test if stored results should not be overwritten. Transfer data before continuing.</p>
“WARNING! Reached result capacity”	<p>Patient, EQC, LQC, or Temperature Test was selected and the analyzer memory was full. Stored results will be overwritten. Message will display only if results transfer is “on”.</p> <p>If Auto-EQC is “on” the message will display when the analyzer exits sleep mode.</p>	<p>B. Press ok to continue the test (results that have not been transferred may be overwritten).</p>

<u>SCREEN MESSAGE</u>	<u>REASON FOR MESSAGE</u>	<u>CORRECTIVE ACTION</u>
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<u>SCREEN MESSAGE</u>	<u>REASON FOR MESSAGE</u>	<u>CORRECTIVE ACTION</u>
DATA TRANSFER		
“Unable to Transfer - No test results to upload”	<p>A. send was pressed when there are no unsent records in the analyzer memory.</p> <p>B. resend was pressed when there are no previously sent records in the analyzer memory.</p>	<p>Press the appropriate button, depending upon the transfer status of the results in the analyzer memory.</p>
“Unable to Transfer - Transfer unsuccessful”	Data transfer between the analyzer and receiving system was unsuccessful.	<ol style="list-style-type: none"> 1. Verify that receiving system is ready (e.g., DeviceCom is running). 2. Verify that cables and adapters are properly connected to both the IRMA TruPoint and receiving system. Use cables and adapters supplied by your service provider. 3. Verify that transfer cable is connected to correct com port (specified in DeviceCom setup). 4. If transferring serially, ensure that the IRMA TruPoint and receiving system baud rates match. If the analyzer is configured to transfer to “idms”, the receiving system must be set to a baud rate of 19200. If the analyzer is configured to transfer to “host”, the receiving system must be set to a baud rate of 9600. 5. If transferring by the LAN 10/100, make sure that the network settings are correct. See <i>Section 7-Communications</i>.

<u>SCREEN MESSAGE</u>	<u>REASON FOR MESSAGE</u>	<u>CORRECTIVE ACTION</u>
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MISCELLANEOUS		
“Unable to Add - Maximum number have been entered”	Displays when adding a control via <i>QC Settings</i> and the maximum number of controls (42), have already been defined.	Press ok to return to the picklist of existing controls to allow deletion of one or more controls.
“Lot expired”	Expired cartridge lot was entered via <i>Test Settings</i> , <i>QC Test</i> , or <i>Patient Test</i> .	Use an in-date cartridge lot.

DEVICESET UPDATE		
“Unable to Transfer - Low Battery”	Insufficient battery power to begin device update.	Press quit to power-off analyzer; replace the battery with a freshly charged battery.
“Communication Error- Verify connections and receiving system”	Data transfer between the analyzer and receiving system was unsuccessful.	<ol style="list-style-type: none"> 1. Verify that receiving system is ready (e.g., DeviceCom is running). 2. Verify that cables and adapters are properly connected to both the IRMA TruPoint and receiving system. Use cables and adapters supplied by your service provider. 3. Verify that transfer cable is connected to correct com port (specified in DeviceCom setup). 4. If transferring serially, ensure that the IRMA TruPoint and receiving system baud rates match. If the analyzer is configured to transfer to “idms”, the receiving system must be set to a baud rate of 19200. If the analyzer is configured to transfer to “host”, the receiving system must be set to a baud rate of 9600. 5. If transferring by the LAN 10/100, make sure that the network settings are correct. See <i>Section 7- Communications</i>.

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Section 6

Maintenance

OVERVIEW

This chapter describes the routine and preventative maintenance procedures that can be performed on the IRMA TruPoint system by the operator, including battery maintenance, printer paper replacement, barometer calibration, general cleaning, and edge connector cleaning and replacement. The IRMA TruPoint system does not require preventative maintenance by service personnel, and there are no user-serviceable parts in the analyzer or its accessories. Only authorized service personnel can service the analyzer. Contact your service provider for servicing.

BATTERY MAINTENANCE

The IRMA TruPoint system includes two rechargeable nickel metal hydride (NiMH) batteries; one can be used to power the analyzer while the other is charging. A battery takes approximately 5.5-10 hours to charge, depending on the existing charge.

GENERAL INSTRUCTIONS

For optimal battery performance, follow these recommendations:

- **Use a battery until the battery icon meter bar is nearly empty.**
When a battery is placed into a charger, the charger first fully discharges, then charges, the battery. The greater the charge remaining on a battery at the time of insertion into a charger, the longer the charge cycle. A fully charged battery takes 4 hours to discharge.
- **Leave a battery in the charger until the green LED flashes continuously.**
The green LED on the charger will blink continuously when the battery is at 100% capacity. A battery should remain in the charger until the green LED blinks continuously. See Section 6-Charging the Battery (Routine) for detailed battery charging information.
- **Leave a fully charged battery in the charger until it is needed for use.**
The charger will continue to top-off a fully charged battery, ensuring that it is at 100% capacity when needed for use in the analyzer.

- **Perform a conditioning charge monthly, or more frequently as the schedule allows.**

A conditioning charge will help ensure optimal battery performance. If a battery must be removed from the charger before it is completely charged, the battery should go through a conditioning charge to restore optimal performance.

Note:

- NiMH batteries (PN 448700) must be charged in a NiMH charger (PN 442900). They are not compatible with the old nickel cadmium (NiCad) charger (PN 423200).

Charge Times and Test Yields

- NiMH batteries take 5.5-10 hours to fully charge, and yield approximately 30-40 tests.

Battery Life

The rechargeable batteries should retain expected performance characteristics for 500 charge cycles.

Touchscreen Battery Icon

A battery icon displays in the upper-right corner of all screens except the *patient test* and *QC test* screens. A dark meter bar in the battery icon represents the battery capacity.



Battery (NiMH) at 100 % capacity.



Battery at 50 % capacity.



Battery at 0 % capacity. A flashing battery icon with no meter bar present represents an empty battery. The battery should be replaced with a fully charged battery.



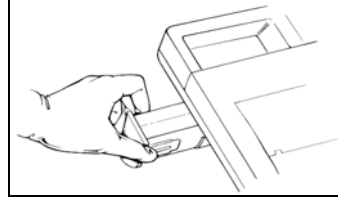
AC Adapter in use.

If the battery icon disappears, the battery should be put through a conditioning charge. See Section 6-Conditioning the Battery.

REMOVING THE BATTERY

Remove the depleted battery from the analyzer by pressing on the clips located on the sides of the battery. Recharge the battery following the procedure in Section 6-Charging the Battery (Routine). (Figure 6-1).

Figure 6-1



CHARGING THE BATTERY (ROUTINE)

1. Connect the power supply to the IRMA TruPoint charger and secure the screw-on locking mechanism.
2. Connect the wall cord to the power supply, and plug the wall cord into an electrical outlet (110 VAC/60Hz or 220 VAC/50Hz).
3. Insert the battery into the battery charger. The battery should 'click' into the charger when properly inserted. The yellow light indicates that the battery is charging.
4. The green LED on the charger will begin to blink (blinks for 30 seconds, off for 4 seconds, blinks for 30 seconds, etc.) when the battery is at approximately 90% capacity. When the battery is at 100% capacity, the green light blinks continuously. Batteries should remain in the charger until the green LED blinks continuously.
5. Leave a fully charged battery in the charger until it is needed for use. The charger will continue to top-off a fully charged battery, ensuring that it is at 100% capacity when needed for use in the analyzer.

Caution:

- Do not remove battery from charger until it is fully charged; doing so may result in less than optimal battery performance.

CONDITIONING THE BATTERY

For optimal battery performance, perform a conditioning charge:

- Prior to initial use;
 - Monthly, or more frequently as the schedule allows;
 - If the battery icon fails to display in the upper right corner of the touchscreen, or if a fully charged battery yields fewer than the expected number of tests. Condition batteries as follows:
1. Insert a battery into the battery charger. The battery should ‘click’ into the charger when properly inserted. The yellow light indicates that the battery is charging. Charge the battery for 24 hours.
 2. After 24 hours, remove the battery from the charger, then reinsert the battery into the charger. Leave the battery in the charger until the green light flashes continuously, indicating that the battery is fully charged. The battery should remain in the charger until it is needed for use in the analyzer.

ANALYZER MAINTENANCE

CHANGING THE PRINTER PAPER

The printer paper should be replaced when a red stripe displays on the side of the roll. Instructions automatically appear on the screen when the printer door is removed. Press **next** from the first screen to see additional instructions.

Note:

- Do not remove the printer door while a test is in progress.

Change the printer paper as follows:

1. Remove the printer door. With the analyzer “on”, push down on the printer door and slide the door away from the analyzer. (Figure 6-2)
2. Remove old paper roll and spindle. Save the spindle.
3. Insert new paper roll. Insert the plastic spindle through the center of the new paper roll. (Figure 6-3)

Figure 6-2

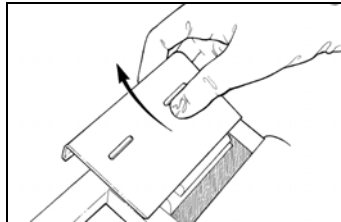
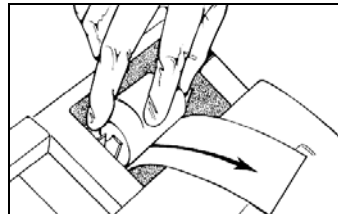


Figure 6-3



4. Place the spindle into the cradle in the paper compartment.
5. Feed paper into printer. Insert the paper into the feed slot ensuring that the tab is under the roller. Use a clean edge or fold corners into a point. Press **feed**. (Figure 6-4)

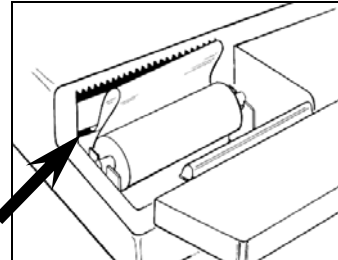


Figure 6-4

The paper will automatically stop advancing after being properly fed into the printer. “IRMA TruPoint Blood Analysis System” will print, confirming that the paper was loaded correctly.

6. Replace printer door. The analyzer will return to the last screen that was displayed before the printer cover was removed.

CALIBRATING THE BAROMETER

The IRMA TruPoint barometer should be calibrated annually to maintain analyzer accuracy. Use a National Institute of Standards and Technology (NIST) traceable barometer for calibration. See Section 7- Calibrate Barometer.

Note:

- The IRMA TruPoint barometer was calibrated at the factory, and should read within ± 5 mmHg of a NIST-calibrated barometer. Use of a noncalibrated reference barometer to adjust the IRMA TruPoint barometric pressure reading is not recommended.
- Do not calibrate the IRMA TruPoint analyzer barometer using values derived from a water barometer.

CLEANING SYSTEM COMPONENTS

CLEANING THE TOUCHSCREEN

Immediately wipe any spilled liquid off of the touchscreen to prevent buildup of film on the screen. Clean the analyzer screen with a soft cloth dampened with isopropyl alcohol, a 10% bleach solution, or distilled water. Dry the screen with a soft cloth following cleaning.

Caution:

- Do not use strong detergents, concentrated bleach, or abrasive cleaning solutions that could scratch or damage the screen. Do not use excessive force.

CLEANING THE BATTERY CHARGER, POWER SUPPLY, AND ANALYZER SURFACES



Immediately wipe any spilled blood or other contaminant from the component surface. Clean using a 10% bleach or detergent solution.

Caution:

- Use proper precautions when cleaning blood from the analyzer.
- Do not immerse the battery charger, power supply, or analyzer in any liquid.
- Unplug the battery charger or power supply before cleaning to prevent electrical shock.

CLEANING THE BATTERY CONTACTS

Periodically examine the battery contacts, battery charger contacts, and analyzer battery compartment contacts for dirt, corrosion, or contamination. Clean the contacts using a swab moistened with isopropyl alcohol, or use a clean pencil eraser.

Caution:

- Do not immerse the battery in any liquid.
- Unplug the battery charger or power supply before cleaning to prevent electrical shock.
- Keep battery contacts away from metal objects.

CLEANING THE INFRARED PROBE

Examine the infrared (IR) probe surface daily for dirt or contamination. Clean the probe surface using a swab moistened with isopropyl alcohol or a 10% bleach solution. (Figure 6-5) The square glass surface of the probe should appear shiny and reflective when clean. Allow the IR probe to completely dry before testing.

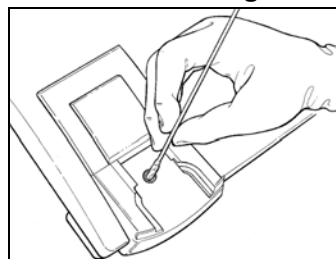


Figure 6-5

CLEANING THE EDGE CONNECTOR

Clean the edge connector only if it is accidentally contaminated with blood or other contaminants, or when EQC, Temp Test, or sensor error codes indicate possible contamination. Use the ITC Edge Connector Cleaning Kit (PN 450000) as follows:

1. Remove battery or AC adapter from IRMA TruPoint Analyzer.
2. Open and completely unfold **WET** pad. Place pad in front of the edge connector.
3. Use **Edge Connector Cleaning Strip** to push pad into edge connector.
4. Pull pad out of edge connector.
5. Repeat cleaning, moving pad left and right in edge connector. Pull pad out of edge connector.
6. Open and completely unfold **DRY** pad. Place pad in front of the edge connector and repeat steps 3 through 5.

Note:

- Do not clean the edge connector on a routine basis.
- Do not clean the edge connector with anything other than the ITC Edge Connector Cleaning Kit, unless instructed to do so by your service provider.

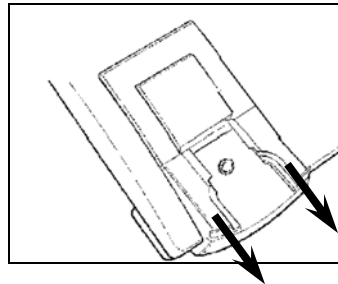
CLEANING THE TEMPERATURE CARD

Inspect the Temp Card leads for dirt or contamination prior to insertion. If the leads appear dirty, or if the Temp Test fails repeatedly, clean the leads using a swab moistened with isopropyl alcohol, or use a clean pencil eraser. Following cleaning, ensure that the leads are dry, and that no eraser residue is present before inserting the Temp Card into the edge connector. The leads should appear shiny when clean.

REPLACING THE EDGE CONNECTOR

Replace the edge connector if instructed to do so by your service provider or if it has been contaminated and cleaning does not resolve the problem.

1. Remove the power source from the analyzer.
2. With the instrument top facing up, remove the right and left cartridge guides by pulling them straight forward and off of the cartridge insertion porch area. (Figure 6-6)
3. Remove the edge connector assembly by removing the two thumbscrews from the underside of the analyzer directly below the serial number label.
4. Lift the edge connector assembly off of the analyzer.
5. Make sure that the connector on the analyzer (where the edge connector assembly plugs into the analyzer) is dry and that no foreign materials are present before installing the new edge connector.
6. Place the new edge connector into the analyzer and push down on the assembly until the cover is flush with the instrument top.
7. Reinsert the left and right guides by sliding each along the edge of the porch until they snap into the edge connector assembly.
8. Reinstall the two thumbscrews from the bottom of the analyzer while holding the cover in place. Do not over-tighten the thumbscrews.



Following installation, verify that a cartridge can be inserted into the edge connector. Perform an EQC test to verify functionality of the analyzer.

Note:

- Do not touch the leads on the edge connector assembly. Contamination of the leads can result in EQC failure and/or sensor errors.

Section 7

System Settings

OVERVIEW

This chapter provides setup instructions for all IRMA TruPoint system settings.

SETTING OPTIONS MENU

System settings are configured through the SETTING OPTIONS menu. Access to Setting Options is controlled by User ID privilege.

- **QA Users** have access to all system settings menus.
- **Non-QA Users** have limited access to the device settings menu only.

Access the SETTING OPTIONS menu by pressing the **Settings** button on the main MENU. The following options are presented:

Menu: Returns to main MENU.

DeviceSet: Appears only with entry of QA User ID. Initiate device update from DeviceSet.

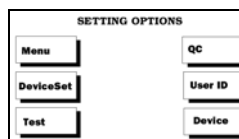
Test: Advances to TEST SETTINGS menu.

Access setup screens for product setup, product lot entry, calculations, test information, correlation, bypass correlation, display units, reportable ranges, and reference ranges.

QC: Advances to the QC SETTINGS menu. Set up or modify liquid controls and QC Lockout schedules.

User ID: Advances to the USER ID OPTIONS menu. Set up or modify user identification numbers and privileges.

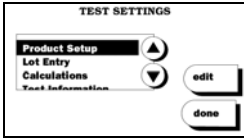
Device: Advances to the DEVICE SETTINGS menu. Access setup screens for beeper, barometer, communications, date format, analyzer date and time, printer, and screen contrast.



All IRMA TruPoint system settings are maintained in the microprocessor's memory, even when the analyzer is turned "off" or the battery is removed.

TEST SETTINGS

QA Users can access **Test Settings** by pressing **Test** from the SETTING OPTIONS menu. A TEST SETTINGS picklist displays. Current test settings can be viewed or changed by highlighting a category in the TEST SETTINGS picklist and pressing **edit**.



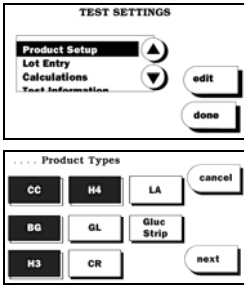
PRODUCT SETUP

QA Users can use the Product Setup option to:

- **Define the product types that are in use at their facility.** With each patient test, the user is prompted to enter the product type being run. Only those product types defined in the Product Setup option will appear on the *Select Product Type* screen with each test; if a single product type is defined, the analyzer assumes that all cartridges inserted for testing are of that type, and no *Select Product Type* screen will appear.
- **Define the analytes that will be reported for each cartridge type.** Note that all analytes will always be reported for BG cartridges.

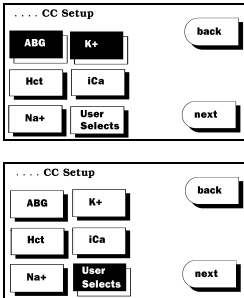
Defining the product type(s) in use

1. Highlight **Product Setup** in the picklist and press **edit**.
2. Highlight each Product Type that will be used at your site. Press **next** to define which analytes will be reported for each cartridge type.

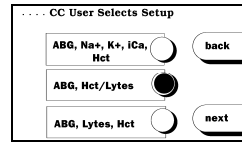


Defining analytes to be reported for each cartridge type.

- **Define which analytes will be reported for each CC test:**
 1. Highlight the analytes to be reported automatically with each CC test. Press **next**.
 2. If the analytes to be reported will vary from test-to-test, highlight **User Selects**. This will prompt individual selection of analytes or analyte groupings with each CC test. Press **next**.

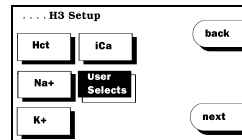


- Highlight the button next to the analyte groupings to be displayed for selection with each CC test. In the example shown, the user would have the choice of selecting **ABG** (pH, pCO₂, pO₂) and/or **Hct/Lytes** (Na⁺, K⁺, iCa, Hct). Press **next** to accept entry and go to setup for the next established product type (if applicable).



- Define which analytes will be reported for other cartridge types (if applicable):

- The procedure is the same as for CC setup, with the exception that there are no analyte grouping choices for User Selects setup; the user will have the choice of selecting the individual analytes available on that product type with each test. Press **next** to complete entry.

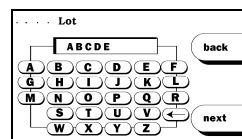
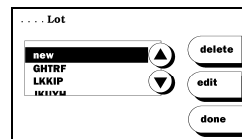
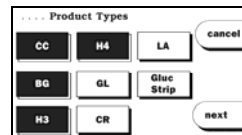
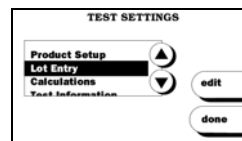


LOT ENTRY

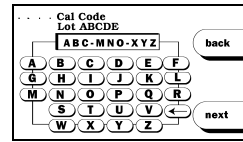
QA Users can enter a new product lot and Cal Code into the analyzer memory using the Lot Entry option. Cal Codes from previously entered product lots can also be edited via this option.

Entering a new product lot

- Highlight **Lot Entry** and press **edit**.
- Highlight the appropriate product type and press **next**.
- Highlight **new** in the picklist. Press **edit**. Up to 3 lots for each product type can be entered; when the maximum of 3 has been reached, the oldest lot for that product type will be deleted.
- Enter the product lot code and press **next**.



- Enter the Cal code and press **next** to return to the Lot picklist. Press **done** to return to TEST SETTINGS.



Note:

- New product lots that are entered via patient test or QC test will appear in the Lot picklist following entry.

Replacing an existing product lot with a new product lot

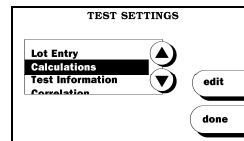
- Highlight **Lot Entry** and press **edit**. Highlight the appropriate product type and press **next**. Scroll down the picklist until the existing lot number is highlighted. Press **edit**.
- Enter the new lot code and press **next**. Enter the new Cal Code and press **next** to return to the Lot picklist. The new lot replaces the old lot in the picklist. Press **done** to return to TEST SETTINGS.

CALCULATIONS

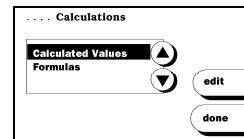
QA Users can define the calculated values to be reported with each test, and the formulas used to derive the calculated values using the Calculations option.

Defining the calculated values to be reported with each patient test

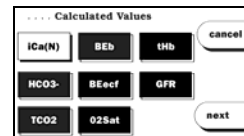
- Highlight **Calculations** and press **edit**.



- Highlight **Calculated Values** from the picklist and press **edit**.



- Highlight the calculated values to be reported (depends on product type) with each patient test, and press **next**.



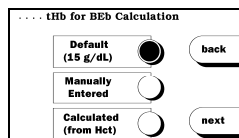
If BEb was not selected, Calculated Values setup is complete.

- If BEb was selected, chose the source of the patient hemoglobin value to be used in the BEb calculation and press **next**. Highlight the button next to one of the following options:

a. Default value: 15g/dL is automatically used in all BEb calculations.

b. Manually Entered value: User manually enters a patient hemoglobin value with each test.

c. Calculated value: If a CC cartridge is run with both blood gas and hct analytes selected, the tHb value that is calculated from the hct test will be used in the BEb calculation.

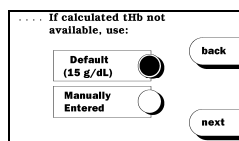


If *Default* or *Manually Entered* was selected, Calculated Values setup is complete.

- If *Calculated* was selected, chose an alternate tHb source to be used when a calculated tHb is not available, and press **next**. Highlight the button next to one of the following options:

a. Default value: 15 g/dL is automatically used in the BEb calculation.

b. Manually Entered value: User manually enters a patient hemoglobin value with each test.

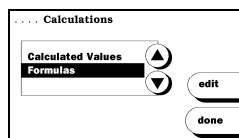


Calculated Values setup is complete.

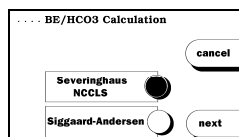
Selecting the formulas to be used to derive the calculated values

- Selecting Base Excess and Bicarbonate Formulas:**

- Highlight **Formulas** and press **edit**.



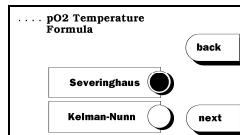
- Highlight the button next to the formula to be used in the calculation of base excess and bicarbonate. Press **next**.



- **Selecting a pO₂ Temperature Formula:**

1. Highlight the button next to the formula to be used in the calculation of patient temperature-corrected results.

These formulas are further described in Appendix C.



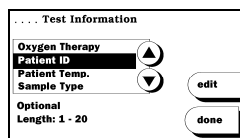
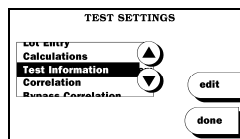
TEST INFORMATION

QA Users can define the Test Information items that can be entered with each test. Test Information includes: oxygen therapy, patient ID, patient temperature, patient hemoglobin, sample type, sample site, patient notes, and QC notes. Each Test Information item may be turned “on” or “off”. See Section 7-Calculations for patient hemoglobin setup instructions.

Test information entered with a test is permanently stored with the test record, will appear on the results printout, and can be transferred to *idms*.

Setting up the test information items that may be entered with each patient test

1. Highlight **Test Information** from TEST SETTINGS and press **edit**.
2. Highlight the test information option of choice from the picklist and press **edit**.
3. Select from the setup choices displayed on the screen. The options available for each entry option item are described below.



Oxygen therapy

There are 3 oxygen therapy options:

- **Off:** No oxygen therapy information may be entered with a test.
- **FIO₂ Only:** FIO₂ may be entered with a test.
- **Detailed Input:** Detailed oxygen therapy information may be entered with a test. Refer to Section 2-Oxygen Therapy Information Entry for instructions on oxygen therapy information entry during a test.

Patient ID

There are 3 patient ID options:

- **Off:** No patient ID information may be entered with a test.
- **Optional:** A patient ID may be entered when a test is run, but is not required to be entered.
 1. Highlight **Optional** button and press **next**.
 2. Enter the minimum number of characters that must be entered if a patient ID is entered (between 1 and 20 characters). Press **next**.
 3. Enter the maximum number of characters that may be entered if a patient ID is entered (between 1 and 20 characters). Press **next**.
- **Required:** Entry of a patient ID is required.
 1. Highlight **Required** button and press **next**.
 2. Enter the minimum number of characters that must be entered (between 1 and 20 characters). Press **next**.
 3. Enter the maximum number of characters that may be entered (between 1 and 20 characters). Press **next**.

Patient temperature

There are 2 patient temperature options:

- **Off:** No patient temperature may be entered with a test.
- **On:** A patient temperature may be entered with a test, and temperature corrected results will be reported.

Sample type/sample site

There are 2 sample type and sample site options:

- **Off:** No sample type or sample site information may be entered with a test.
- **On:** Sample type and/or sample site information may be entered with a test.

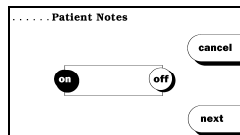
Patient notes/QC notes

There are 2 patient notes and QC notes options:

- **Off:** No patient or QC notes may be entered with a test.
- **On:** Patient or QC notes may be entered with a test.

Setting up Patient Notes:

1. Turn Patient Notes “on” and press **next**.

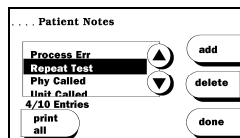


2. Default or established patient notes appear in a picklist.

a. Deleting Patient Notes: Highlight the desired note and press **delete**.

b. Adding Patient Notes: Press **add** and enter a new note via the touchscreen keypad.

Patient notes may be up to 12 characters in length, and a maximum of 15 patient notes may be established.



Setting up QC Notes:

1. Turn QC Notes “on” and press next.

2. Default or established QC notes appear in a picklist.

a. Deleting QC Notes: Highlight the desired note and press **delete**.

b. Adding QC Notes: Press **add** and enter a new note via the touchscreen keypad. QC notes may be up to 12 characters in length, and a maximum of 15 QC notes may be established.

CORRELATION

QA Users can establish correlation parameters for each IRMA TruPoint product type to adjust IRMA TruPoint patient test results to values that would be expected if samples were run on another analyzer (i.e., designated reference analyzer). These correlation factors are based on split-sample blood results from a statistically valid number of samples. The IRMA TruPoint analyzer can be run without using the Correlation feature, even if correlation values have been entered into the analyzer.

There are 2 correlation options:

- **Off:** Correlation parameters will not be used by the analyzer to adjust IRMA TruPoint patient test results.
- **On:** Correlation parameters will be used by the analyzer to adjust IRMA TruPoint patient test results.

Collecting Correlation Data:

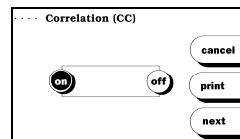
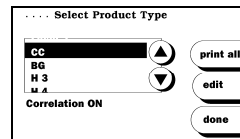
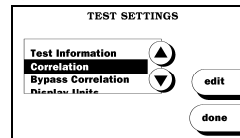
1. Ensure that the Correlation option is “off” when collecting correlation data.
2. Ensure that the reference analyzer is properly maintained prior to the start of data collection to ensure accurate correlation.
3. Obtain at least **50** split-sample results for each analyte using the IRMA TruPoint analyzer and the reference analyzer. For each split sample, use the same syringe, the same analysis order, and perform both analyses within 5 minutes of each other.

The measurement range over which the test method is assessed must span the entire clinical range. In general, this range will extend from below the normal range to substantially higher than the normal range.

4. Graph the reference analyzer results against the IRMA TruPoint analyzer results for each set of values. Plot the results for each analyte separately. Make the reference analyzer results the Y (dependent) variable; make the IRMA TruPoint analyzer the X (independent) variable.
5. Perform a linear regression analysis on the results.
6. Delete any data points that are more than 3 standard deviations from the regression line. Replace them with data acquired from additional split-sample analyses and redetermine the regression line.
7. The slope and intercept values of the regression line are the factors used for the analyzer-to-analyzer correlation function.

Activating/deactivating the correlation setting

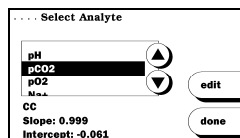
1. Highlight **Correlation** from TEST SETTINGS and press **edit**. An Attention message appears, stating that adjusting correlation factors will affect future patient test results. Press **ok**.
2. Highlight the desired Product Type and press **edit**.
3. Highlight “on” or “off” button and press **next**. If “on” is selected, go to “Establishing or Changing Correlation Factors”.



Establishing or changing correlation factors

1. Ensure that Correlation is “on” (see previous section). Press **next** from *Correlation* screen.

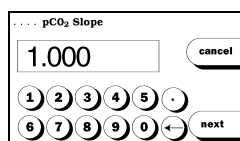
2. Correlation for each analyte can be configured independently from the *Select Analyte* screen. Highlight the first analyte in the picklist for which correlation factors are to be entered.



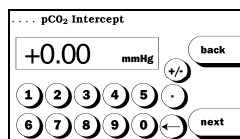
The current slope and intercepts for the highlighted analyte will appear below the picklist. If the Correlation mode is being accessed for the first time, the default values appear. If the factors have been changed previously, the current values display. If a record of these existing correlation settings is desired, the operator should transcribe the data before moving to the next step. Existing correlation parameters will be deleted following the completion of new data entry.

3. Press **edit** to enter the slope and/or intercept value for the highlighted analyte.

4. Enter **slope** value and press **next**.



5. Enter intercept value and press **next** to return to the *Select Analyte* screen. Refer to Appendix B, Table B-10 for correlation factor limits for each parameter.



6. Repeat for each analyte to be correlated. Press **done** from the *Select Analyte* screen when finished.

Note:

- Correlation parameters will be used in the calculation of patient results only when *Correlation* is turned “on”. The slopes and intercepts will be stored in the analyzer memory, but will not be used in the calculation of results when *Correlation* is turned “off”.
- Correlation should be deactivated when proficiency samples are analyzed.
- Using the correlation feature will alter the calculation of all subsequent patient test results, but will not affect results previously performed.

BYPASS CORRELATION

QA Users can establish correlation factors for samples from patients on cardiopulmonary bypass, to adjust IRMA TruPoint patient test hematocrit results to values that would be expected if samples were run on another analyzer (i.e., designated reference analyzer). These correlation factors are based on split-sample blood results from a statistically valid number of samples.

When established, the user has the option of selecting either “On Bypass” (bypass correlation factors are used to calculate the hematocrit result) or “Off Bypass” (bypass correlation factors are not used in the hematocrit measurement) with each patient test.

Collecting bypass correlation data

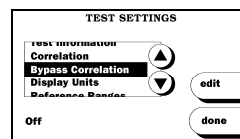
1. Follow the instructions in steps 1-2 of Section 7-Collecting Correlation Data.
2. Obtain at least **20** split-sample hematocrit results from at least 5 patients on cardiopulmonary bypass. **USE ONLY SAMPLES COLLECTED FROM PATIENTS ON BYPASS; PRE- AND POST- BYPASS SAMPLES SHOULD BE EXCLUDED.**

Hematocrit samples collected from cardiopulmonary bypass typically yield results below 35%. Therefore it is unlikely that samples collected to establish bypass correlation will span the entire clinical range.

3. Follow the instructions in steps 4-7 of Section 7-Collecting Correlation Data.

Activating/deactivating the bypass correlation setting

1. Highlight **Bypass Correlation** from TEST SETTINGS and press **edit**.
2. Highlight “on” or “off” button and press **next**. If “on” selected, go to “Establishing or Changing Bypass Correlation Factors”.



Establishing or changing bypass correlation factors

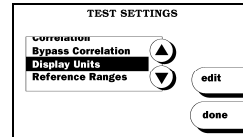
1. Ensure that Bypass Correlation is “on” (see previous section). Press **next** from *Bypass Correlation* screen.
2. Enter slope value (between 0 and 10.000) and press **next**.
3. Enter intercept value (between -999.00 and +999.99) and press **next**.

DISPLAY UNITS

QA Users can designate the units of measure for barometric pressure, temperature, and analyte concentration using the Display Units option.

Defining units of measure

1. Highlight **Display Units** from TEST SETTINGS and press **edit**.
2. Highlight the test parameter of choice from the picklist and press **edit**.
3. Select the desired unit of measure and press **next**.
4. If multiple parameters were selected, select desired units for each parameter, pressing **next** from each screen until complete.

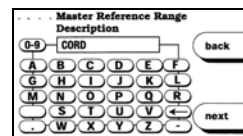
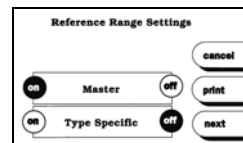
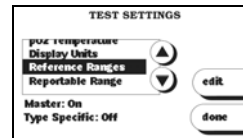


REFERENCE RANGES

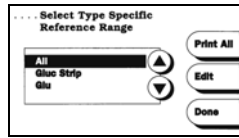
QA Users can establish a reference range consisting of an upper and lower limit for each analyte by patient and sample type and a title/description of the range. An out-of-range patient test result will be flagged “H” (High) or “L” (Low) on the printout and the result will flash on the touch screen. Reference ranges used at the time of a test are permanently stored with the results. Reference ranges can be changed without affecting the ranges associated with previous results. Type specific reference ranges can be established by patient and analyte for each sample type.

Setting up reference ranges

1. Highlight **Reference Ranges** from the TEST SETTINGS menu. Press **edit**.
2. For master only defaults, select Master “on” and Type Specific “off”. Press **next**.
 - a. To activate previously defined values, press **ok**.
(This message will only be displayed if a reference range has been established.)
 - b. Enter a Reference Range Description (up to 12 characters). Press **next**.



c. Select desired analyte from the picklist. If reference ranges will be entered for multiple analytes, select "All". Press **edit**.

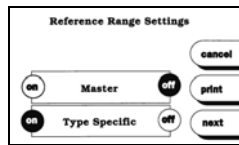


d. Enter the lower reference limit and press **next**.

e. Enter the upper reference limit and press **next**.

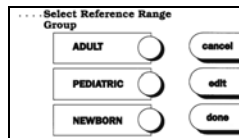
f. Continue for all appropriate analytes. When complete, press **done**.

3. To set Type Specific reference ranges, select Type Specific "on" and Master "off". Press **next**.



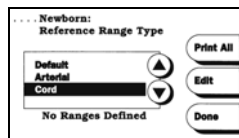
a. To activate previously defined values, press **ok**.

b. Select Reference Range Group. Press **edit**.



c. Enter Reference Range Group Name. Press **next**.

d. Select Reference Range Type. Press **edit**.



e. Select desired analyte from picklist. If reference ranges will be entered for multiple analytes, select "All". Press **edit**.

f. Enter the lower reference limit and press **next**.

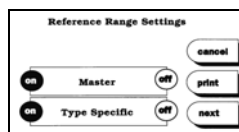
g. Enter the upper reference limit and press **next**.

h. Continue for all appropriate analytes. When complete, press **done**.

i. Repeat the steps **3c** to **3g** for the reference range types.

j. When complete, press **done**.

4. For Master and Type Specific defaults, select Master "on" and Type Specific "on". Press **next**.



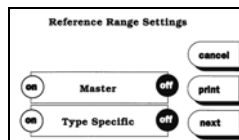
a. To activate previously defined values, press **ok**.

b. Please follow the above Master Default steps for **2b** through **2f**.

c. Please follow the above Master Type Specific steps for **3b** through **3j**.

d. When complete, press **done**.

5. For no Reference Ranges, select Master "off" and Type Specific "off". Press **next** and **done**.



REPORTABLE RANGES

The default reportable range for each analyte can be found in Appendix B, Table B-8. Due to regulatory requirements, some facilities may want to specify more narrow reportable ranges for certain analytes. QA Users can establish a custom reportable range consisting of an upper and lower limit for each analyte.

Note:

- Changing reportable ranges may affect stored records. Stored results should be uploaded to *idms* before reportable ranges are changed.
- An error message will appear upon entry of a reportable range that conflicts with established QC limits or reference ranges (e.g., a QC or reference range limits cannot be outside a reportable range limit).

Changing reportable ranges

1. If applicable, upload stored results to *idms* and confirm that existing QC limits and reference ranges do not conflict with the reportable ranges that will be entered.
2. Highlight **Reportable Ranges** from the TEST SETTINGS menu. Press **edit**.
3. Highlight the appropriate button:
 - a. Select **Default** to set analyzer to default reportable ranges for all analytes. Press **next** to complete entry.
 - b. Select **User Defined** to enter custom reportable ranges. Press **next**. An analyte picklist is displayed.
4. Select the desired analyte from the picklist and press **edit**. If reportable ranges will be changed for multiple analytes, select "All".
5. Enter the lower reportable range limit and press **next**.
6. Enter the upper reportable range limit and press **next**.
7. Continue for all appropriate analytes.

QUALITY CONTROL (QC) SETTINGS

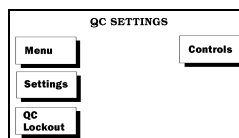
QA Users can access **QC Settings** by pressing **QC** from the **SETTING OPTIONS** menu. The following options are presented:

Menu: Returns to main MENU.

Settings: Returns to **SETTING OPTIONS** menu.

QC Lockout: Allows definition of the number of electronic (EQC) and/or liquid (LQC) quality control tests required to support patient testing.

Controls: Allows set-up of new controls and editing or deletion of established controls for IRMA TruPoint cartridge and SureStepPro Glucose Module tests. If the glucose module is in use, refer to the SureStepPro Glucose Module User Manual for details.



QC LOCKOUT

QA Users can designate the number of QC tests (electronic and/or liquid QC) required to support patient testing. Separate QC lockout schedules may be established for each product type and analyte or analyte group. When QC Lockout is activated, either 1, 2, or 3 successful quality control tests must be run during a shift or the analyzer will deny access to the patient test screen. Shifts can be specified as 8-, 12-, or 24- hours in length.

Example: An 8 hour shift length and one EQC tests per shift is defined. A 1 hour grace period is provided at the start of each shift in which the patient test screens may be accessed even if QC requirements have not been met. If the shift begins at 7 a.m., the grace period is from 7-8 a.m. After the grace period, patient test screens cannot be accessed until a successful EQC test has been run. QC must be run after the shift start time established in the set-up (in this example, 7 a.m.) to count toward satisfying the QC Lockout requirement. Shift times are based on the analyzer's internal clock.

General QC lockout rules

- When EQC Lockout is on, an EQC test failure at any time (i.e., even if EQC passed earlier on the same shift) will lockout patient testing. Following an EQC test failure, a passed EQC test is required to resume patient testing.
- When liquid QC limits have been established, results must fall within the established QC limits to be considered a successful test and satisfy QC lockout requirements.

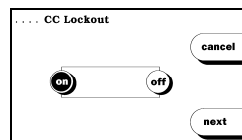
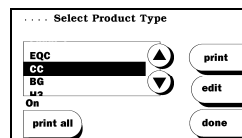
- When NO liquid QC limits have been established, running the designated number of controls will satisfy QC lockout requirements, for all non-suppressed results.
- If an individual sensor on a cartridge errors during the analysis phase of an liquid QC test, the result for that sensor and any other sensors that are dependent on that sensor will be suppressed. Suppressed results will be dashed-out on both the screen and printout, and will not satisfy QC lockout requirements for the associated analyte group (with or without QC limits established).
- If a patient test is initiated and QC Lockout is “on” and Lockout requirements have not been met, a lockout information screen displays. Refer to Section 2-QC Lockout Screens for details on QC Lockout screen messages.

Automatic EQC

When the IRMA TruPoint analyzer is being operated with the AC adapter, EQC may be configured to run automatically according to a predefined EQC lockout schedule. When due, an EQC test will automatically run 15 seconds after the analyzer goes into sleep mode (i.e., after analyzer screen backlight turns off following 2 minutes of inactivity). All of the general QC lockout rules apply to auto-EQC. (See Section-3 for more information)

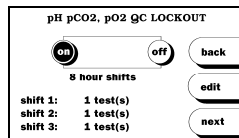
Activating or deactivating QC lockout

1. Press **QC Lockout** on the QC SETTINGS menu. The *Select Product Type* screen displays a product type picklist.
2. Highlight the desired product type and press **edit**.
3. Press “on” to activate or “off” to deactivate QC Lockout for the selected product type and press **next**. The *Analyte Lockout* screen displays when “on” is selected.



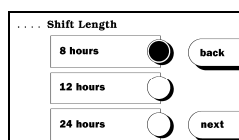
Setting up or modifying QC lockout schedule

4. The *Analyte Lockout* screen displays the current settings for the first analyte/analyte group available on the product type selected. Press “on” to activate or “off” to deactivate QC Lockout for the selected analyte/analyte group. If “on” selected:

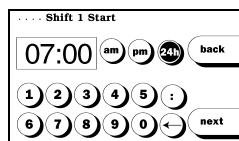


- a. Press **next** to keep current settings and advance to the *QC lockout settings* screen for the next analyte available on the product type.
- b. Press **edit** to change settings.

5. Select shift length (8, 12, or 24 hours) from the Shift Length screen. Press **next**.

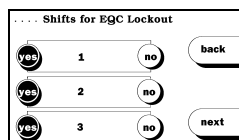


6. Select Shift 1 Start time using the numeric and colon keys. Press **next**.

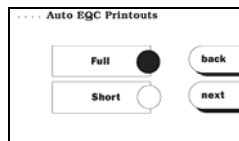


7. The screens that follow will depend upon whether EQC or Liquid QC Lockout is being configured:

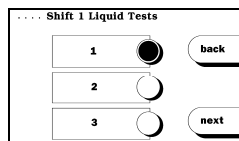
- a. **EQC Lockout:** Select Shifts for Lockout (1, 2, or 3) by highlighting the **yes** button next to desired shifts. Press **next** to return to the *Select Product Type* screen.



- b. **Auto EQC Printout:** The auto EQC report can be printed in a detailed (full) or abbreviated (short) report. The short report provides a printout indicating pass or failed EQC. For a detailed report, press “Full” and press “Short” for an abbreviated report.



- c. **Liquid QC Lockout:** Select the number of controls to be run on shift 1 (1, 2, or 3). Press **next**. Repeat step to define number of controls to be run on each shift. Press **next** to advance to lockout setup for each analyte.



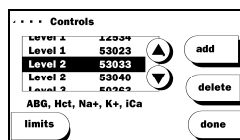
CONTROLS

QA Users can set up liquid controls for each product type. The analyzer will store a maximum of 42 individual control entries for cartridge product types. Once this limit is reached, an existing control must be deleted before a new control can be added.

QC limits may be entered into the analyzer for each control (optional). These limits are used during quality control testing to verify that the analysis system is performing properly. QC results will be flagged only when limits are defined.

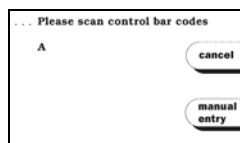
Setting up a new control

1. Press **QC** on the **SETTING OPTIONS** menu.
2. Press **Controls** on the **QC SETTINGS** menu.
3. Highlight the product type of choice. Press **next**.



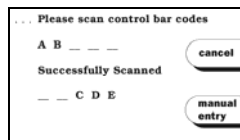
4. The *Controls* screen displays a picklist of current controls. Press **add** for a new control.
5. Select Level, (1, 2, or 3). Press **next**.

- a. If the bar code scanner is attached to IRMA TruPoint, the *Please scan control* screen will appear.



- > Scan the barcodes from the expected values sheet. These sheets are available at www.itcmed.com.

- > The touchscreen will track bar code scan progress.

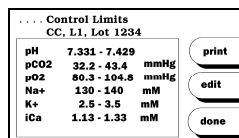


- b. If the barcode scanner is not being utilized, proceed as follows:

6. Enter Control Lot (1-7 alpha-numeric characters) for the new control. Press **next**.
7. Enter Expiration Date (MM/YY). Press **next**.
8. Select Analytes to be reported for the new control by highlighting all desired analytes. Press **next**.
9. Follow the series of Limits entry screens to establish control limits for each of the selected analytes. The product type, control level, and control lot number appear on each screen.
10. Enter numeric lower and upper limits, or press **next** through each screen to enter no limits.

Editing an established control

1. Press **QC** on the **SETTING OPTIONS** menu.
2. Press **Controls** on the **QC SETTINGS** menu.
3. Highlight the product type of choice. Press **next**.
4. The *Controls* screen displays a picklist of current controls. Highlight the control to be edited, and press **limits**.
5. The analyzer displays the current limits for the highlighted control. Press **edit** and follow the series of entry screens to edit control expiration date, analytes to be reported for the control, and control limits.



Deleting a control

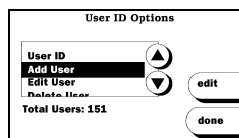
1. Press **QC** on the **SETTING OPTIONS** menu.
2. Press **Controls** on the **QC SETTINGS** menu.
3. Highlight the button next to the product type of choice. Press **next**.
4. The *Controls* screen displays a picklist of current controls. Highlight the control to be deleted. Press **delete**.
5. A screen appears to verify the deletion request for the selected control. Press **ok** to delete the selected control. The screen returns to the *Controls* screen. The control is deleted, but associated QC results remain in the analyzer memory. Results for a deleted control may be recalled only via the Search All option, not by control lot number.

USER ID SETTINGS

The analyzer can maintain a maximum of 600 User IDs. Each ID can be from 1 to 16 alpha-numeric characters in length. QA Users can access User ID Options by pressing User ID from the **SETTING OPTIONS** menu. A picklist with following options is presented:

UserID: User ID can be turned “on” or “off” and configured to appear on IRMA TruPoint results printout.

Add User: New User IDs can be added to analyzer memory and granted privileges from one of 3 categories: **QA Users**, **General Users**, or **Gluc Strip Users**.



- > **QA Users** have access to all analyzer setting and testing functions, including User ID settings.
- > **General Users** may perform and recall all tests, (as configured by QA User), but have limited access to analyzer set-up functions.
- > **Gluc Strip Users** may perform and recall only glucose strip, EQC, and Temperature tests (if applicable), and have limited access to analyzer set-up functions.

Edit User: Privileges can be changed for existing User IDs.

Delete User: Existing User IDs can be deleted from analyzer memory.

Print Lists: A list of all User IDs, grouped by Privileges category, can be printed.

Note:

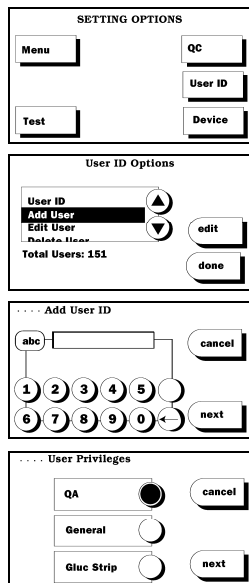
- The **Gluc Strip User** privilege is available for users that have purchased the SureStepPro Glucose Module, an optional side attachment to the IRMA TruPoint analyzer. Refer to the SureStepPro Glucose Module User Manual for details.
- The **General User** privilege allows both IRMA TruPoint cartridge and glucose strip testing (if glucose module is present).

DEFAULT QA USER ID

The IRMA TruPoint analyzer is shipped with a default QA User ID of 123456. Use the default QA User ID to access the User ID Options screen and enter a new QA User ID(s). Add new QA Users before deleting the default QA User ID.

ADDING A NEW QA USER ID

1. Press **User ID** from the **SETTING OPTIONS** menu.
2. Highlight **Add User** from the picklist on the *User ID Options* screen. Press **edit**.
3. Enter the new QA User ID. Press **next**.
4. Highlight button next to **QA** on the *User Privileges* screen. Press **next**.



USER ID OPTIONS

QA Users can access the *User ID Options* screen by pressing **User ID** on the SETTING OPTIONS menu. To access a User ID setting, highlight the desired option from the picklist and press **edit**.

User ID

There are 2 User ID options:

- **Off:** Entry of a valid User ID is not required prior to performing tests.
 - **On:** Entry of a valid User ID is required prior to performing tests.
1. Highlight the “on” or “off” button. If “on” selected, go to step 2.
 2. The Print ID setting determines whether or not the User ID associated with a test appears on the results printout. Select “on” or “off” and press **done**.

Add User

1. Add new User ID. Press **next**.
2. Highlight button next to desired privileges category and press **next** to save entry.

Edit user (privileges)

1. Enter User ID to be edited. Press **next**.
2. Highlight button next to desired Privileges category and press **next** to save entry.

Delete user

1. Enter User ID to be deleted. Press **next**.
2. Press **ok** from confirmation screen to complete deletion.

Print lists

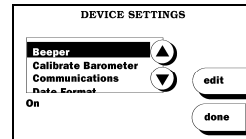
1. Highlight button(s) next to desired Privileges categories and press **print**.
2. Press **print** from the confirmation screen to print list, or press **edit** to return to list selection screen.

DEVICE SETTINGS

Device Settings determine the operating functions for the IRMA TruPoint system.

- **Non-QA Users** can access and change the beeper, date format, time, printer, and screen contrast functions.
- **QA Users** can access and change the above functions as well as the change the date calibrate barometer, and communications functions.

All users can access the DEVICE SETTINGS menu by pressing **Device** from the SETTING OPTIONS menu. To access a device setting, highlight the desired option from the picklist and press **edit**.



BEEPER

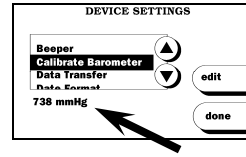
There are 2 beeper options:

- **Off:** The beeper is disabled.
- **On:** The analyzer automatically beeps to alert the operator when an action is required or a result displays.

1. Highlight the “on” or “off” button and press **next**.

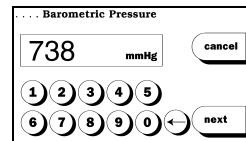
CALIBRATE BAROMETER

1. Run an EQC test. When the test is completed, compare the IRMA TruPoint barometer reading to the reference barometer reading by accessing DEVICE SETTINGS from the SETTINGS OPTIONS menu.



Scroll down until *Calibrate Barometer* is highlighted. IRMA TruPoint's current barometric pressure displays below the DEVICE SETTINGS scroll box. Compare the value displayed on IRMA TruPoint to the reference barometer. If they are the same, press **done**.

2. If the barometer needs adjustment, press **edit** and enter the value from the reference barometer. IRMA TruPoint accepts values from 350 - 900 mmHg. Save the value entered by pressing **next**.



Note:

- The IRMA TruPoint barometer was calibrated at the factory, and should read within ± 5 mmHg of a NIST-calibrated barometer. Use of a non-NIST traceable reference barometer to adjust the IRMA TruPoint barometric pressure reading is not recommended.

COMMUNICATIONS

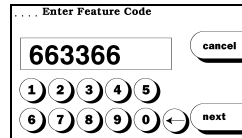
QA Users can establish the bi-directional IRMA TruPoint communications methods for the transfer of IRMA TruPoint test results to the Integrated Data Management System (*idms*) or a host system (e.g., LIS, HIS), and the transfer of device updates from DeviceSet to IRMA TruPoint analyzers.

Communications methods

- **Serial Port:** An RS232 serial port is located on the backside of the IRMA TruPoint analyzer, below the printer. A double-ended RJ45 crossover cable and cable adapter are available from your local service provider. The cable adapter allows the cable to be connected to a computer com port.
Note: External serial servers connect to the IRMA TruPoint serial port.

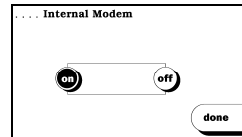
- **Internal Modem:** The internal modem default setting is “disabled”. The modem must be enabled prior to establishing modem results transfer settings. Enable the internal modem as follows:

1. Turn the IRMA TruPoint analyzer “off”.
2. Touch the right side of the touchscreen while simultaneously holding down the lower left corner of the touchscreen to access the *Enter Feature Code* screen.
3. Enter the modem feature code **663366** and press **next**.
4. Turn the internal modem “on” and press **done**.



Note:

- Not all IRMA TruPoint analyzers are equipped with an internal modem. Contact your service provider if you have questions about your system.

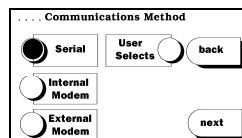


- **External Modem:** An external modem may be used with the IRMA TruPoint analyzer.
- **Internal LAN 10/100 device:** A LAN 10/100 port is located on the backside of IRMA TruPoint analyzers equipped with an internal LAN 10/100 device. A CAT 5e patch cable is used to connect the IRMA TruPoint to the receiving system.

Setting up communications

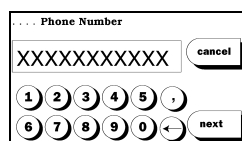
1. Highlight **Communications** in the DEVICE SETTINGS picklist. Press **edit**.

2. Select a data Communications Method. If more than one method will be used, select the **User Selects** option which allows selection of a communications method each time data transfer is initiated. If only one method is selected, that method will automatically be used whenever data transfer is initiated. Press **next**.

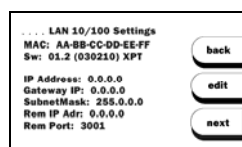


- a. If Serial is highlighted, go to step 5.
- b. If Internal Modem or External Modem is highlighted, or User Selects is highlighted on an analyzer that has Internal or External Modem as an option, go to step 3.
- c. If LAN 10/100 is highlighted, or User Selects is highlighted on an analyzer that has LAN 10/100 as an option, go to step 4.

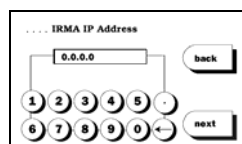
3. Enter the phone number of the receiving system. Enter a comma (,) after any digits that may result in a phone line switching delay (e.g., after “9” is pressed to access an outside line). Press **next**. Go to step 5.



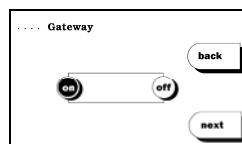
4. The *LAN 10/100 Settings* screen displays.
 - a. If the information displayed is correct, press **next** and go to step 5.
 - b. If the information is incorrect, press **edit**.



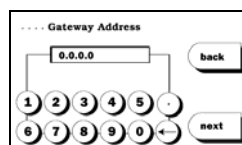
- b1. The *IRMA TruPoint IP Address* screen displays. Enter the IRMA TruPoint IP Address using the format “aaa.bbb.ccc.ddd”, where “aaa”, “bbb”, “ccc”, and “ddd” are each a 1 to 3 digit value ranging from 0 to 255. Press **next**.



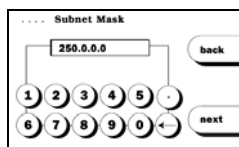
- b2. The *Gateway* screen displays. Highlight the “on” button to enable Network Gateway support, or the “off” button to disable Network Gateway support. Press **next**.



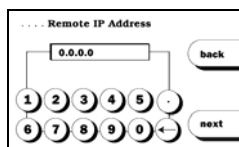
If “on” was selected, enter the Gateway IP Address and press **next**.



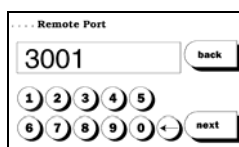
- b3. The *Subnet Mask* screen displays. This screen defines which bits are significant. The default setting is “255.0.0.0”; other common settings are “255.255.0.0” and “255.255.255.0”. Enter the appropriate setting and press **next**.



- b4. The *Remote IP Address* screen displays. Enter the Remote IP Address using the format “aaa.bbb.ccc.ddd”, where “aaa”, “bbb”, “ccc”, and “ddd” are each a 1 to 3 digit value ranging from 0 to 255. Press **next**.



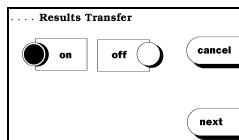
- b5. The *Remote Port* screen displays. This screen sets the IP Port of the remote *idms* computer. The default setting is “3001”. Enter the appropriate setting and press **next**. Go to step 5.



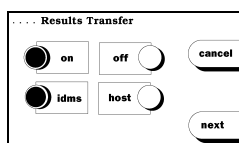
5. There are two IRMA TruPoint test Results Transfer settings:

- **Off:** The IRMA TruPoint Results Transfer feature is disabled.
- **On:** IRMA TruPoint results may be transferred to *idms* or other connected system via serial port, LAN 10/100 or modem. All results transfers utilize the “ASTM standard 1394-91: Standard Specification for Transferring Messages Between Clinical Laboratory Instruments and Computer Systems”, and “ASTM standard 1381-91: Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems”.

Highlight the “on” or “off” button and press **next**. If “on” selected, go to step 6.



6. Highlight “*idms*” if IRMA TruPoint results will be transferred to *idms*, or “*host*” if results will be transferred directly to a host system (e.g., LIS, HIS). Press **next** to setup Automatic Results Device Transfer.



Note:

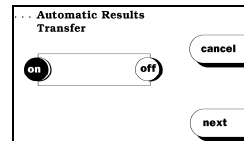
- Selection of “*idms*” sets the IRMA TruPoint serial data transfer (i.e., direct serial connection, external modem, or connection to a network server such as the Lantronix device) baud rate to 19200. Configure *idms* for a 19200 baud rate.
- Selection of “host” sets the IRMA TruPoint serial data transfer (i.e., direct serial connection, external modem, or connection to a network server such as the Lantronix device) baud rate to 9600. Configure the host for a 9600 baud rate.
- The *Results Transfer* settings are ignored when Internal Modem or LAN 10/100 are selected as the communication method.
- The **Automatic Results Transfer** option is not available when User Selects is configured as the Communications Method.

Automatic Results Transfer

IRMA TruPoint analyzers that are powered by AC adapter may be configured to automatically transfer test results to *idms* or another connected system. There are two Automatic Results Transfer settings:

- **Off:** The Automatic Results Transfer feature is disabled.
- **On:** IRMA TruPoint results will automatically be transferred to *idms* or other connected system when certain conditions are met (see *Section 4-Automatic Results Transfer* for details). Configure Automatic Results Transfer as follows:

1. Highlight the “on” or “off” button and press **next** to setup the Automatic Results Transfer feature.



Automatic Device Updates (via DeviceSet)

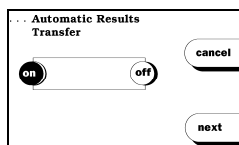
DeviceSet is a PC software application that provides an easy and efficient way to create, modify, restore and manage configuration settings on all IRMA TruPoint analyzers at a site. Settings profiles are established in DeviceSet and may be downloaded to IRMA TruPoint serially, via modem, or over a network. A settings profile is a collection of IRMA TruPoint settings that includes most of the IRMA TruPoint settings that may be established manually via the IRMA TruPoint SETTING OPTIONS menu. There are 2 Automatic Device Update settings:

- **Off:** The IRMA TruPoint Automatic Device Update feature is disabled.
- **On:** IRMA TruPoint analyzers can automatically receive profile updates from DeviceSet, and software and language updates when available.

Automatic device updates occur after IRMA TruPoint results are transferred to *idms* or another connected system. After results are sent, the analyzer requests updates. If updates are available, the transfer will proceed automatically.

Following software upgrades, DeviceSet automatically restores settings in the IRMA TruPoint which would otherwise revert to factory default settings. Configure Automatic Device Updates as follows:

1. Highlight the “on” or “off” button and press **next** to setup the Automatic Results Transfer feature.



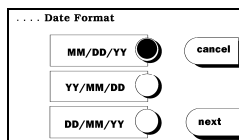
Note:

- QA Users can manually request updates from DeviceSet via the IRMA TruPoint SETTING OPTIONS menu.

DATE FORMAT

There are 3 date format options:

- **MM/DD/YY** (Month/Day/Year)
- **YY/MM/DD** (Year/Month/Day)
- **DD/MM/YY** (Day/Month/Year)

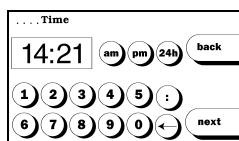
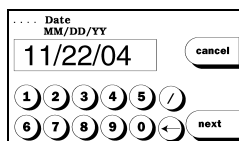


1. Highlight the desired date format. Press **next**.

DATE/TIME

The date and time are appended to each patient and QC test record, error, and printer output.

1. Enter the current Date using the previously established format. Entry of the backslash (/) is required for a valid date format.
2. Enter the current Time in the format hh:mm, and select the appropriate label by pressing **am**, **pm**, or **24h**. Entry of the colon (:) is required for a valid time format (Only QA users have the privilege to edit a date. All other users can change the time).

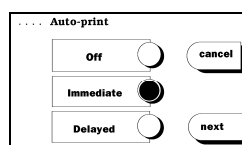


AUTO PRINT

There are 3 auto print options:

- **Off:** Test results do not automatically print upon completion of sample analysis. A printout may be obtained by pressing the **print** button on the *Results* screen.
- **Immediate:** Test results and sample information entered during the test will automatically print upon completion of sample analysis.
- **Delayed:** Test results automatically print when the done button is pressed from the *Results* screen.

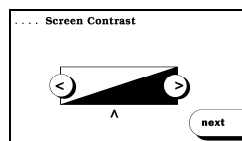
1. Highlight the desired print format. Press **next**.



SCREEN CONTRAST

Screen contrast can be set to different levels for optimal viewing in different ambient light conditions. The first level provides the least contrast between the background and characters; the last level provides the greatest contrast between the background and characters. Screen contrast changes immediately upon pressing the selected contrast setting.

1. Use the left (<) and right (>) arrows to select the optimal contrast setting. Press **next**.

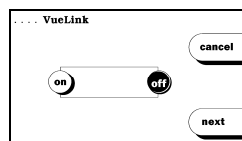


VUELINK

VueLink is an optional module for the Philips/Agilent monitoring system that allows IRMA TruPoint patient test results to be displayed on the Philips/Agilent bedside monitor. There are two IRMA TruPoint VueLink settings:

- **Off:** The IRMA TruPoint VueLink option is disabled. IRMA TruPoint cannot send test results to the patient bedside monitor, even if it is physically connected to a VueLink module.
- **On:** IRMA TruPoint results can be transferred to the patient bedside monitoring system when connected to a VueLink module via the IRMA TruPoint serial port.

1. Highlight the desired VueLink setting. Press **next**.



Appendix A

Limitations and Safety Precautions

This appendix describes limitations of the IRMA TruPoint system.

LIMITATIONS

Measurements on the IRMA TruPoint analyzer are accurate and precise, as shown in Appendix D, Performance Characteristics. However, sources of error can arise from improper collection and handling of blood specimens (pre-analytical errors) and certain physiological conditions.

COMMON SOURCES OF SAMPLING ERRORS

The IRMA TruPoint system was designed to eliminate many pre-analytical errors associated with testing delays and sample storage and processing. Analysis errors can arise from improper collection or handling of blood specimens. These errors can be related to phlebotomy technique, heparin type and concentration, speed of syringe fill, inadequate sample mixing, improper storage of sample, and delays in analysis. The NCCLS Manual is an excellent reference for sample collection and handling.^{1, 6}

The following sources of sampling error should be considered anytime test results are inconsistent with the patient's condition or a previously established trend:

Pre-Analytical Error

- The sample was not analyzed promptly after collection. Glycolysis by leukocytes, platelets, and reticulocytes may cause pCO₂ and ionized calcium values to increase, and pH, pO₂, and glucose values to decrease.⁹
- The sample was not collected anaerobically, resulting in room air contamination. pH, pCO₂, pO₂, and ionized calcium values may change due to exposure to room air.⁹
- A sample was improperly stored.
 - > Samples chilled prior to analysis may result in falsely elevated potassium values due to potassium leakage from erythrocytes and other cells.⁹
 - > Samples for pH and blood gases were not analyzed within 5 minutes of collection, and were stored at room temperature, resulting in value changes.

- Delayed tourniquet release during venipuncture can result in falsely elevated potassium values or dilution effects.
- Hemolysis during sample collection can result in falsely elevated potassium values.
- The sample was drawn in a syringe that is not compatible with the IRMA TruPoint system. See Section 2, Syringe Requirements.
- The sample was not well-mixed prior to sample analysis.
- The sample was not injected forcefully enough to displace the calibrant.
- Improper injection technique introduced bubbles into the sample path; bubbles were not displaced from the sample path prior to analysis phase.

Effects of Physiological Conditions on Test Results

- Blood from patients receiving certain therapeutic treatments, or with certain physiological conditions, can interfere with the performance of blood sensors. Refer to standard documents such as "Effects of Diseases on Clinical Laboratory Tests"² for more information.
- Accuracy of conductivity-based hematocrit measurements are dependent on a specific range of white blood cell count and total protein concentration³. Total protein levels may be low in patients on cardiopulmonary bypass, potentially affecting the conductivity of the sample, and therefore, the hematocrit results.⁷ When a patient comes off cardiopulmonary bypass, they may still be hemodiluted. Each facility should establish protocols to determine when a patient should be considered to no longer be hemodiluted.
- The calculated total hemoglobin (tHb) is based on assumptions which may not apply to some physiological conditions.^{4, 5}
- The calculated parameters for TCO₂, HCO₃⁻, BEb, BEecf, tHb, and O₂Sat are based on assumptions which may not apply to some physiological conditions.^{1, 2}
- The IRMA TruPoint system measures electrolyte ion activity, and automatically adjusts electrolyte results to be consistent with results from indirect methods.⁸ This adjustment is valid only for an assumed activity coefficient and a typical concentration of plasma water.⁵

INTERFERENCES

Interference studies were based on NCCLS EP7-P. Serum or whole blood was spiked with potentially interfering substances. The concentrations tested and the expected effects are shown below.

Chloride

Substance (concentration)	Expected Effect
SCN (17 mmol/L)	Decrease Cl ⁻ by 12 mmol/L

BUN

Substance (concentration)	Expected Effect
SCN (17 mmol/L)	Decrease BUN by 2 mg/dL

Glucose

Substance (concentration)	Expected Effect
Glutathione (1 mg/dL)	Increase glucose by 10% at the 280 mg/dL glucose level
Hydroxy Urea (500 umol/L)	Increase glucose by 100% at the 120 mg/dL glucose level, and by 15% at the 325 mg/dL glucose level
Iodoacetate (900 mg/dL)	Increase glucose by >300% at the 120 mg/dL glucose level, and by 25% at the 330 mg/dL level
Isoniazide (7 mg/dL)	Increase glucose by 10% at the 80 mg/dL glucose level
Pralidoxime Iodide (PAM) (16 mg/dL)	PAM concentrations of 16 mg/dL and higher can significantly affect glucose measurements
Sodium Fluoride (1000 mg/dL)	Decrease glucose by 55% at the 325 mg/dL glucose level, and increase glucose by 100% at the 20 mg/dL level
Thiopental (25 mg/dL) (13 mg/dL)	Decrease glucose by 30 - 40% Decrease glucose by >10%

Creatinine

Substance (concentration)	Expected Effect
Acetaminophen (20 mg/dL)	Increase creatinine by 0.2 mg/dL at creatinine levels <2 mg/dL. Results were variable at levels <8 mg/dL
Creatine (> 5 mg/dL)	Suppressed creatinine levels were observed at creatine levels >5 mg/dL.
Hydroxy Urea (<500 µmol/L)	Decreased creatinine results by approximately 0.2 mg/dL at normal creatinine levels.
Iodoacetate (900 mg/dL)	Decreased creatinine results by approximately 50% at both the 0.9 and 8.7 mg/dL creatinine levels.
Isoniazide (7 mg/dL)	Decreased creatinine results by approximately 15% at the 0.9 mg/dL creatinine level. No effect was observed at the 8.7 mg/dL creatinine level.
Sodium Bromide (100 mg/dL)	Decreased creatinine results by (approximately 25% at the 2 mg/dL creatinine level.
Sodium Fluoride (1000 mg/dL)	Decreased creatinine results by approximately 70% at both the 0.9 and 8.7 mg/dL creatinine levels.
Thiopental (25 mg/dL)	Decreased creatinine results by 25% at both the 0.9 and 8.7 mg/dL creatinine levels.

Lactate

Substance (concentration)	Expected Effect
Acetaminophen (20 mg/dL)	Increase lactate by 40% at lactate levels <18 mg/dL.
Acetaminophen (100 mg/dL)	Increase lactate by 25% at lactate levels <18 mg/dL.
Cysteine (10 mg/dL)	Decreased lactate levels by 30%.
Glycolic Acid (10 mM)	Produces variable results at lactate levels <18 mg/dL.
Hydroxy Urea (500 µmol/L)	Decreased lactate results by approximately 30% at normal lactate levels <18 mg/dL.
Sodium Bromide (200 mg/dL)	Decreased lactate results by approximately 20% at lactate levels <18 mg/dL.
Uric Acid (20 mg/dL)	Decreased lactate results by 20% at lactate levels approximately 72 mg/dL.

SAFETY PRECAUTIONS FOR BLOOD HANDLING

- Use generally accepted techniques for collecting and handling blood [NCCLS: *Standard for the Percutaneous Collection of Arterial Blood for Laboratory Analysis*, 1992, and *Protection of Laboratory Workers From Infectious Disease Transmitted by Blood, Body Fluid and Tissue*, Second Edition, Tentative Guideline (1991)].
- Both the cartridge and the collection device should be disposed of in a biohazard container.
- Collection device and cartridge may have to be separated before disposal if small medical waste containers are used.

OTHER SAFETY PRECAUTIONS

- Do not place metallic objects on or near the battery charger; electrical shock or charger damage could result.
- Do not immerse the analyzer, battery, or battery charger in water or any other liquid.
- Use only ITC batteries with the IRMA TruPoint analyzer.
- Do not operate the battery charger if the power cord or plug is damaged.
- Prevent liquid cleaning solution from entering the battery charger or analyzer battery compartment.
- Disconnect the battery charger before cleaning to prevent accidental shock.
- Do not allow battery contacts to touch metal objects.
- Battery charger is not intended for use in immediate patient vicinity.

REFERENCES

1. National Committee for Clinical Laboratory Standards (NCCLS): Percutaneous collection of arterial blood for laboratory analysis, Document H11-A 1985.
2. "Effects of diseases on clinical laboratory tests", *Clinical Chemistry* 1980, 6:4.
3. McMahon et. al., " A Comparison of Conductivity-Based Hematocrit Determinations With Conventional Laboratory Methods in Autologous Blood Transfusions", *ANESTH ANALG*, 1990;71:541-4.
4. Henry et. al., *Clinical Diagnosis and Management by Laboratory Methods*, 16th ed., Philadelphia, PA. W.B. Saunders and Co. 1983.

5. Oesch et. al., "Ion-Selective Electrodes for Clinical Use", *Clinical Chemistry*, 1986, vol 32, no 8, p.1448.
6. National Committee for Clinical Laboratory Standards (NCCLS): *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture*, Document H3-A 3,1991.
7. Riley JB, Burgess BM, Smith CA, Crowley JC, Soronen SW: In vitro measurement of the accuracy of a new patient side blood gas, pH, hematocrit and electrolyte monitor, *J Extra Corpor Technol* 19(3):322-329, 1987.
8. Maas et. al., "Ion Selective Electrodes for Sodium and Potassium: A New Problem of What is Measured and What Should be Reported", *Clinical Chemistry*, Vol 31, no. 3, 1985 p 482.
9. Burtis CA, Ashwood ER eds., *Tietz Fundamentals of Clinical Chemistry*, 5th ed., 2001.

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Appendix B

System Specifications and Cartridge Information

This appendix includes IRMA TruPoint system specifications and IRMA TruPoint cartridge information.

SYSTEM SPECIFICATIONS


General Specifications

Table B-1

<u>Category</u>	<u>Specification</u>
Operating Temperature:	12–30°C (54–86°F)
Measurement Temperature:	37°C (Blood gases)
Analyzer Shipping/Storage Temperature:	0–50°C
Operating Relative Humidity:	0–80% (non-condensing)
Operating Barometric Pressure:	350–900 mmHg (measured by an onboard barometer)
Sample Size:	0.125 –5.0 mL
Analysis time:	Approximately 60 to 300 seconds after sample injection (depends on parameters)
Size (LxWxH) and Weight:	
Cartridge/Temperature Card:	2.6" x 1.3" x 0.6"; 0.5–0.7 oz. 66 x 33 x 15.24mm; 15–21 g
Analyzer:	11.5" x 9.5" x 5"; 5 lbs., 4 oz. 292.1 x 241.3 x 127mm; 2381g
Battery Charger/Power Supply:	7.5" x 3.5" x 3.5"; 2 lbs. 190.5 x 89 x 89mm; 907g
Rechargeable Battery:	6.25" x 2.25" x 1.25"; 14 oz. 159 x 57 x 32mm; 397g


General Specifications, continued

Table B-1

<u>Category</u>	<u>Specification</u>
Display:	Liquid Crystal Display (LCD) touch screen
Power Requirements:	
Cartridges:	none
Analyzer:	7.2 V, 2 amp by rechargeable battery or AC adapter
Battery Charger/Power Supply:	100 - 240 Vac, 1 Amp, 50 - 60 Hz; The battery charger is a Class 1LED Product
AC Adapter:	100 - 240 Vac, 1.0 Amps, 50 - 60 Hz
Empty Battery Recharge Cycle:	2.5-7 hours (NiMH)
 Analyzer and AC Adapter Classifications:	When used at the bedside either with battery or AC Adapter, Equipment Classifications As Defined Per IEC60601-1:2003/ IEC60601-1 2nd Edition
	<ul style="list-style-type: none"> • Protection Against Electrical Shock: Class II, Internally Powered Equipment with no applied parts • Protection Against Ingress of Liquids: Ordinary (no protection as defined by IEC 529) • Product Cleaning and Disinfection: Only according to recommendations of the manufacturer's accompanying documentation • Mode of Operation Of Equipment: Short-time • Degree of Safety of Application in the Presence of Flammable Anesthetic Mixture With Air, Oxygen or Nitrous Oxide: Not Suitable
Note:	<ul style="list-style-type: none"> • as defined in the above standards, the classification of Not Suitable is not intended to indicate that the instrument is not suitable for use in an Operating Room (OR) environment. Rather, it is intended to indicate that the instrument is not suitable for use in the direct presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide.
Device Disposal (at end-of useful life):	<p>The analyzer and accessories may be returned to ITC.</p> <p>Nickel Metal Hydride (NiMH) batteries are classified as a non-hazardous waste and should be disposed of in accordance with the local, state, or federal regulations where they are used. Contact your local government for disposal practices in your area. Although NiMH batteries are considered environmentally friendly, they may also be recycled. Recycling options available in your local area should be considered when disposing of this product or batteries may be returned to ITC for recycling.</p>

Environmental Conditions for Vac - Powered Equipment

Table B-2

	The AC adapter and battery charger are intended for indoor use and operation. They should be transported and used within the following conditions.
Temperature Range:	5 - 40 °C (41 - 104°F)
Relative Humidity Range:	0 - 80%
Voltage and frequency fluctuations:	No greater than ±10% of the main power source

Electromagnetic Emissions and Immunity, continued

Table B-3

<ul style="list-style-type: none"> • CISPR 11 (1997), w/A1: 1999 (Class B Group 1) • EN 55011 / 1998, w/A1: 1999 & A2: 2002 (Class B Group 1) • EN 60601-1-2: 2001 - Emission Requirements This equipment has been tested and found to comply with the limits for medical devices to EN 60601-1-2: 2001. This testing shows that the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures: <ul style="list-style-type: none"> - reorient or relocate the devices - increase the separation between the devices - connect the equipment to an outlet on a different circuit - consult the manufacturer or field service technician for help <p>Equipment connected to the serial port must comply with the respective IEC standards (e.g., IEC 950 for data processing equipment and IEC 601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 601-1-1. Anybody who connects additional equipment to the signal input or output part is considered to be configuring a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 601-1-1. If in doubt, consult the technical service department or your local representative.</p> <ul style="list-style-type: none"> • IEC 1000-4-2: 1995 / EN 61000-4-2: 1995 • IEC 1000-4-3: 2002 / EN 61000-4-3: 2002 • IEC 1000-4-4: 1995 / EN 61000-4-4: 1995 • IEC 1000-4-5: 1995 / EN 61000-4-5: 1995 • IEC 1000-4-6: 1996 / EN 61000-4-6: 1999 • IEC 1000-4-8: 1993 / EN 61000-4-8: 1994 • IEC 1000-4-11: 1994 / EN 61000-4-11: 1994 • Part 68 FCC Regulations • Use in aircraft: the use of IRMA TruPoint with an unterminated distal end of a data transmission cable will result in emissions that exceed FAA radiative emissions test RTCADO 160C.










Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The IRMA TruPoint Blood Analysis System AC adapter is intended for use in the electromagnetic environment specified below. The customer or the user of the IRMA TruPoint Blood Analysis System AC adapter should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The IRMA TruPoint Blood Analysis System AC adapter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The IRMA TruPoint Blood Analysis System AC adapter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The IRMA TruPoint Blood Analysis System AC adapter is intended for use in the electromagnetic environment specified below. The customer or the user of the IRMA TruPoint Blood Analysis System AC adapter should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical domestic, commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T for 0.5 cycle) 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T for 0.5 cycle) 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the IRMA TruPoint Blood Analysis System AC adapter requires continued operations during power mains interruptions, it is recommended that the IRMA TruPoint Blood Analysis System AC adapter be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Symbol Definitions

Definitions for symbols that appear on IRMA TruPoint product labels are shown in Table B-4.

Table B-4

<u>Symbols</u>	<u>Definition</u>
	Batch code
REF	Catalogue number
	Caution, refer to accompanying documents
	Consult instructions for use
	Do not re-use
IVD	In vitro diagnostic medical device
	Manufactured by
SN	Serial number
	Temperature limitation
	Use by
	Class II Electrical Shock Protection
	Name and address of authorized representative in the European Community (EU)

Patents

Table B-5

<p>The IRMA TruPoint Blood Analysis System is manufactured under one or more of the following patents: 5,232,667; D351,910; and 6,066,243.</p> <p>IRMA TruPoint cartridges are manufactured under one or more of the following patents: 5,223,433; 5,325,853; 5,384,031; 5,781,024; D351,913; 5,968,329.</p> <p>Other patents pending.</p>
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CARTRIDGE/ANALYTE CONFIGURATIONS

IRMA TruPoint cartridges are available in the following analyte configurations:

Table B-6

Cartridge	Measured	Calculated
BG	pH, pCO ₂ , pO ₂	HCO ₃ ⁻ , TCO ₂ , BEb, BEecf, O ₂ Sat
CC	pH, pCO ₂ , pO ₂ , Hct, Na ⁺ , K ⁺ , iCa	HCO ₃ ⁻ , TCO ₂ , BEb, BEecf, O ₂ Sat, tHb, iCa(N)
H3	Hct, Na ⁺ , K ⁺ , iCa	tHb
H4	Hct, Na ⁺ , K ⁺ , Cl ⁻ , BUN/urea	tHb
GL	Glu, Na ⁺ , K ⁺ , Cl ⁻	
CR	Creatinine	MDRD GFR
LA	Lactate	

CARTRIDGE EQUILIBRATION TIMES

Following removal from their shipping container, IRMA TruPoint cartridges must equilibrate to their storage environment prior to use (see Section 1-Cartridge Storage and Equilibration Procedure). Equilibration times depend on the product type as follows:

Table B-7

<u>Cartridge</u>	<u>Equilibration Time (Hours)</u>	<u>Storage Temperature</u>	<u>Warm-up Time (Minutes)</u>
BG	72	15 - 30 °C (59 - 86°F)	None
CC	72	15 - 30 °C (59 - 86°F)	None
H3	1	15 - 30 °C (59 - 86°F)	None
H4	1	15 - 30 °C (59 - 86°F)	None
GL	1	15 - 30 °C (59 - 86°F)	None
CR	None	2 - 8 °C (35.6 – 46.4°F)	15
LA	1	15 - 30 °C (59 - 86°F)	None

Refrigerated cartridges must be removed from the refrigerator and sit at room temperature before they can be used (Table B-7).

REPORTABLE RANGES

The default reportable ranges for each parameter are shown in Table B-8*:

Table B-8

Measured	
pH	6.000 - 8.000 pH units
pCO ₂	4.0 - 200.0 mmHg (0.53 - 26.66 kPa)
pO ₂	20.0 - 700.0 mmHg (2.67 - 93.33 kPa)
Hct	10.0 - 80.0 % (.100 - .800 SI)
Na ⁺	80.0 - 200.0 (mM, mEq/L)
K ⁺	1.00 - 20.00 (mM, mEq/L)
iCa	0.20 - 5.00 mM (0.80 - 20.04 mg/dL; 0.40 - 10.00 mEq/L)
Cl ⁻	30.0 - 150.0 (mM, mEq/L)
BUN/urea	
BUN	3 - 150 mg/dL (1.1 - 53.5 mM)
Urea	6 - 321 mg/dL (1.1 - 53.4 mM)
Glu	20 - 500 mg/dL (1.1 - 27.8 mM)
Creatinine	0.2 - 12 mg/dL (18 - 1061 μmol/L)
Lactate	0.30 - 12 mmol/L (2.7 - 108 mg/dL)
Calculated	
HCO ₃ ⁻	0 - 99.9 mM
TCO ₂	0 - 99.9 mM
Beb	±99.9 mM
Beecf	±99.9 mM
O ₂ Sat	0 - 100%
tHb	3.4 - 27.2 g/dL (2.1 - 16.9 mM)
iCa(N)	0.20 - 5.00 mM (0.80 - 20.04 mg/dL; 0.40 - 10.00 mEq/L)
*Note: "mM" is the IRMA TruPoint display abbreviation for "mmol/L".	

DISPLAY RESOLUTION

The display resolution for each parameter is as follows*:

Table B-9

<u>Measured</u>		<u>Calculated</u>	
pH	0.001 pH units	HCO ₃ ⁻	0.1 mM
pCO ₂	0.1 mmHg (0.01 kPa)	TCO ₂	0.1 mM
pO ₂	0.1 mmHg (0.01 kPa)	Beb	0.1 mM
Hct	0.1% (.001 SI)	Beecf	0.1 mM
Na ⁺	0.1 (mM , mEq/L)	O ₂ Sat	0.1 %
K ⁺	0.01 (mM , mEq/L)	tHb	0.1 (mM, g/dL)
iCa	0.01 (mM , mEq/L, mg/dL)	iCa(N)	0.1 (mM , mEq/L, mg/dL)
Cl ⁻	0.1 (mM , mEq/L)		
BUN/urea	1 mg/dL (0.1 mM)		
Glucose	1 mg/dL (0.1 mM)		
Creatinine	0.01 mg/dL (1 μmol/L)	MDRD GFR	10.00 (mL / min/1.73m ²)
Lactate	0.1 (mM ,mg/dL)		

* Note: “mM” is the IRMA TruPoint display abbreviation for “mmol/L”. Default display units are bolded.

CORRELATION FACTOR LIMITS

Refer to Section 7-Correlation for a description of the correlation feature and instructions. Correlation factors must be within the following limits:

Table B-10

<u>Parameter</u>	<u>Slope</u>	<u>Intercept</u>
pH	0 to 10.000	-9.9999 to +9.9999
pCO ₂	0 to 10.000	-999.99 to +999.99 mmHg -133.32 to +133.32 kPa
pO ₂	0 to 10.000	-999.99 to +999.99 mmHg -133.32 to +133.32 kPa
Na ⁺	0 to 10.000	-999.99 to +999.99 mM, mEq/L
K ⁺	0 to 10.000	-9.999 to +9.999 mM, mEq/L
iCa	0 to 10.000	-9.999 to +9.999 mM -20.00 to +20.0 mEq/L -40.08 to +40.08 mg/dL
Cl ⁻	0 to 10.000	-999.99 to +999.99 mM, mEq/L
Hct	0 to 10.000	-999.00 to +999.00 (%) -9.9900 to +9.9900 SI
BUN	0 to 10.000	-999.9 to +999.9 mg/dL -356.96 to +356.96 mM
Urea	0 to 10.000	-2139.8 to +2139.8 mg/dL -356.27 to +356.27 mM
Glucose	0 to 10.000	-999.9 to +999.9 mg/dL -55.55 to +55.55 mM
Creatinine	0 to 10.000	-99.999 to +9.999 mg/dL -8839.9 to +8839.97 μmol/L
Lactate	0 to 10.000	-99.99 to +99.99 mM -899.91 to +899.91 mg/dL

REFERENCE VALUES

While published values represent the general population, each laboratory should establish its own “normal” values which reflect the local patient population and equipment used at the site. The following published ranges should only serve as a guide.^{1,2}

Table B-11

<u>Measured</u>	<u>Reference Range</u>
pH:	7.35-7.45 (arterial) ¹ ; 7.32-7.43 (venous) ¹
pCO ₂ :	35-48 mmHg/4.7-6.4 kPa (arterial) ¹ ; 41-55 mmHg/5.5-7.3 kPa (venous) ¹
pO ₂ :	83-108 mmHg/11.1-14.4 kPa (arterial) ¹
Sodium:	136-145 mmol/L or mEq/L ¹
Potassium:	3.5-5.1 mmol/L or mEq/L ¹
Ionized Calcium:	1.15-1.27 mmol/L (2.30-2.54 mEq/L) (4.60-5.08 mg/dL) ¹
Chloride:	98-107 mmol/L or mEq/L ¹
BUN/Urea:	5-23 mg/dL (1.8-8.2 mmol/L urea) ¹
Glucose:	30-60 mg/dL; 1.7-3.3 mmol/L (neonate) ¹ 60-100 mg/dL; 3.3-5.6 mmol/L (child) ¹ 74-106 mg/dL; 4.1-5.9 mmol/L (adult) ¹ (Concentration of glucose is higher in arterial than in venous samples) ¹
Creatinine:	0.3-1.0 mg/dl; 27-88 μmol/l (neonate) ¹ 0.2-0.4 mg/dl; 18-35 μmol/l (infant) ¹ 0.3-0.7 mg/dl; 27-62 μmol/l (child) ¹ 0.5-1.0 mg/dl; 44-88 μmol/l (adolescent) ¹ 0.9-1.3 mg/dl; 80-115 μmol/l (adult male 18-60 years) ¹ 0.6-1.1 mg/dl; 53-97 μmol/l (adult female 18-60 years) ¹
Hematocrit:	32-42% (2-6 years); 33-45% (6-14 years) ¹ 39-51% (adult male); 35-47% (adult female) ¹
Lactate:	0.5 - 1.6 mmol/L; 4.5 - 14.4 mg/dL (arterial) ¹ 0.5 - 2.2 mmol/L; 4.5 - 19.8 mg/dL (venous) ¹

<u>Calculated</u>	<u>Reference Range</u>
HCO ₃ ⁻ :	22-26 mmol/L (arterial) ¹ ; 21-28 mmol/L (venous) ³
TCO ₂ :	19-24 mmol/L (arterial) ¹ ; 22-29 mmol/L (venous) ³
BE:	(-2) - (+3) mmol/L (arterial or venous) ¹
O ₂ Sat:	94-98% (arterial) ¹ ; 60-85% (venous) ²
tHb:	11.0-14.5 g/dL or 6.9-9.1 mmol/L (2-9 years) ¹ 12.0-15.0 g/dL or 7.5-9.4 mmol/L (9-12 years) ¹ 11.7-17.4 g/dL or 7.4-10.9 mmol/L (12-74 years, male) ¹ 11.5-16.1 g/dL or 7.2-10.1 mmol/L (12-74 years, female) ¹
MDRD GFR ⁴ :	Age (Years): Average GFR
	20-29 : 116 mL/min/1.73 m ²
	30-39 : 107 mL/min/1.73 m ²
	40-49 : 99 mL/min/1.73 m ²
	50-59 : 93 mL/min/1.73 m ²
	60-69 : 85 mL/min/1.73 m ²
	70+ : 75 mL/min/1.73 m ²

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4. Coresh J, Astor B, Greene T, Eknoyan G, Levey A, Prevalence of chronic kidney disease and decreased kidney function in the adult US population: Third national health and nutrition examination survey. Am J of Kidney Disease, 41 (1) 1-12.

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Appendix C

Principles of Operation

This appendix describes the measurement technology of the IRMA TruPoint blood analysis system.

MEASUREMENT TECHNOLOGY

The IRMA TruPoint system utilizes potentiometric, amperometric, and conductimetric measurement methodologies to measure the analyte concentration in whole blood as described in the following table.

<u>Sensor</u>	<u>Measurement Technology</u>
reference	silver/silver chloride electrode
pH, pCO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , iCa, BUN/urea	potentiometric measurement utilizing ion specific electrode (ISE) technology ¹⁴ ; for the BUN/urea sensor, the NH ₄ ⁺ generated from the reaction of urea with urease is detected
pO ₂	amperometric measurement based on the principles of the Clark electrode ¹³
hematocrit	conductimetric measurement
glucose	amperometric measurement; the H ₂ O ₂ generated from the reaction of glucose with glucose oxidase is detected
creatinine	amperometric measurement; the H ₂ O ₂ generated from the enzymatic reaction of sarcosine (as produced by the enzymatic reaction of creatinine in the presence of creatinine amidohydrolase and creatine in the presence of creatine amidohydrolase) in the presence of sarcosine oxidase is detected
Lactate	amperometric measurement; the H ₂ O ₂ generated from the reaction of lactate with lactate oxidase is detected

Potentiometric measurements

The IRMA TruPoint potentiometric sensors generate a voltage which is related to ion concentration according to the Nernst equation:

$$E = E^{\circ} + S \log (C1/C2)$$

- > E is the voltage generated
- > E° is a constant for the sensor
- > S is the sensitivity of the sensor
- > C1 and C2 are the ion activities outside and inside the sensor membrane.

The IRMA TruPoint system uses direct (undiluted) measurement methods. Differences are known to exist between direct and indirect (diluted) methods due to the measurement of ion activity rather than concentration¹. Direct measurements read up to 7% higher than indirect methods for electrolytes because of the excluded volume occupied by plasma proteins and lipids. The IRMA TruPoint system measures electrolyte ion activity, and has been calibrated to agree with standard laboratory reference methods that are performed on plasma or serum².

Amperometric measurements

The IRMA TruPoint amperometric sensors generate a current which is related to analyte concentration according to the relationship:

$$i = S (C) + B$$

- > i is the current generated
- > C is the analyte concentration or partial pressure of the test sample
- > B is the current generated in the absence of the analyte

Whole blood glucose measurements are approximately 12% to 15% lower than plasma concentrations¹⁵. The IRMA TruPoint system measures glucose concentrations in whole blood, and has been calibrated to agree with standard laboratory reference methods that are performed on plasma or serum.

Conductimetric measurements

The IRMA TruPoint analyzer determines hematocrit based on electrical conductivity, which is related to hematocrit in whole blood:

$$\% \text{ hematocrit} = f (1 / \Omega)$$

- > Ω = sample resistance
- > conductivity = $1 / \Omega$

CALCULATED PARAMETERS

Other parameters can be calculated by the IRMA TruPoint analyzer based on the measured values of a blood sample. See Appendix B, Table B- 8 for the list of calculated parameters reported by the IRMA TruPoint system. The following equations are used to calculate each of the parameters:

Bicarbonate ^{3,11}

Two formulas are available for the calculation of bicarbonate: **Severinghaus/NCCLS** or **Siggaard-Andersen**. Refer to Section 7-Calculations for instructions on formula selection.

Severinghaus/NCCLS formula is based on the Henderson Hasselbach equation:

$$[\text{HCO}_3^-] = 0.0307 \times \text{pCO}_2 \times 10^{(\text{pH}-6.1)}$$

Siggaard-Andersen formula:

$$[\text{HCO}_3^-] = 0.230 \times \text{pCO}_2 \times \text{antilg}(\text{pH}-\text{pKp})$$

$$\text{pKp} = 6.125 - \lg\{1 + \text{antilg}(\text{pH}-8.7)\}$$

Total Carbon Dioxide ^{3,11}

Total carbon dioxide, $[\text{TCO}_2]$, is the sum of bicarbonate and dissolved CO_2 .

$$\text{TCO}_2 = [\text{H}_2\text{CO}_3] + [\text{HCO}_3^-]$$

Severinghaus/NCCLS Bicarbonate formula:

$$[\text{H}_2\text{CO}_3] = 0.0307 \times \text{pCO}_2 \text{ or}$$

$$\text{TCO}_2 = 0.0307 \times \text{pCO}_2 + [\text{HCO}_3^-]$$

Siggaard-Andersen Bicarbonate formula:

$$[\text{H}_2\text{CO}_3] = 0.230 \times \text{pCO}_2 \text{ or}$$

$$\text{TCO}_2 = 0.230 \times \text{pCO}_2 + [\text{HCO}_3^-]$$

Base Excess of Blood ^{4,12}

Base excess of blood, (BEb), also called in vitro or actual base excess, is the difference in concentration of strong base in whole blood and in the same blood titrated with strong acid or base to pH=7.40/pCO₂=5.33kPa at 37°C.

Two formulas are available for the calculation of base excess: **Severinghaus/NCCLS** or **Siggaard-Andersen**. Refer to Section 7- Calculations for instructions on formula selection.

Severinghaus/NCCLS formula:

$$\text{BEb} = (1 - 0.014 \times \text{Hb}) [\text{HCO}_3^- - 24.8 + (1.43 \times \text{Hb} + 7.7)(\text{pH} - 7.4)]$$

> Hb is the hemoglobin value entered

Siggaard-Andersen formula:

$$\text{BEb} = \frac{0.5(8a' - 0.919)}{a'} + \frac{0.5[(0.919 - 8a')^2 - 4(24.47 - \text{HCO}_3^- \{5.33\})]}{a'}^{1/2}$$

> $a' = 0.00404 + 0.000425 \times \text{Hb}$

> $\text{HCO}_3^- (5.33) = 0.230 \times 5.33 \times \text{antilg}[(\text{pH}(\text{st}) - 6.161) / 0.9524]$

> $\text{pH}(\text{st}) = \text{pH} + \text{lg}(5.33 / \text{pCO}_2) \times [\text{pH}(\text{Hb}) - \text{pH}] / [\text{lg}(\text{pCO}_2 (\text{Hb})) - \text{lg}(7.5006 \times \text{pCO}_2)]$

> $\text{pH}(\text{Hb}) = 0.0406 \times \text{Hb} + 5.980 - 1.920 \times \text{antilg}(-0.16169 \times \text{Hb})$

> $\text{lg}(\text{pCO}_2 (\text{Hb})) = -0.017674 \times \text{Hb} + 3.4046 + 2.12 \times \text{antilg}(-0.15158 \times \text{Hb})$

Base Excess of Extracellular Fluid ^{5,11}

Base excess of extracellular fluid (BEecf), also called in vivo base excess, or standard base excess, is a quantity that reflects only the non-respiratory component of pH disturbances. Two formulas are available for the calculation of base excess: **Severinghaus/NCCLS** or **Siggaard-Andersen**. Refer to Section 7-Calculations for instructions on formula selection.

Severinghaus/NCCLS formula:

$$\text{BEecf} = [\text{HCO}_3^-] - 24.8 + 16.2(\text{pH} - 7.4)$$

Siggaard-Andersen formula:

$$\text{BEecf} = \text{BEb for Hb} = 3 \text{ mmol/L}$$

Oxygen Saturation⁶

Oxygen saturation (O₂Sat) is the amount of oxyhemoglobin in a solution expressed as a fraction of the total amount of hemoglobin able to bind oxygen (oxyhemoglobin plus deoxyhemoglobin). The IRMA TruPoint analyzer calculates oxygen saturation from a measured pO₂ and an assumed oxyhemoglobin dissociation curve. These results differ significantly from direct measurement. Clinically significant errors can result from incorporation of this calculated value in further calculations, such as shunt fraction, or by assuming that the value obtained is equivalent to the oxyhemoglobin fraction.

$$\text{O}_2\text{Sat} = \frac{100 [(p\text{O}_2)'^4 - 67.07(p\text{O}_2)'^3 + 2121(p\text{O}_2)'^2 - 8532 \times p\text{O}_2']}{[(p\text{O}_2)'^4 - 67.07(p\text{O}_2)'^3 + 2396(p\text{O}_2)'^2 - 31350 \times p\text{O}_2' + 936000]}$$

› pO₂' = pO₂ × 10^[0.48(pH-7.4)]

Total Hemoglobin

Total Hemoglobin (tHb) is estimated from % hematocrit using the following equation:

$$\text{tHb (g/dL)} = \% \text{ Hct} \times \text{MCHC} / 100$$

› MCHC, Mean Corpuscular Hemoglobin Concentration, is assumed to be 34 g/dL.

$$\text{› tHb(mM)} = \frac{\text{tHb(g/dL)}}{1.6114}$$

pH Normalized Ionized Calcium

pH Normalized iCa results can be reported for pH values between 7.2 and 7.6. pH Normalized iCa results represent the iCa result normalized to a pH value of 7.400 using the following equation:

$$\text{iCa(N)} = \text{iCa}(1 - [0.53 \times (7.4 - \text{pH})])$$

Patient Temperature Correction^{7, 8, 9, 10}

Patient temperature can be entered into the IRMA TruPoint analyzer if it deviates from 37°C. The measured pH and blood gas values are recalculated at the input temperature (T) with the following equations:

$$\begin{aligned} \text{pH}_{(T)} &= \text{pH}_{(37^\circ\text{C})} - 0.0147(T-37) + 0.0065(7.40 - \text{pH}_{(37^\circ\text{C})})(T-37) \\ \text{pCO}_{2(T)} &= \text{pCO}_{2(37^\circ\text{C})} \times 10^{(0.019)(T-37)} \\ \text{Severinghaus pO}_2 \text{ equation:} \\ &\left\{ \left[\frac{5.49 \times 10^{-11} \times \text{pO}_2^{3.88} + 0.071}{9.72 \times 10^{-9} \times \text{pO}_2^{3.88} + 2.30} \right] (\Delta \text{Temp}) \right\} \\ \text{pO}_{2\text{Final}} &= \text{pO}_2 \times 10 \\ &> \Delta \text{Temp is } T-37^\circ \\ \text{Kelman-Nunn pO}_2 \text{ equation:} \\ \text{pO}_{2\text{Final}} &= \text{pO}_2 \times 10^{\{0.0052 + 0.027(1-10^{-0.13(100-\text{O}_2\text{Sat})})\}} (\Delta \text{Temp}) \\ &> \Delta \text{Temp is } T-37^\circ \end{aligned}$$

MDRD GFR

MDRD GFR (mL/min/1.73m²) = 186 X (CR*)^{-1.154} x (age^{**})^{-0.203} X (0.742 if female) x (1.21 if black) mg/dL

* = mg/dL

** = years

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Appendix D

Performance Characteristics

ACCURACY

Accuracy was determined by analyzing human whole blood samples on both the IRMA TruPoint blood analysis system and a reference method. Least squares analysis was used to determine the line-of-best-fit.

pH

Number of samples:	94
Range evaluated:	6.860 - 7.710
Slope:	0.936
Intercept:	0.456
Correlation Coefficient (r):	0.997
Sy.x:	0.017

pCO₂

Number of samples:	94
Range evaluated (mmHg):	4.4 - 149.4
Slope:	0.972
Intercept:	0.308
Correlation Coefficient (r):	0.999
Sy.x:	1.88

pO₂

Number of samples:	94
Range evaluated (mmHg):	17.9 - 356.5
Slope:	0.996
Intercept:	1.494
Correlation Coefficient (r):	0.999
Sy.x:	2.91

Sodium (Na⁺)

Number of samples:	137
Range evaluated (mM):	86.0 - 168.0
Slope:	1.110
Intercept:	-22.71
Correlation Coefficient (r):	0.998
Sy.x:	2.14

ACCURACY - CONTINUED

Potassium (K⁺)

Number of samples:	137
Range evaluated (mM):	1.5 - 13.8
Slope:	0.961
Intercept:	-0.033
Correlation Coefficient (r):	0.999
Sy.x:	0.217

Ionized Calcium (iCa)

Number of samples:	137
Range evaluated (mM):	0.80 - 5.70
Slope:	1.019
Intercept:	-0.063
Correlation Coefficient (r):	0.997
Sy.x:	0.136

Chloride (Cl⁻)

Number of samples:	56
Range evaluated (mM):	74.8 - 136.4
Slope:	0.956
Intercept:	4.64
Correlation Coefficient (r):	0.986
Sy.x:	3.0

Hematocrit (Hct)

Number of samples:	137
Range evaluated (%):	22.0 - 60.5
Slope:	0.883
Intercept:	2.645
Correlation Coefficient (r):	0.978
Sy.x:	2.45

Blood Urea Nitrogen (BUN)

Number of samples:	56
Range evaluated (mg/dL):	12.5 - 74.6
Slope:	0.985
Intercept:	0.46
Correlation Coefficient (r):	0.995
Sy.x:	1.9

ACCURACY - CONTINUED

Glucose (Glu)

Number of samples:	37
Range evaluated (mg/dL):	19 -338
Slope:	0.970
Intercept:	5.47
Correlation Coefficient (r):	0.992
Sy.x:	11.08

Creatinine (Cr)

Number of samples:	110
Range evaluated (mg/dL):	0.5 - 10.1
Slope:	0.940
Intercept:	0.16
Correlation Coefficient (r):	0.981
Sy.x:	0.55

Lactate (LA)

Number of samples:	117
Range evaluated (mmol/L):	1.1-11.5
Slope:	0.959
Intercept:	-0.032
Correlation Coefficient (r):	0.98
Sy.x:	0.46

PRECISION

Precision was performed on commercially available liquid control solutions. Typical precision was observed as follows.

<u>pH</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Day 1			
Number of samples:	15	15	15
Mean:	7.228	7.416	7.631
SD:	0.007	0.005	0.011
CV (%):	0.1	0.1	0.2

Day 2			
Number of samples:	15	15	15
Mean:	7.228	7.414	7.625
SD:	0.006	0.005	0.008
CV (%):	0.1	0.1	0.1

<u>pCO₂</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Day 1			
Number of samples:	15	15	15
Mean (mmHg):	70.7	38.5	17.7
SD:	2.2	1.7	0.7
CV (%):	3.1	4.3	3.7

Day 2			
Number of samples:	15	15	15
Mean (mmHg):	71.4	39.1	18.1
SD:	3.4	0.7	0.5
CV (%):	4.7	1.7	2.8

<u>pO₂</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Day 1			
Number of samples:	15	15	15
Mean (mmHg):	71.9	99.4	163.8
SD:	2.9	1.9	2.3
CV (%):	4.0	1.9	1.4

Day 2			
Number of samples:	15	15	15
Mean (mmHg):	70.9	101.1	165.9
SD:	2.4	1.6	2.1
CV (%):	3.3	1.6	1.3

PRECISION - CONTINUED

<u>Na⁺</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
Day 1				
Number of samples:	14	16	15	14
Mean (mM):	99.5	120.4	153.1	130.8
SD:	1.9	2.9	1.6	2.3
CV (%):	1.9	2.4	1.1	1.8

Day 2				
Number of samples:	15	14	15	15
Mean (mM):	100.6	120.9	152.3	131.3
SD:	1.9	1.6	1.8	2.1
CV (%):	1.9	1.4	1.2	1.6

<u>K⁺</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
Day 1				
Number of samples:	14	16	15	14
Mean (mM):	1.76	3.93	5.74	6.03
SD:	0.037	0.080	0.103	0.105
CV (%):	2.1	2.0	1.8	1.7

Day 2				
Number of samples:	15	14	15	15
Mean (mM):	1.79	3.96	5.76	6.06
SD:	0.028	0.066	0.098	0.106
CV (%):	1.6	1.7	1.7	1.8

<u>iCa</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
Day 1				
Number of samples:	14	16	15	14
Mean (mM):	1.41	1.05	0.52	1.01
SD:	0.020	0.011	0.008	0.020
CV (%):	1.4	1.0	1.6	2.0

Day 2				
Number of samples:	15	14	15	15
Mean (mM):	1.42	1.05	0.52	1.00
SD:	0.023	0.013	0.014	0.027
CV (%):	1.6	1.2	2.8	2.7

PRECISION - CONTINUED

<u>Cl⁻</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Day 1			
Number of samples:	15	15	14
Mean (mM):	30.5	56.9	86.6
SD:	0.72	0.36	1.2
CV (%):	2.4	0.6	1.4
Day 2			
Number of samples:	14	15	14
Mean (mM):	30.4	57.1	85.8
SD:	0.65	0.24	1.6
CV (%):	2.1	0.4	1.9
Hct	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Day 1			
Number of samples:	14	16	14
Mean (%PCV):	38.8	22.7	46.9
SD:	1.17	2.52	1.16
CV (%):	3.0	11.1	2.5
Day 2			
Number of samples:	15	14	15
Mean (%PCV):	37.8	22.4	47.2
SD:	0.97	1.57	1.31
CV (%):	2.6	7.0	2.8
BUN	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Day 1			
Number of samples:	15	15	14
Mean (mg/dL):	17.6	34.3	64.7
SD:	1.76	2.77	3.82
CV (%):	10.0	8.1	5.9
Day 2			
Number of samples:	15	15	15
Mean (mg/dL):	17.1	33.8	67.9
SD:	1.25	2.09	2.63
CV (%):	7.3	6.2	3.9

PRECISION - CONTINUED

<u>Glu</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Level 4</u>
Day 1				
Number of samples:	11	12	12	12
Mean (mg/dL):	48.2	102.7	200.7	353.4
SD:	3.54	6.16	6.90	18.96
CV (%):	7.3	6.0	3.4	5.4
Day 2				
Number of samples:	12	11	12	12
Mean (mg/dL):	48.6	105.9	203.3	351.7
SD:	2.17	3.01	7.53	9.19
CV (%):	4.5	2.8	3.7	2.6
Day 3				
Number of samples:	12	12	12	12
Mean (mg/dL):	47.6	103.7	194.5	351.2
SD:	2.54	2.75	7.68	19.75
CV (%):	5.3	2.7	3.9	5.8
Day 4				
Number of samples:	12	11	12	11
Mean (mg/dL):	47.2	101.9	196.2	349.9
SD:	2.97	3.22	7.81	20.14
CV (%):	6.3	3.1	4.0	5.8
Day 5				
Number of samples:	12	12	12	12
Mean (mg/dL):	46.7	101.0	198.1	350.5
SD:	3.01	5.80	7.00	16.77
CV (%):	6.4	5.7	3.5	4.8

PRECISION - CONTINUED

<u>Cr</u>	<u>Level 1</u>	<u>Level 2</u>	
<u>Day 1</u>			
Number of samples:	12	11	
Mean (mg/dl):	1.5	8.2	
SD:	0.09	0.46	
CV (%):	6.1	5.6	
<u>LA</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Mean (mmol/L):	0.7	2.5	6.7
SD:	0.056	0.085	0.331
% CV:	7.7	3.4	4.9

Appendix E

Default Settings

This section describes factory default settings for the IRMA TruPoint blood analysis system.

DEFAULT SETTINGS: TABLE E-1

Refer to **Section 7 (System Settings)** for instructions on establishing IRMA TruPoint system settings. The factory default system settings are as follows:

Category	Default Setting
User ID Settings	
• QA User ID	123456
• User ID	Off
• User ID on printout	Off
Device Settings	
• Beeper	On
• Communications	Communications Method - Serial Results Transfer - Off Results Transfer Destination - idms Automatic Results Transfer - Off Automatic Device Update - Off
• LAN 10/100 (if applicable):	IP Address: 0.0.0.0 Gateway: Off Gateway IP Address: 0.0.0.0 Subnet Mask: 255.0.0.0 Remote IP Address: 0.0.0.0 Remote Port: 3001
• Date Format	MM/DD/YY
• Date/Time	Current (U.S. CST) 24 Hour Clock
• Auto-Print Results	Immediate
• Screen Contrast	Middle Setting (5)

Category	Default Setting
Test Settings	
• Product and Parameter Setup	All products and parameters enabled
• Calculations	On (HCO ₃ ⁻ , TCO ₂ , BEb, BEecf, O ₂ Sat, tHb and MDRD GFR) Off (iCa(N))
• Patient tHb (for BEb Calc.)	15 g/dL (Default)
• BE/ HCO ₃ ⁻ Calculation	Severinghaus/NCCLS
• pO ₂ Temperature Formula	Severinghaus
• Correlation/Bypass Correlation	Off
• Display Units	See Appendix B, Table B-8
• Reference Ranges	Off
• Reportable Ranges	Default
Test Settings - Test Information	
• Oxygen Therapy	Off
• Patient ID	Optional (0-20 characters)
• Patient Temperature	On
• Sample Type/Sample Site	Off
• Patient Notes	Off
• QC Notes	Off
QC Settings	
• QC Lockout	Off

Appendix F

IRMA TruPoint Capillary Collection Device

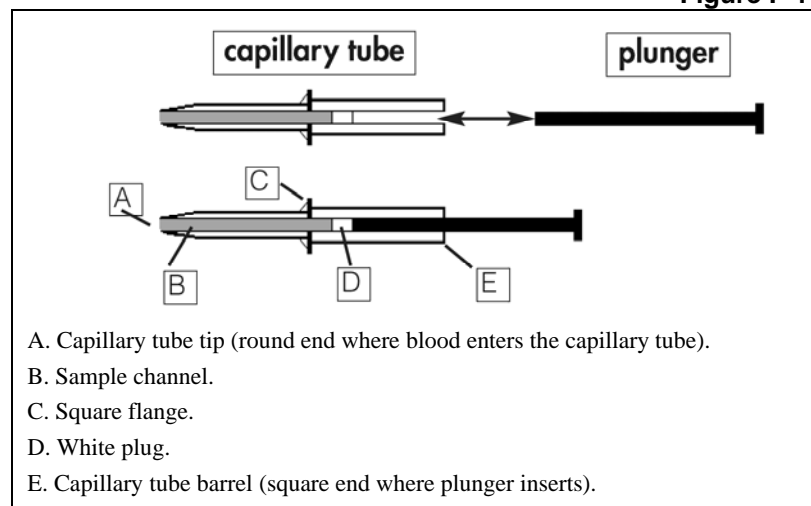
INTENDED USE

The IRMA TruPoint Capillary Collection Device is intended for blood collection and the transfer of whole blood samples into IRMA TruPoint cartridges.

DESCRIPTION

Each capillary collection device contains 70 IU/mL balanced heparin and has a fill volume of 125uL. Each device consists of a capillary tube and a plunger, which is packaged separately. The capillary tube fills via capillary action until the sample contacts the white plug. The upper end of the capillary tube is sealed when blood contacts the white plug, preventing the sample from running back out the tip of the device during handling (see Figure F-1). Following sample collection, the plunger is inserted into the capillary tube, and the device is attached to the IRMA TruPoint cartridge Luer port. The sample is introduced into the cartridge by quickly and completely depressing the plunger in one smooth motion until it stops.

Figure F-1



WARNINGS AND LIMITATIONS OF USE:

- Read instructions for the IRMA TruPoint system and capillary device before use.
- For in vitro diagnostic use only.
- For capillary sample collection and analysis. This device is not sterile and is not intended to be used as a syringe.
- Blood sample collection must be performed under proper medical supervision. Avoid excessive squeezing of the puncture site to prevent sample hemolysis and contamination of the sample with tissue fluid. Tissue fluid may dilute the sample.
- **The capillary tube sample channel must be completely filled with blood and contain no air bubbles. If the sample channel is not completely filled (i.e., blood is not in contact with the white plug), the sample may run out of the device.**
- The presence of bubbles in the sample channel may result in erroneous or suppressed results. If bubbles are present in the sample channel, remove them by angling the tip downward and allow the sample to flow back towards the tip to push the air bubble out the tip, or blot sample from the device. Refill the device with additional sample.
- If using a cartridge with a Cal cap, let the sample sit in the capillary tube for one minute following collection before attaching the capillary tube to the cartridge. For all other cartridge types, analyze the sample immediately following collection, or place a luer cap (P/N 033501) on the tip of the capillary tube to prevent room air contamination. Properly label the device and analyze the sample within **5 minutes**.
- Do not ice samples collected in this device.
- Use of this device with instruments other than the IRMA TruPoint Blood Analysis System must be validated to ensure proper sample volume and functionality.

STORAGE

Store at room temperature away from direct sunlight.

INSTRUCTIONS FOR USE

1. The black plunger comes packaged separately from the capillary tube. Samples may be collected with the plunger in or out of the barrel of the capillary tube, but most users find it easier to collect the sample with the plunger out of the barrel. If the plunger is out of the barrel during sample collection, insert it into the barrel after sample collection is complete. **Do not force the plunger against the white plug when inserting the plunger;** the plunger tip should rest against the white plug, but should not move the plug.
2. Select, prepare, and puncture the collection site according to your facility's protocol.
3. Remove the first drop of blood from the site with gauze and touch the tip of the device to the site to begin filling. Hold the capillary tube at a horizontal or slightly downward angle during collection.
4. Allow the capillary tube to fill completely via capillary action. If bubbles are present in the sample channel, remove them by angling the tip downward and allow the sample to flow back towards the tip to push the air bubble out the tip, or blot sample from the device. Refill the device with additional sample. Remove air bubbles or voids before the sample contacts the white plug. Once the sample contacts the white plug, the device will stop filling, and air can no longer be removed.
5. When blood contacts the white plug, the device is completely filled. Do not wipe or blot the tip of the device after filling. Doing so may accidentally wick sample from the sample channel, resulting in a sample void at the tip.
6. Inject the sample into an IRMA TruPoint cartridge:
 - a. When cartridge calibration is complete, remove the luer cap (if applicable) from the cartridge. Firmly seat the tip into the luer injection port of the cartridge to make an air-tight seal. The sample may leak if not tightly sealed.

- b. Anchor the device with your thumb and index finger, right below the square flange of the capillary device (Figure F-2).

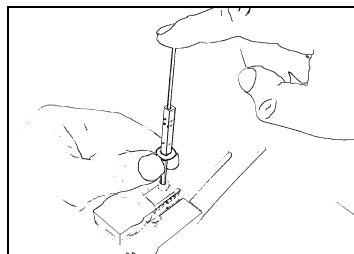
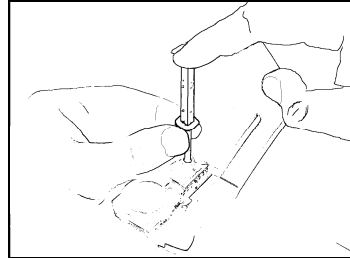


Figure F-2

Figure F-3

c. With the index finger of the other hand, dispense the sample by **quickly depressing the plunger straight down in one smooth motion until it stops** (Figure F-3).



d. Verify that there are no bubbles or calibrant present in the sample path, and press **test**. If bubbles or calibrant are present, press **cancel** to stop the test, discard the single-use cartridge, and begin again with a new cartridge. Proper injection technique will prevent air bubbles or calibrant from being present in the sample path following injection.

7. Following test completion, dispose of the device and cartridge in accordance with established guidelines for your facility. Do not reuse the plunger.

Appendix G

Software Updates

ANALYZER SOFTWARE UPDATES

Refer to the *ITC Device Communications Utility User Manual* and the instructions provided with the software update.

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Appendix H

Warranty

LIMITED WARRANTY

International Technidyne Corporation (“the Company”) warrants the IRMA TruPoint Analyzer, Battery Charger, and Temperature Card to be free from defects in material and workmanship under normal use and service for a period of one (1) year after date of shipment, warrants the Battery to be free from defects in material and workmanship under normal use and service for a period of ninety (90) days after date of shipment, and warrants the IRMA TruPoint cartridges to be free from defect in material and workmanship under normal use until its stated expiration date, subject to the following terms and conditions:

Claims of defects in material or workmanship must be reported to the Company and the product returned to the Company, transportation prepaid, within the warranty period.

If found by the Company's inspection to be defective in material or workmanship, the IRMA TruPoint Analyzer, Battery Charger, Battery, and Temperature Card will either be repaired or replaced, at the Company's election, free of charge, and returned to the purchaser, transportation prepaid. If a cartridge is found to be defective, it will be credited to the purchaser's account.

If inspection by the Company does not disclose any defect in material or workmanship, the Company's regular repair or replacement charges will apply.

Improper use of or service to, or the defacing or altering of, the IRMA TruPoint Analyzer, Battery Charger, Battery, Temperature Card, or cartridge will void this warranty.

Limitation of Remedies

The remedy of repair or replacement, provided in this written warranty, shall be the exclusive remedy of the purchaser for any defect in the product of the Company. Any purchaser of an ITC product agrees that ITC will not be liable for any other expenses, including, but not limited to, incidental or consequential damages and loss.

All obligations of the Company shall terminate one (1) year after date of original shipment.

Warranty Disclaimer

Every ITC product carries an express, written limited warranty, which is the only warranty, express or implied, of any ITC product.

ITC disclaims all other warranties, including implied warranties of merchantability or fitness.