Piccolo® Point-of-Care Chemistry Analyzer Operator's Manual

For in vitro diagnostic use

Abaxis, Inc.
3240 Whipple Road
Union City, California, USA
94587

800-822-2947
Customer Service and Technical Support

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Piccolo Operator's Manual
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Section 1: Piccolo Features and Components

1.1 Intended use

The Piccolo® Point-of-Care Chemistry Analyzer provides quantitative in vitro determinations of clinical chemistry analytes in heparinized whole blood, heparinized plasma, or serum.

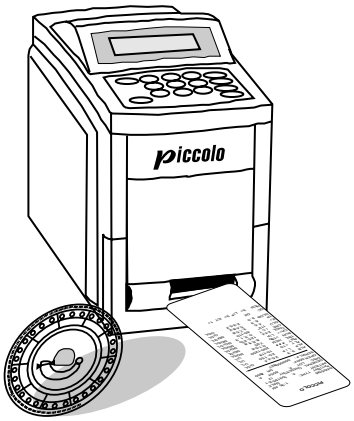
1.2 Universal precautions

Operator health and safety require that universal precautions be observed at all times while handling human blood samples or working with the Piccolo® Point-of-Care Chemistry Analyzer in any way. The complete text of the document "OSHA 29 CFR Part 1910, Occupational Exposure to Bloodborne Pathogens" can be found on the Internet at www.osha-slc.gov/Preamble/Blood_toc_by_sect.html.

1.3 Near-patient testing efficiency

This near-patient portable clinical chemistry system provides the clinician with routine multi-chemistry profiles and electrolytes for panels of blood tests within minutes. Less than 2 minutes of hands-on time is required to perform the test. The Piccolo® Point-of-Care Chemistry Analyzer eliminates the need to transport samples to a central laboratory, and reduces such problems as misplaced samples, inaccurate labeling and transcription, improper icing and bagging, and sample degradation. Important criteria for test efficiency include ease of use, along with minimal handling and processing steps. The Piccolo provides automation, easy operation, and reliable results to operators of almost any skill level.

1.4 Overview of the procedure

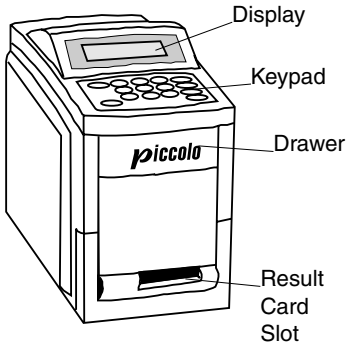


The Piccolo® system consists of the Piccolo® Point-of-Care Chemistry Analyzer, single-use disposable reagent discs, and result cards printed by the analyzer or transmitted to a data manager. External and internal features of the analyzer are described and illustrated below.

The operator begins the Piccolo® procedure by introducing 100 µL of whole blood, plasma, or serum sample into a self-contained reagent disc and loading the disc into the analyzer. No sample preparation is required. The operator then enters patient, operator, and physician ID numbers using the keypad and display screen. The analyzer performs the remainder of the testing protocol automatically in less than 13 minutes. The used reagent disc is removed and the analyzer is ready for the next sample.

The chemical reactions carried out by this analyzer are designed to produce a reaction that absorbs light at known wavelengths. Analyte concentration is calculated from light absorbance data. Results can be printed on result cards for purposes of assessment and for inclusion in the patient's medical chart. Results are stored in the analyzer memory, and can be transmitted to an external computer.

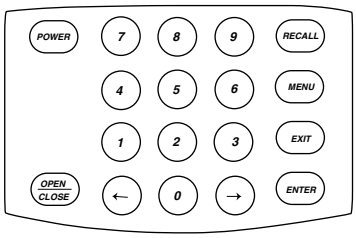
1.5 External features



The Piccolo® Point-of-Care Chemistry Analyzer is a lightweight portable instrument that allows patient testing at the point of care. Its small footprint allows convenient placement of the analyzer in a near-patient environment. The top surface has a 4-line display screen and keypad, and a recessed carrying handle. A sliding drawer and a slot for inserting result cards into the internal printer are on the front surface. The back surface includes connections for AC and DC power supply, as well as RS232 ports.

1.5.1 Display and keypad

The keypad and 4-line display screen facilitate interactive communication between the analyzer and the operator. The display indicates the status of the analyzer, and presents procedural instructions and error messages. It also reflects information input via the keyboard so it can be verified or corrected.



The operator inputs data through the 10 numeric keys, 6 function keys, and 2 arrow keys. Refer to the figure at the right for the keyboard layout. The specific uses of these keys are described in **Sections 2**, **3**, and **4**.

The POWER key is used to power the analyzer up or down and to cancel a run in progress. Refer to **2.2.3**. The OPEN/CLOSE key operates the sliding drawer where the reagent disc sits. This key is referred to in the text as either the OPEN or CLOSE key as appropriate in context. Closing a drawer containing a reagent disc initiates an analysis. Two of the function keys, MENU and RECALL, provide access to special functions described in detail in **Sections 3** and **4**.

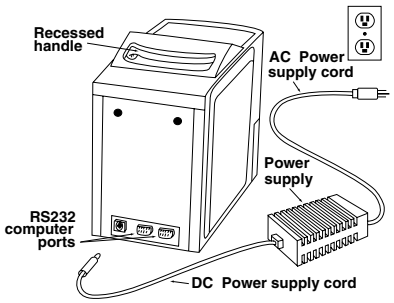
1.5.2 Disc drawer

The disc drawer slides in and out to transport the reagent disc into the analyzer and hold it in place during the analysis. Keep the analyzer drawer closed when not loading or unloading a reagent disc. Always use the OPEN/CLOSE key to change the position of the drawer. **Do not push on the drawer to close it. This may damage the instrument.**

1.5.3 Result card slot

The result card slot, on the front surface of the analyzer below the disc drawer, provides access into the internal thermal printer. Refer to **1.6**, **2.2.2**, and **Section 4** for information about printing result cards.

1.5.4 Power supply



The analyzer runs on AC or DC power, providing portability in point-of-care testing environments.

Two power supply components are included. The **DC power supply** plugs into the socket on the lower left back of the analyzer. An **AC power cord** connects the DC power adaptor to a grounded electrical outlet. A "universal" DC-to-AC power convertor is also available, as well as an accessory that can plug into a vehicle's lighter socket, allowing a 12-volt battery to be used as the power source.

1.5.5 Computer ports

Two RS232 ports support 2-way communication between the analyzer and external devices. Port 1 [labeled RS232(1)] is used for connecting the analyzer to a computer to transmit results. Port 2 is used for connecting an optional bar code scanner. Refer to **1.11** for information on linking the analyzer to an external computer.

1.5.6 Symbols used in labeling

The following symbols are found on the label on the bottom panel or above the connections on the back panel.

Symbol	Explanation
⎓	Direct current
	Caution (refer to accompanying documents)
	Serial ports

1.5.7 Physical and environmental specifications

Height:	24.2 cm	9.5 inches
Width:	15.3 cm	6 inches
Depth:	29.2 cm	11.5 inches
Weight of the analyzer:	6.8 kg	15 pounds
Weight of the power adapter:	0.6 kg	1.3 pounds
Mode of operation:		Continuous
Protection against ingress of fluids:		Ordinary equipment (IPXO)
Ambient operating temperature:		15–32°C 59–90°F
Humidity:		0–95%, non-condensing
Reaction temperature:		37°C 98.6°F
Power requirements:		240–100 volts AC 50–60 Hz or 12–15 volts DC
Thermal protection rating:		70°C 178°F

1.6 Internal components

Inside the analyzer is a variable speed motor to spin the disc, a spectrophotometer to measure analyte concentrations, two microprocessors to control testing and analytical functions, system software on a PCMCA card, and a thermal line printer for imprinting result cards. A heating system maintains the temperature of the disc at 37°C while reactions are in progress.

1.6.1 Optics

The measurement optics consist of a discrete wavelength spectrophotometer with a xenon lamp as a light source.

1.6.2 Microprocessors and memory

The architecture of the instrument consists of two microprocessors: a real-time controller that monitors and controls all the measurements; and an I/O (input/output) controller for memory management, calculations, and data storage. The two processors cross-check each other's performance continuously, which allows a very high level of confidence in the working of the instrument, and consequently of the results and the integrity of the data.

The analyzer stores 70 patient results, 70 control results, and system quality control data. All data stored in memory can be accessed via the Recall function. Refer to **Section 4**.

1.6.3 Software

The analyzer software comprises two matched programs. One program controls the measurement engine itself, i.e., it schedules the flashing of the light source and collects the light intensity data for different cuvettes at different times during the reaction; and it collects all the information generated in the analytical part of the instrument. The second program processes that information and reports analyte concentration. It also stores data related to each run (time, date, user ID, patient results, and control data).

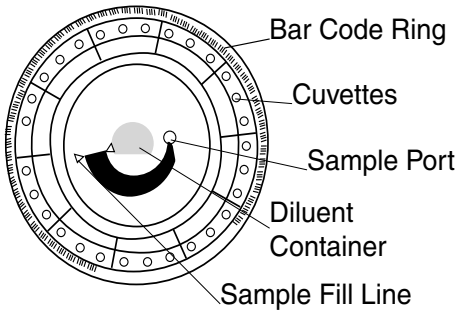
Software upgrades are distributed to registered users on a PCMCA card and installed on site. Refer to **5.3** for instructions on installing a software card.

1.7 Piccolo reagent discs

1.7.1 Disc structure and function

In the Piccolo® system, all chemistry reactions are performed inside clear plastic reagent discs, 8 cm in diameter and 2 cm in depth, specially designed to perform all the steps required to convert a few drops of whole blood, plasma, or serum into a panel of test results. Each disc contains all the components and reagents needed to perform one or more tests on a single sample.

A total of 30 **cuvettes** are located around the periphery: 4 system cuvettes contain QC reagent beads for instrument and chemistry quality control (refer to 1.9); a minimum and a maximum absorbance cuvette are employed in calibrating the spectrophotometer; a specially designed cuvette detects whether sufficient sample volume was applied; one cuvette verifies that a sufficient aliquot of diluted sample was delivered to the reaction cuvettes; an empty cuvette captures excess fluids. The remaining 21 cuvettes contain test-specific lyophilized reagent beads.



The **bar code ring** attached to the top of the reagent disc contains calibration data specific for the chemistries in the disc. It also contains the disc identification code, lot number, and expiration date. The analyzer automatically checks the code and rejects an expired disc. The bar code ring also protects the optical surfaces of the cuvette from fingerprints and other debris, and helps minimize contamination of the analyzer by capturing small drops of blood that may be on the disc surface.

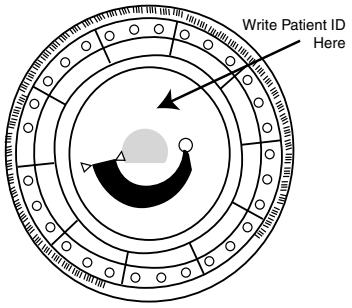
The **sample port,** demarcated by an arrow pointing to a circle molded onto the upper surface of the disc, provides access to the **sample chamber**. When sufficient sample has been loaded into the sample chamber, the **sample fill line** forms between two arrows molded on the disc surface.

A sample **diluent** is sealed in a container inside the center of the disc. At the beginning of the reaction cycle, the analyzer opens the container and releases the diluent.

The analyzer separates a heparinized whole blood sample by centrifugation inside the disc. Plasma and serum samples are unaffected. Precisely measured quantities of sample and diluent are delivered to the **mixing chamber**. Then centrifugal and capillary forces deliver the diluted sample to the cuvettes, where it dissolves the reagent beads and initiates the chemical reactions. Reaction products in the cuvettes are measured photometrically.

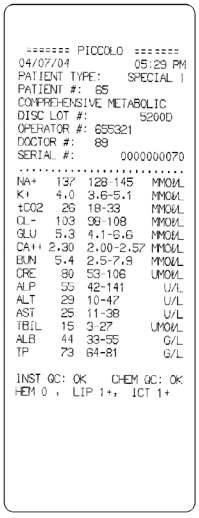
1.7.2 Disc storage and handling

- Store all reagent discs as described on their respective labels. When stored as described as described on their respective labels, all reagents in the disc are stable until the expiration date printed on the foil pouch and encoded on the bar code ring. The analyzer will reject an expired disc.
- A disc can be used directly from the refrigerator (stored at 2–8°C) without warming.
- A disc can remain in its sealed pouch at room temperature for a cumulative period of 48 hours. Longer time at room temperature can cause suppression of chemistries and disc aborts.
- Do not expose discs, in or out of the foil pouches, to direct sunlight or to temperatures above 32°C (90°F).
- Inspect the unopened foil pouch for tears and punctures. A torn or damaged pouch may allow moisture to reach the disc and reduce reagent performance.
- Open the disc pouch at the notch on the top right edge of the package. A disc must be used within 20 minutes of opening the pouch. Once the pouch is opened, do not place the disc back in the refrigerator for use at a later time.
- Discs are fragile. Handle with care. Do not tap the disc on the table or work bench to empty the sample port. Do not use a disc that has been dropped.
- Keep discs clean. Handle them only at the edges to avoid smudges on the optical surfaces. Use a lint-free tissue to remove blood from the disc surface.
- Write the patient identification number on the disc surface in the space indicated in the figure to the right (optional). Do not write anywhere else on the disc or on the bar code ring.



- Hold reagent discs flat after introducing the sample or control to avoid spillage.
- The used disc can be replaced in the pouch for disposal.
- BIOHAZARD: Used reagent discs contain body fluids. Follow good laboratory working practices. Handle all used discs as if they are contaminated with hepatitis or other infectious diseases. Check with the appropriate state agency regarding disposal regulations.

1.8 Result cards



Result cards are durable paper strips, about 7.5 inches long by 2.5 inches wide, designed for use with the Piccolo® Point-of-Care Chemistry Analyzer, on which test results and other information can be printed after testing is complete. Result cards are also used for printing the QC report and the troubleshooting report to assist in the interpretation of error codes. Additional copies of the result card can be printed at any time for any analysis held in memory. Refer to **2.2.2** and **Section 4** for information about printing result cards, QC report cards, and troubleshooting reports. Refer to **1.13** for ordering information.

The result card has an adhesive backing so it can be placed into the patient's file. The operator should follow the institution's procedures for disposition of the result card.

1.9 Intelligent QC (iQC™)

The Piccolo® Point-of-Care Chemistry Analyzer includes design and user interface features that perform comprehensive system-wide quality control checks during each run. These features, collectively called "intelligent QC" (iQC™), ensure that operators at a wide range of skill levels can achieve accurate and reliable results. Two types of QC reagent beads (instrument and chemistry) are included in each disc. Refer to **1.7.1** for information about disc structure. When these methods confirm that all parameters are within expected ranges, `INSTRU QC:OK CHEM QC:OK` is printed on the result card. Otherwise, no result card is printed and an error message is displayed. Error messages indicate analyzer or disc malfunctions, and explain why results may not be available. Whenever an error message is displayed, refer to **5.6** for troubleshooting procedures.

System and chemistry QC data from each patient sample are stored in the analyzer memory with the sample results. System and chemistry QC data from each control run are stored with control results, separately from sample results. Standard information storage and retrieval techniques are employed to ensure the integrity of the data. All QC data stored in memory can be called up for review at any time. Refer to **Section 4** for complete information and detailed instructions.

iQC™ greatly reduces the requirement for routine control testing. Refer to **2.4** for recommendations and procedure for control testing. Operators requiring assistance setting up control testing procedures should contact Abaxis Technical Support at 800-822-2947.

1.9.1 Instrument iQC™

The analyzer hardware is subjected to a self-test at power-up. The self-test ensures that all optics, the flash lamp, and the circuit board components are functioning properly, and also verifies the memory functions. If any component does not meet specification, an error message is displayed. The disc motor, flash lamp, temperature, and optics are monitored continuously throughout each analysis. The spectrophotometer is automatically recalibrated at the beginning of each analysis.

Simultaneously with each analysis, advanced optical sensing and electronic systems monitor reactions involving instrument QC reagent beads to verify the functioning of the analyzer and the disc

1.9.2 Reagent iQC™

Reactions involving chemistry QC reagent beads reveal and quantify any degradation of the test-specific reagents in the disc due to suboptimal storage conditions. The value reported is the actual absorbance as a percent of the expected absorbance. The value must exceed a defined minimum for the reagents to meet performance standards. Otherwise, the run is aborted and an error message is displayed.

A lot-specific cutoff value for chemistry QC absorbance is used to separate the various tests on the disc into two groups, based on different sensitivity to heat exposure. If the chemistry QC value falls below this cutoff level but above the defined minimum, the results from the less heat-sensitive tests are expected to meet performance standards. The results of these tests are printed. The results of the more heat-sensitive tests may show some degradation and are suppressed. (This cutoff level is not printed on the quality control report.)

1.9.3 Performance iQC™

Disc checks performed during the analysis include: checking the barcode for current dating and for the presence of all required calibration factors; confirming that sample volume is sufficient; confirming the presence of all reagent beads and that all reagent beads have dissolved in diluted sample; verifying diluent and sample mixing; and monitoring fluid movement throughout the disc for proper sequence and timing of the reactions.

The iQC system monitors the performance of the reactions. For rate chemistries, the analyzer confirms that the reactions are linear; that the absorbances from which the rates are calculated, as well as the rates themselves, are within defined ranges; and whether the substrate has been depleted. In endpoint chemistries, the analyzer verifies that all measurements are within the dynamic range of the photometer and that the reaction has reached completion, ie, there are no changes in absorbance as a function of time.

The analyzer measure the levels of hemolysis, lipemia, and icterus. If there was interference with the analyte, information about the interference is printed on the result card. Refer to **2.3** for additional information.

1.10 Setup and power supply

1.10.1 Shipping verification

Remove the analyzer from the shipping carton and place it on a level surface. Check the components you received against the following list.

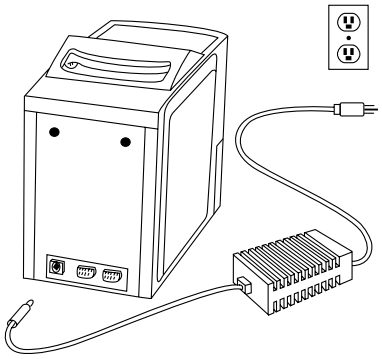
- Piccolo® Point-of-Care Chemistry Analyzer
- Piccolo® Operator's Manual
- DC power adapter and connector cord
- AC power cord
- warranty card

Note: *Fill out the warranty card and mail it to Abaxis within 10 days of system installation to start the warranty period. You will be put on the Abaxis customer list to receive any information pertaining to your analyzer and ancillary products, including product updates.*

1.10.2 Powering up

- Use only the power supply components provided with the analyzer. Using other power supply components will damage the instrument and void the warranty.
- Connect the analyzer only to a *grounded* electrical outlet.
- To prevent power surges or drain, do not plug the analyzer into the same circuit as a centrifuge or any other high-current device. Alternatively, use an ancillary surge protector or uninterruptable power supply (UPS).
- Place the analyzer on a level surface free of vibration and sudden jolts, and where the ambient temperature is 15–32°C (59–90°F). Do not place it near a sunny window or other heat source.
- There should be at least 6 inches clearance behind the analyzer for access to the power connection and RS232 ports.
- Place the analyzer where airborne matter such as dust, lint, and hair is limited; ie, do not place it near a fan or where air circulation is high.

Step 1. Connect the power supply.
Refer to the figure at the right. Plug the DC adapter into the socket on the back of the analyzer. Connect the AC power cord to the DC adapter. Plug the AC power cord into a *grounded* electrical outlet. The self-test message will appear on the display. The self-test is described in **1.9.1**. If the display is blank, check all power supply connections.



```
Performing
self-test
```

Step 2. Allow the analyzer to warm to operating temperature.
Depending on the ambient temperature, warming may take more time than the self-test.
⇒ ***The analyzer is in standby mode, i.e., ready to run a disc, when the display reads*:**

```
Open drawer to
run a disc.
```

Step 3. Check the date and time.
Check the analyzer date and time to ensure they are correct. Refer to **3.3** to change the date and time.

Step 4. Link the analyzer to an external computer. (Optional)
Refer to **1.11**.

Step 5. Perform control testing.
Perform one or more runs using recommended controls before running patient samples to confirm that the analyzer is functioning to specification. Refer to **2.4** for control run procedures.

1.10.3 Powering down

The power should remain on unless you are moving the analyzer to a new location. Always power down using the POWER key rather than by unplugging the analyzer. The POWER key does not power down the analyzer when there is a reagent disc in the drawer.

This message appears when the POWER key is pressed. Press EXIT to cancel the system shutdown procedure and return the analyzer to standby mode.

```
Turn analyzer OFF?
Press POWER/OFF to
turn off, or EXIT to
continue operation.
```

Press POWER again to initiate system shutdown. The analyzer turns off when the system shutdown is complete.

```
Performing
system shutdown.
```

1.11 Connecting to an external computer

A facility may want to connect the analyzer to an external computer for any or all of the following reasons: to incorporate testing data into patient records; to provide records for regulatory compliance; or to connect with automated billing systems. By default, the analyzer does not transmit data, but it can be configured to transmit data in simple ASCII text, or in ASTM E 1394-97. Contact Abaxis for detailed information on connecting the analyzer to a computer.

1.12 Bar Code Scanner Option/Requirements

For ease of entry of patient identification, the Piccolo Point-of-Care Blood Analyzer can be used with any Bar Code Scanner that meets the following requirements:

1.12.1 Communication Interface

The communication interface must be a serial connection using a female 9-pin D-SUB connector. The TX (transmit) should be on pin 2, and the RX (receive) should be on pin 3.

1.12.2 Communication Parameters

Data is received at 9600 Baud, No Parity, 8 Bits, and 1 Stop Bit (9600,N,8,1).

1.12.3 Barcode Formats

The scanner should auto discriminate at a minimum Code 39 and Code 128 symbologies. There can be no preamble in the output data. The postamble in the output data shall have CR (Carriage Return [0x0D]), LF (Line Feed [0x0A]) and NULL [0x00]).

1.13 Consumables and ancillaries

Contact Abaxis or your authorized distributor to order reagent discs, result cards, controls, and sample collection equipment and supplies.

1.14 Customer service and technical support

Call Abaxis Customer Service and Technical Support at 800-822-2947 with questions regarding the operation the Piccolo® Point-of-Care Chemistry Analyzer.

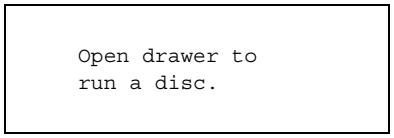
Section 2: Testing Procedure and Interpretation of Results

2.1 Sample requirements

- The Piccolo® Point-of-Care Chemistry Analyzer accepts heparinized whole blood, heparinized plasma, or serum samples.
- Lithium heparin is the only anticoagulant recommended for use with the Piccolo® Point-of-Care Chemistry Analyzer.
- For use of the CLIA '88 Waived Lipid Panel Disc, the only sample that may be used is lithium heparinized whole blood.
- A sample size of 90–120 µL is required.
- Whole blood must be analyzed within 60 minutes of collection, or separated into plasma or serum.
- To prevent hemolysis, do not refrigerate or shake whole blood.
- If not analyzed immediately, plasma or serum (separated) may be stored at room temperature for no longer than 5 hours after centrifugation. If storage for more than 5 hours is required, the sample should be refrigerated in the stoppered tube at 2–8°C (36–46°F) for no longer than 48 hours; or stored at –10°C for up to 5 weeks in a freezer without a self-defrost cycle. Under these conditions, there will be no clinically important changes in most analyte concentrations.
- For accurate interpretation of results, the sample should be collected from a patient who has fasted for at least 12 hours (to avoid lipemic samples).
- Operator health and safety require that Universal Precautions be observed at all times while handling human blood samples or working with the Piccolo® Point-of-Care Chemistry Analyzer in any way. The complete text of the document "OSHA 29 CFR Part 1910, Occupational Exposure to Bloodborne Pathogens" can be found on the Internet at www.osha-slc.gov/Preamble/Blood_toc_by_sect.html.

2.2 Testing procedure

- Wear powder-free gloves while handling reagent discs or operating the analyzer. Powder may disrupt the optical components.
- If necessary, power up the analyzer before beginning the procedure. The power-up procedure is described in **1.10.2**.
- Ensure that the ambient temperature is 15–32°C (59–90°F).
- **The analyzer is in standby mode, i.e., ready to run a disc, when the display reads**:

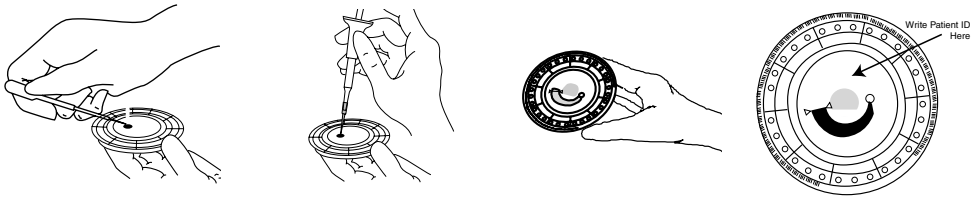


2.2.1 Preparing the reagent disc

- Refer to **1.7** for complete information about Piccolo® reagent discs, including handling instructions. Please become thoroughly familiar with this information before beginning the procedure.
- Refer to **2.1** for sample handling and storage requirements.
- The analysis must begin immediately (no more than 10 minutes) after dispensing the sample into the reagent disc.

Step 1. Dispense the sample.

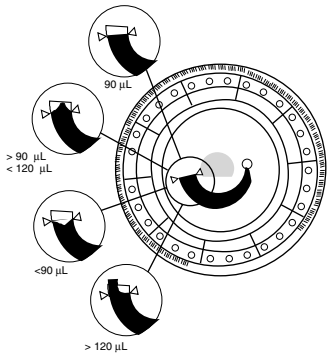
Use a micropipette (one is included with the Piccolo) or other transfer device to dispense approximately 100 µL of sample into the disc via the sample port.



a. Fill the sample port.

Expel air bubbles from the tip of the micropipette. Place the micropipette in the sample port and tilt it until it is perpendicular to the disc surface. Push down on the plunger with a slow, continuous motion.

Take care not to overfill the sample chamber. A 100 µL sample will fill the sample chamber and form a line between the two arrows molded on the disc. More than 120 µL of sample will overfill the chamber, and less than 90 µL will underfill. Discard the pipette tip into a biohazard container.



b. Fill the sample chamber.

Tilt the disc to 45° with the sample port above the fill line, so that the entire sample flows into the sample chamber. Clean the reagent disc. Use a lint-free tissue to remove any sample spilled on the outside of the disc, taking care that the tissue does not withdraw any sample from the sample port. Dispose of the tissue in a biohazard container.

c. Carry the prepared disc to the analyzer.

Hold the disc by its edges in a flat position.

2.2.2 Running a patient sample

- The analyzer must be in standby mode to begin the procedure.
- Use the numeric and arrow keys to enter patient, operator, and physician IDs while the analysis is proceeding. The → key inserts a dash; the ← key deletes the character to the left.
- The reference range set and patient, operator, and physician IDs must be entered before results can be calculated. If you wait until the run is complete before entering these numbers, the analyzer will require an additional one minute to calculate the results.
- If an error message is displayed at any time during the run, refer to **5.6** for troubleshooting procedures associated with the specific error code.

Step 2. Open the drawer and insert the disc.

Press OPEN. The following messages are displayed sequentially:


```
Opening drawer...
```

```
Close drawer to
start analysis.
```

Place the disc in the drawer. Press CLOSE. The display reads:

```
Closing drawer...
```

The analysis begins when the drawer closes.

Step 3. Select the reference range set.

By default, the reference range set for the previous sample is displayed. The reference range set for the current sample must be selected for correct interpretation of results. Use the numeric keys to select the correct reference range set. Press ENTER when the correct number appears to the right of `Select`.

```
Select:1 MALE
1- Male    3- Special
2- Female  4- Control
ENTER to accept.
```

Step 4. Enter the patient ID.

A patient ID (up to 14 characters) must be entered to continue. Press ENTER.

```
Input Patient #:
_______________

ENTER when finished.
```

Step 5. Enter the operator ID.

Enter the operator ID for the current sample, up to 14 characters. Press ENTER.

```
Input Operator #:
_______________

ENTER when finished.
```

Step 6. Enter the physician ID.

Enter the physician ID for the current sample, up to 14 characters. Press ENTER.

```
Input DR #:
_______________

ENTER when finished.
```

Step 7. Automatic sample processing.

The analyzer processes the sample and calculates results in less than 13 minutes with no further operator input. During the run, the analyzer displays the following message, including time remaining to complete the analysis (XX:XX) and patient ID.

```
Results ready in
XX:XX
for patient #:
XXXXXXXXXXXXXX
```

Sample processing is complete when the analyzer beeps and displays these messages sequentially:

```
Analysis complete. Open
drawer or insert card
to print results.
```

```
Insert card to
print results.
```

Step 8. Print results.

To end the procedure without printing results, press EXIT and continue to step 9.

If a `Run Cancelled` error message is displayed, refer to **5.6** for an explanation and further instructions.

Place the result card in the result card slot. Remove the card when directed to do so on the display. These messages appear sequentially:

```
Printing results...
```

```
Remove card.
```

```
Opening drawer...
```

```
Remove disc
and close drawer.
```

If the results card shows one or more rows of diamonds (♦ ♦ ♦) in place of analyte concentration, this indicates **suppressed results**. Refer to **2.3.2 B.** In this situation, insert a second results card when prompted.

Step 9. Return the analyzer to standby mode.

Remove the reagent disc from the drawer and dispose of it, following your lab's biohazard procedures. Press CLOSE to return the analyzer to standby mode.

2.2.3 Canceling an analysis in progress

Press POWER to cancel an analysis in progress. The display requests verification that the analysis should be canceled:

```
Cancel analysis?
POWER/OFF to cancel
run, or EXIT to
continue analysis.
```

Press POWER again to cancel the analysis. These messages appear sequentially:

```
Analysis
canceled.
```

```
Opening drawer...
```

```
Remove disc
and close drawer.
```

Remove the reagent disc from the drawer. Press CLOSE to return the analyzer to standby mode.

For the run cancellation to take effect, the operator must press POWER before the analyzer has calculated the results. If the cancellation procedure is initiated after the analyzer has calculated the results, the cancellation will not take effect. The results are stored in memory and can be printed. The `Analysis complete` message appears. Continue from step 8, above.

```
Analysis complete.
Open drawer or
insert card to
print results.
```

2.3 Interpreting patient results

Results are stored in internal memory, and, if the analyzer is connected to an external computer, automatically transmitted. Results can be printed on a result card. Refer to **2.2.2**, Step 8. An adhesive backing allows the result card to be placed in the patient's chart and become part of their permanent medical record. Refer to **1.8** for basic information about the result card. Follow your lab or facility's procedure for transferring the card to the patient's chart.

2.3.1 Reading the result card

The **result card heading** includes:

- test date and time
- reference range set
- patient, operator, and physician IDs; or control level
- reagent disc type and lot number
- analyzer serial number.

The **test results section** of the card is printed in four columns:
- analyte
- analyte concentration
- units of measurement
- reference range in specified units.

An asterisk (*) printed to the right of the analyte concentration indicates **results outside the reference range**.

A greater than (**>**) or less than (**<**) symbol printed to the left of the value in the analyte concentration column indicates **results outside the dynamic range** of the assay. Refer to **2.3.2 A.**, below.

⚠ is printed when the analyte concentration is lower than would normally be expected (diluted sample).

A row of diamonds (♦♦♦) printed in place of analyte concentration indicates **suppressed results**. Refer to **2.3.2 B.** below.

`HEM`, `LIP`, or `ICT` is printed in place of the analyte concentration when results are affected by **interference from hemolysis, lipemia, or icterus**. When a result is affected by hemolysis and either or both of the other interferents, `HEM` is printed. When a result is affected by both lipemia and icterus, `LIP` is printed. Examine the sample indices printed at the bottom of the card to determine if more than one interferent is affecting results. Refer to **2.3.2 C.** below for further instructions.

`INST QC: OK and CHEM QC: OK` printed near the bottom of the result card when iQC testing indicates that all instrument, disc, and chemistry parameters meet specifications.

Sample indices for hemolysis, lipemia, and icterus are printed at the bottom of the card. The sample is rated for these interferents on the following scale:

`0`	clear
`1+`	slight
`2+`	moderate
`3+`	gross

2.3.2 Abnormal results: interpretation and further action

A. Results outside the dynamic range

Refer to the disc package insert for information about the dynamic range of any assay included in the disc. When the sample concentration falls below or exceeds the dynamic range of the assay, the analyzer cannot calculate the concentration. The numeric value that appears in the analyte concentration column is the upper or lower limit of the dynamic range of the assay, preceded by **>** or **<** , respectively. For example, the dynamic range of glucose is 10–700 mG/DL; a sample concentration of glucose below this range would be printed as `<10 mG/DL`; a sample concentration of glucose above this range would be printed as `>700 mG/DL`.

Results outside the dynamic range should be reported as below or above the value indicated.

B. Suppressed results (♦ ♦ ♦)

A result may be suppressed when any of the internal QC steps detect an abnormal condition.

If a chemistry result (analyte) should be suppressed (♦ ♦ ♦), the analyzer prompts the operator to insert a print card to obtain the troubleshooting report. Hemolytic (HEM), lipemic (LIP), and icteric (ICT) are not considered chemistry suppressions.

Collect a new sample and rerun the test. If results for the second sample are suppressed, call Abaxis Technical Support at 800-822-2947 for further assistance.

C. Interferents

When the sample is hemolytic, collect a new sample and rerun the test. Abaxis recommends that the new sample be separated into serum or plasma so that the degree of hemolysis can be verified. If the new sample is hemolytic, use an alternative testing method or send the sample to a reference laboratory.

Samples with hematocrit in excess of 60% packed red cell volume may be reported on the result card as HEM. Follow the instructions above for retesting hemolyzed samples.

Lipemia may be due to diet. The patient should be instructed to fast for at least 10 to 12 hours before another sample is collected. For grossly lipemic samples from fasting patients or for icteric samples, use an alternative testing method or send a sample to another laboratory.

2.4 Running controls

Abaxis recommends control testing as follows:

- at least every 30 days
- whenever laboratory conditions have changed significantly
- when training or retraining of personnel is indicated
- when test results do not match patient symptoms or clinical findings

Good laboratory practices include the recording of the QC data according to the laboratory's established written procedures. A permanent record of control results should be retained.

Samples and controls are run identically by the analyzer. However, using the Run Controls option in the Menu function stores control results separately from patient results in the analyzer memory. Control results can be printed on a result card immediately after the conclusion of the control run, or whenever the control run results are recalled. Refer to Section 4 for the use of the RECALL key. Control results are automatically transmitted to a linked computer.

Handle the control as described in the control package insert. For assistance in interpreting control results, call Abaxis Technical Support at 800-822-2947.

Step 1. Prepare the reagent disc.

Use a micropipette (provided with the Piccolo) or other transfer device to dispense approximately 100 µL of control into the sample port. Refer to **2.2.1** for detailed instructions on preparing the reagent disc.

Step 2. Press OPEN.

The drawer opens and the following messages are displayed sequentially:

```
Opening drawer...
```

```
Close drawer to
start analysis.
```

Insert the disc. Press CLOSE. This message appears briefly:

```
Closing drawer...
```

Step 3. Select Control, then press ENTER.

Use the numeric keys to select Control. Press ENTER.

```
Select:1 MALE
1- Male    3- Special
2- Female  4- Control
ENTER to accept.
```

Step 4. Choose the correct control level.

By default, the display shows the control level for the previous control run. Use the numeric keys to choose the correct control level for the current run. Press ENTER.

```
Control Selection
CONTROL LEVEL I
1-9 keys to change,
ENTER to accept.
```

Step 5. Enter the operator ID.

Enter the operator ID for the current control run, up to 14 characters. Press ENTER.

```
Input Operator #:
_______________

ENTER when finished.
```

Step 6. Enter the physician ID.

Enter the physician ID for the current run, up to 14 characters. Press ENTER.

```
Input DR #:
_______________

ENTER when finished.
```

Step 7. Automatic control processing.

The analyzer displays the control level and time remaining for completing the analysis.

```
Results ready in
XX:XX
for control:
LEVEL XXXX
```

When the analysis is complete, the analyzer beeps and displays these messages sequentially:

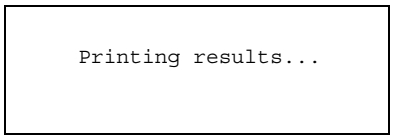
```
Analysis complete. Open
drawer or insert card
to print results.
```

```
Insert card to
print results.
```

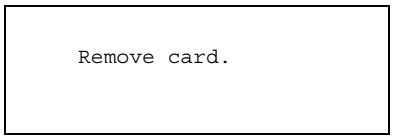
Step 8. Print control results.

If you choose not to print the results immediately following the control run, press EXIT and continue with step 9.

To print results immediately following the control run, insert a result card into the slot. This message is displayed while results are printing:



Remove the result card when directed to do so on the display. After the result card is removed, the drawer opens automatically. Proceed to step 9.



If the results card shows one or more rows of diamonds (♦ ♦ ♦) in place of analyte concentration, this indicates **suppressed results**. Refer to **2.3.2 B.** In this situation, insert a second results card when prompted.

Step 9. Return the analyzer to standby mode.

Remove the reagent disc from the drawer and dispose of it according to your lab's standard procedures. Press CLOSE. The analyzer returns to standby mode.

2.5 Limitations of the procedure

- Refer to **5.6** when error messages are displayed.
- Samples with hematocrit in excess of 60% packed red cell volume may be reported on the result card as HEM. Refer to **2.3.2 C.** for instructions.
- The analyzer suppresses results when the precision is significantly affected by hemolysis, lipemia, or icterus. Refer to **2.3.2 C.**

Section 3: The Menu Functions

Several special functions programmed into the Piccolo® Point-of-Care Chemistry Analyzer are accessed through the MENU key. The Menu functions are available from standby mode, i.e., when no analysis is in progress and the drawer is closed. From within any of these menus and functions, press EXIT to return to the previous display. Press EXIT repeatedly to return to standby mode.

Function	Description	To access, press...	Refer to...
View analyzer ID	View the analyzer serial number and software version	MENU	**3.2**
Change date and time	Set the date and time	MENU two times, then ENTER	**3.3**
Select date format	Choose month / day / year or day / month / year	MENU two times, then ENTER, then MENU	**3.4**
Select time format	Choose 12-hour or 24-hour clock	MENU two times, then ENTER, then MENU two times	**3.5**
Customize reference ranges	Set reference ranges for the specific patient population	MENU three times, then ENTER	**3.6**
Print reference ranges	Print the reference ranges in a specified set	MENU three times, then ENTER, then MENU	**3.7**
Transmit reference ranges	Transmit all stored reference ranges to a linked computer	MENU three times, then ENTER, then MENU two times	**3.8**
Select language	Select 1 of 5 languages	MENU four times	**3.9**
Select units	Choose international units (SI) or units commonly used in the United States	MENU four times, then ENTER, then MENU	**3.10**
Select data format	Select the format used for serial data output	MENU four times, then ENTER, then MENU two times	**3.11**

3.1 Accessing a particular special function

The Menu functions can be used only when the analyzer is in standby mode (the message `Open a drawer to run a disc` appears in the display). To access the menus or functions needed, press MENU and ENTER as shown in this section.

Step 1. Begin from the standby mode display.

```
Open drawer to
run a disc.
```

Step 2. Press MENU.

```
Press ENTER to
view analyzer ID,
MENU for next option
EXIT to leave.
```

Step 3. Press MENU a second time.

```
Press ENTER for
date & time menus,
MENU for next option
EXIT to leave.
```

Step 4. Press MENU a third time.

```
Press ENTER for
reference range menu
MENU for next option
EXIT to leave.
```

Step 5. Press MENU a fourth time.

```
Press ENTER for
analyzer setup menu
MENU for next option
EXIT to leave.
```

Step 6. Press MENU again to return to the first display.

```
Press ENTER to
view analyzer ID,
MENU for next option
EXIT to leave.
```

Step 7. Press EXIT to return to standby mode.

```
Open drawer to
run a disc.
```

3.2 Viewing analyzer identification

Use this Menu function to verify the serial number of the analyzer and the version number of its installed software.

Step 1. Access the View Analyzer ID function.
From standby mode, press MENU.

```
Press ENTER to
view analyzer ID,
MENU for next option
EXIT to leave.
```

Step 2. Display the serial number and software version.
Press ENTER.

```
Serial #: XXXXXXXXXX
Software Version:
X.XXX
Press ENTER.
```

Step 3. Press EXIT to return to the View Analyzer ID function, or press EXIT twice to return to standby mode.

NOTE: The software version also appears on-screen while the analyzer is starting up.

3.3 Changing the date and time

The date and time are checked during the set up procedure. Refer to **1.10.2**, Step 3. Adjust as needed.

*NOTE: If needed, change the date or time format **before** changing the date or time. Refer to **3.4** and **3.5**.*

Step 1. Access the Date & Time menu.
From standby mode, press MENU twice

```
Press ENTER for
date & time menus,
MENU for next option
EXIT to leave.
```

Step 2. Access the Change Date & Time function.
Press ENTER.

```
Press ENTER to
change date & time,
MENU for next option
EXIT to leave.
```

Step 3. Display the date or time in the current format.
Press ENTER.

```
Select:2 Time
xx/xx/xx  xx:xx XM
1-Date    2-Time
ENTER to accept.
```

Step 4. Select the date.
Press 1, then ENTER.

```
Date: xx/xx/xx
0-9 keys to change,
←, → to move cursor,
ENTER to accept.
```

Step 5. Change the date.
Use ← → and the numeric keys to enter the correct date. Press ENTER to accept.

```
Select:2 Time
xx/xx/xx  xx:xx XM
1- Date   2-Time
ENTER to accept.
```

Step 6. Select the time.
Press ENTER.

```
Time: xx:xx:xx XM
0-9 keys to change,
←, → to move cursor,
ENTER to accept.
```

Step 7. Change the time.
Use ← → and the numeric keys to enter the correct time. If the 12-hour clock option is active, press 1 or 2 to select AM or PM. (If the 24-hour clock is active, this option will not appear on the screen. Refer to **3.4**.)

```
Time: xx:xx:xx XM
1 for AM, 2 for PM,
←, → to move cursor,
ENTER to accept.
```

Step 8. Verify the date and time settings.
Press ENTER. If the date or time entered is valid, the following is displayed. (To make more changes, press 1 or 2, then ENTER, and repeat the above from Step 4 or Step 6.)

```
Select:2 Time
xx/xx/xx xx:xx XM
1- Date 2-Time
ENTER to accept.
```

If an invalid date (such as 14 for the month) or time (30 for hours) was entered, one of the following messages appears:

```
Entry for date was
invalid. Enter date
value again.
Press EXIT.
```

or

```
Entry for time was
invalid. Enter time
value again.
Press EXIT.
```

If needed, press EXIT, return to Step 4 or Step 6, then correct the date or time.

Step 9. Press EXIT once to return to the Change Date & Time function, twice to return to the Date & Time menu, or three times to return to standby mode.

3.4 Selecting the date format

Two options are available: month/day/year, and day/month/year.

Step 1. Access the Date & Time menu.
Press MENU twice.

```
Press ENTER for
date & time menus,
MENU for next option
EXIT to leave.
```

Step 2. Access the Select Date Format function.
Press ENTER, then MENU.

```
Press ENTER to
select date format,
MENU for next option
EXIT to leave.
```

Step 3. Choose the date format.
Press ENTER to display the current date format. Press 1 or 2 to change the format.

```
Select:1    MM/DD/YY
1-MM/DD/YY  05/16/04
2-DD/MM/YY  16/05/04
ENTER to accept.
```

Press ENTER to accept the format and return to the Select Date Format function (shown in Step 2).

Step 4. Press EXIT once to return to the Date & Time menu, or twice to return to standby mode.

3.5 Selecting the time format

Two options are available: 12-hour clock and 24-hour clock.

Step 1. Access the Date & Time menu.
From standby mode, press MENU twice

```
Press ENTER for
date & time menus,
MENU for next option
EXIT to leave.
```

Step 2. Access the Select Time Format function.
Press ENTER, then press MENU twice.

```
Press ENTER to
select time format,
MENU for next option
EXIT to leave.
```

Step 3. Choose the time format.
Press ENTER to display the current time format. Press 1 or 2 to change the format.

```
Select:1    XX HOUR
1-12 hour   04:19 PM
2-24 hour   16:19
ENTER to accept.
```

Press ENTER to accept the format and return to the Select Time Format function (shown in Step 2).

Step 4. Press EXIT once to return to the Date & Time menu, or twice to return to standby mode.

3.6 Customizing reference ranges

Change the analyzer's reference ranges to match the specific reference ranges for the patient population.

NOTE: Change reference ranges in common units or in SI units, not both. The analyzer automatically converts units.

NOTE: If the lower and upper ranges are both 0 for a specific method, the reference ranges will not print for that method.

Step 1. Access the Reference Range menu.
From standby mode, press MENU three times.

```
Press ENTER for
reference range menu
MENU for next option
EXIT to leave.
```

Step 2. Access the Edit Reference Ranges function.
Press ENTER.

```
Press ENTER to edit
reference ranges,
MENU for next option
EXIT to leave.
```

Step 3. Select the method (analyte).
Press ENTER to display the current method. Use ← → to choose a different method. Press ENTER to accept.

```
Select Method:
XXXX
Press ←, → to scan,
ENTER to accept.
```

Step 4. Select the reference range set.
Use the numeric keys to select a set. Press ENTER to accept.

```
Select:1 MALE
1-Male    3-Special
2-Female  4-Control
ENTER to accept.
```

Step 5. ***Special and Control reference ranges only*****: select the range.**
Use the numeric keys to select the reference range. Press ENTER.

```
Special Selection
SPECIAL XX
1-9 keys to change,
ENTER to accept.
```

or

```
Control Selection
CONTROL LEVEL XX
1-9 keys to change,
ENTER to accept.
```

Step 6. Change the reference range values.
The current method (analyte) and its reference range set and values are displayed. Use ← → and the numeric keys to change the range values.

```
<method>     <gender>
<range>      <unit>
0-9 keys to change,
ENTER to accept.
```

Step 7. Verify reference range settings.
Make sure the settings are correct. Press ENTER to accept. If the range values are valid, the following is displayed.

```
Select Method:
XXXX
Press ←, → to scan,
ENTER to accept.
```

If an invalid value was entered, the following is displayed. Press EXIT. The reference range changes are discarded. Repeat Step 6 with valid data.

```
Reference range
entry not valid.

Press EXIT.
```

Step 8. Change the reference ranges for other methods (analytes).
Repeat Step 3 through Step 7 as needed.

Step 9. Print and the verify reference ranges.
Verify the reference ranges by printing them on a result card: from the screen shown below, press EXIT, then MENU to bring up the Print Reference Ranges function (refer to **3.7**).

```
Select Method:
XXXX
Press ←, → to scan,
ENTER to accept.
```

NOTE: The date and time shown on the card refer to when the card was printed, not when the reference ranges were changed. To record the date the ranges were changed, write it on the card.

Step 10.Press EXIT once to return to the Print Reference Ranges function, twice to return to the Reference Range menu, or three times to return to standby mode.

3.7 Printing reference ranges

Print the reference ranges for a specific reference range set.

NOTE: To print reference ranges, lower and upper ranges must be greater than 0.

NOTE: The date and time shown on the card refer to when the card was printed, not when the reference ranges were changed. To record the date the ranges were changed, write it on the card.

Step 1. Access the Reference Range menu.
From standby mode, press MENU three times.

```
Press ENTER for
reference range menu
MENU for next option
EXIT to leave.
```

Step 2. Access the Print Reference Ranges function.
Press ENTER, then MENU.

```
Press ENTER to print
reference ranges,
MENU for next option
EXIT to leave.
```

Step 3. Select the reference range set to print.
Press ENTER. Use the numeric keys to select the reference range set. Press ENTER.

```
Select:1 MALE
1-Male    3-Special
2-Female  4-Control
ENTER to accept.
```

Step 4. ***Special and Control reference ranges only*****: select the range.**
Use the numeric keys to select the reference range. Press ENTER.

```
Special Selection
SPECIAL XX
1-9 keys to change,
ENTER to accept.
```

or

```
Control Selection
CONTROL LEVEL XX
1-9 keys to change,
ENTER to accept.
```

Step 5. Print the reference range set.
Make sure the correct reference range set is displayed. Insert a result card. Follow the instructions on the display.

```
Insert card to print
XXXXXXXXXXXXXXX
reference ranges or
EXIT to quit.
```

```
Printing ranges...
```

```
Remove card.
```

Step 6. Print additional reference ranges.
After the card is removed, the following display is shown. Repeat Step 3 through Step 5 as needed.

```
Select:1 MALE
1-Male    3-Special
2-Female  4-Control
ENTER to accept.
```

Step 7. Press EXIT once to return to the Print Reference Ranges function, twice to return to the Reference Range menu, or three times to return to standby mode.

3.8 Transmitting reference ranges

The reference ranges stored in the analyzer memory can be transmitted to a linked computer. Refer to **1.11** for instructions for linking to an external computer.

NOTE: The date and time recorded are when the transmission was made, not when the reference ranges were changed.

Step 1. Access the Reference Range menu.
From standby mode, press MENU three times.

```
Press ENTER for
reference range menu
MENU for next option
EXIT to leave.
```

Step 2. Access the Transmit Reference Ranges function.
Press ENTER, then press MENU twice.

```
ENTER to transmit
reference ranges,
MENU for next option
EXIT to leave.
```

Step 3. Select the reference range set to transmit.
Press ENTER. Use the numeric keys to select the reference range set. Press ENTER.

```
Select:1 MALE
1-Male    3-Special
2-Female  4-Control
ENTER to accept.
```

Step 4. *Special and Control reference ranges only*: select the range.
Use the numeric keys to select the reference range.

```
Special Selection
SPECIAL XX
1-9 keys to change,
ENTER to accept.
```

or

```
Control Selection
CONTROL LEVEL XX
1-9 keys to change,
ENTER to accept.
```

Step 5. Transmit the reference range set.
Press ENTER. During the transmission, the following is displayed.

```
Transmitting ranges
to computer.
```

Step 6. Transmit additional reference ranges
After the transmission, the following display is shown. Repeat Step 3 through Step 5 as needed.

```
Select:1 MALE
1-Male    3-Special
2-Female  4-Control
ENTER to accept.
```

Step 7. Press EXIT once to return to the Transmit Reference Ranges function, twice to return to the Reference Range menu, or three times to return to standby mode.

3.9 Selecting a language

Five languages are available: English, French, German, Spanish, and Italian.

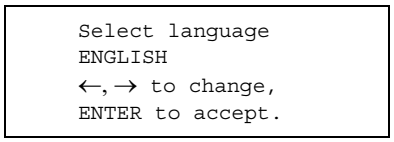
Step 1. Access the Analyzer Setup menu.
From standby mode, press MENU four times.

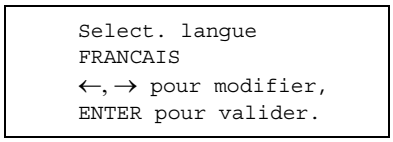
```
Press ENTER for
analyzer setup menu
MENU for next option
EXIT to leave.
```

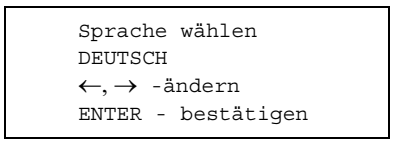
Step 2. Access the Select Language function.
Press ENTER.

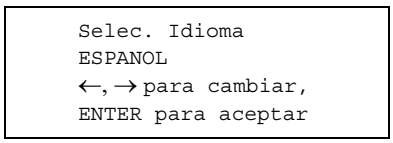
```
Press ENTER to
Select language,
MENU for next option
EXIT to leave.
```

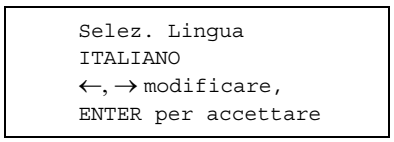
Step 3. Accept or change the current language.
Press ENTER to display the current language. Use ← → to select another language. Press ENTER to accept.









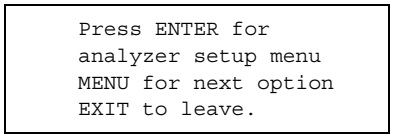


Step 4. Press EXIT once to return to the Analyzer Setup menu, or twice to return to standby mode.

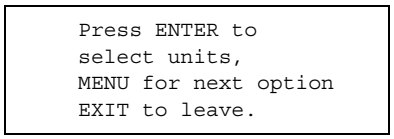
3.10 Selecting units

Two options are available for reporting results: common units (e.g., mg / dL) or SI units (e.g., mmol / L).

Step 1. Access the Analyzer Setup menu.
From standby mode, press MENU four times.



Step 2. Access the Select Units function.
Press ENTER, then MENU.



Step 3. Accept or change the current option.
Press ENTER to display the current units. Press ← → to change the units. Press ENTER to accept.

```
Common Units

←, → to change,
ENTER to accept.
```

or

```
SI (Int'l) units

←, → to change
ENTER to accept.
```

Step 4. Press EXIT once to return to the Analyzer Setup menu, or twice to return to standby mode.

3.11 Selecting the data format

Three options are available for the format used to transmit data: ASTM E 1394-97, ASCII text dump, or none.

Step 1. Access the Analyzer Setup menu.
From standby mode, press MENU four times.

```
Press ENTER for
analyzer setup menu
MENU for next option
EXIT to leave.
```

Step 2. Access the Set Data Format function.
Press ENTER, then press MENU twice.

```
Press ENTER to
set data format,
MENU for next option
EXIT to leave.
```

Step 3. Accept or change the current option.
Press ENTER to display the current data format. Press ← → to change the format. Press ENTER to accept.

```
Serial Data Output
NONE
←, → to change,
ENTER to accept.
```

or

```
Serial Data Output
ASTM E 1394-97
←, → to change,
ENTER to accept.
```

or

```
Serial Data Output
ASCII Text Dump
←, → to change,
ENTER to accept.
```

Step 4. Press EXIT once to return to the Analyzer Setup menu, or twice to return to standby mode.

NOTE: The transmit portions of the RECALL menus and reference range transmission are available only when ASCII Text Dump is selected.

Section 4: The Recall Function

The RECALL key allows access to patient results, control results, and system QC data stored in the analyzer memory. The analyzer memory stores the results for the last 70 patient samples and the last 70 control samples, in reverse chronological order. (Refer to **1.9** for information about system QC data.) Results or system QC for a specified sample or control that remains in memory can be recalled using run-specific parameters, or by viewing the entries in chronological order.

Note that results stored on an external computer must be accessed through the computer.

The Recall menus and functions are available from standby mode, i.e., when no analysis is in progress and the drawer is closed. They cannot be accessed from the Menu functions. From within any of these menus and functions, press EXIT to return to the previous display. Press EXIT repeatedly to return to standby mode

- Use the numeric and arrow keys to enter patient, operator, and physician IDs. The → key functions as a dash; the ← key functions as a backspace (delete key).
- The message `No results in memory` may be displayed if the analyzer memory has been cleared during servicing. If it appears at any other time, refer to **5.6** for troubleshooting procedures under the error code number.

4.1 Viewing or printing patient records

Use the following procedure to view or print selected patient result records, quality control records, or error flag records.

Step 1. Access the Recall Results menu.
From standby mode, press RECALL.

```
Press ENTER to
Recall Results
MENU for next option
EXIT to leave.
```

Step 2. Access the Recall Patient Results function.
Press ENTER.

```
Recall
patient results
←, → to change,
ENTER to accept.
```

Step 3. Select the type of records to view.
Use the ← → keys to select patient result records, iQC records, or flag records.

```
Recall
patient results
←, → to change,
ENTER to accept.
```

```
Recall
patient iQC
←, → to change,
ENTER to accept.
```

```
Recall
patient flags
←, → to change,
ENTER to accept.
```

Press ENTER to accept. One of the following appears, depending on the selection

```
Recall:1 Single
1-Single result card
2-All patients
ENTER to accept.
```

```
Recall:1 Single
1-Single iQC card
2-All patient iQC
ENTER to accept.
```

```
Recall:1 Single
1-Single flag card
2-All patient flags
ENTER to accept.
```

Step 4. Choose a specific patient result record, iQC record, or flag record.
Press 1, ENTER.

```
Select:1 Print
1-Print result card
2-Transmit patient
ENTER to accept.
```

```
Select:1 Print
1-Print iQC card
2-Transmit patient
ENTER to accept.
```

```
Select:1 Print
1-Print flag card
2-Transmit patient
ENTER to accept.
```

Step 5. Accept the print option.
Press 1, ENTER. By default, the patient ID, date, and time of the most recent record are displayed.

```
Pt # XXXXXXXXXXXXXX
xx/xx/xx    xx:xxXM
←, → to view results,
ENTER to print.
```

```
Pt # XXXXXXXXXXXXXX
xx/xx/xx    xx:xxXM
←, → to view iQC,
ENTER to print.
```

```
Pt # XXXXXXXXXXXXXX
xx/xx/xx    xx:xxXM
←, → to view flags,
ENTER to print.
```

NOTE: If the analyzer has no records in memory, one of the following appears instead. Press ENTER to return to Step 1.

```
No patient
results found.

Press ENTER.
```

```
No patient
iQC found.

Press ENTER.
```

```
No patient
flags found.

Press ENTER.
```

Step 6. View or search for patient records.
Patient records can be viewed sequentially, or located by patient ID.

- **To view records sequentially:**

  Use ← → to view the records. The records are stored in reverse chronological order, so ← shows older records, and → shows newer records. The analyzer beeps twice when there are no more records to view.

  Find the record to be printed, then proceed with Step 7, below. To exit without printing, press EXIT.

- **To search for records by patient ID:**

  Press RECALL.

  ```
  Search for patient #
  _ _ _ _ _ _ _ _ _ _ _ _ _ _
  ENTER to search.
  ```

  Use the numeric keys to enter the patient ID. Use ← to erase displayed characters, and → to enter a dash (–). Press ENTER to search.

  If any records have a matching patient ID, the analyzer displays the patient ID number, date, and time of the most recent matching result, along with the number of the record displayed (`nnn`, below), and the total number of records found (`ttt`). Use ← → to find the record of interest.

  ```
  Pt.# XXXXXXXXXXXXXX
  xx/xx/xx   xx:xxXm
  nnn of ttt, ←,→ to
  view, ENTER to print.
  ```

  If no matching records are found, the following is displayed.

  ```
  Pt.# XXXXXXXXXXXXXX
  not found.

  Press ENTER.
  ```

  If this occurs, press ENTER, make sure the patient ID is correct (or choose another ID), and search again.

Step 7. Print the patient record.
Press ENTER, and follow the displayed instructions. (If a computer is connected to the analyzer, record data are automatically transmitted to the computer. Refer to **1.11**.)

```
Insert card to
print results.
```

```
Printing results...
```

```
Remove card.
```

Step 8. Print additional records.
To print additional records, return to Step 6 on page 4-2.

Step 9. Return to standby mode.
Press EXIT repeatedly until "`Open drawer to run a disc`" is displayed.

4.2 Viewing or printing control records

Use the following procedure to view or print selected control result records, iQC records, or flag records.

Step 1. Access the Recall Controls menu.
From standby mode, press RECALL, MENU.

```
Press ENTER to
Recall Controls
MENU for next option
EXIT to leave.
```

Step 2. Access the Recall Control Results function.
Press ENTER.

```
Recall
control results
←, → to change,
ENTER to accept.
```

Step 3. Select the type of records to view.
Use the ← → keys to select control result records, iQC records, or flag records.

```
Recall
control results
←, → to change,
ENTER to accept.
```

```
Recall
control iQC
←, → to change,
ENTER to accept.
```

```
Recall
control flags
←, → to change,
ENTER to accept.
```

Press ENTER to accept. One of the following appears, depending on the selection

```
Recall:1 Single
1-Single result card
2-All controls
ENTER to accept.
```

```
Recall:1 Single
1-Single iQC card
2-All control iQC
ENTER to accept.
```

```
Recall:1 Single
1-Single flag card
2-All control flags
ENTER to accept.
```

Step 4. Choose to print a single control result record, iQC record, or flag record.

Press 1, ENTER.

```
Select:1 Print
1-Print result card
2-Transmit control
ENTER to accept.
```

```
Select:1 Print
1-Print iQC card
2-Transmit control
ENTER to accept.
```

```
Select:1 Print
1-Print flag card
2-Transmit control
ENTER to accept.
```

Step 5. Accept the print option.
Press 1, ENTER. By default, the control level, date, and time of the most recent record are displayed.

```
Control level XX
xx/xx/xx    xx:xxXM
←, → to view results,
ENTER to print.
```

```
Control level XX
xx/xx/xx    xx:xxXM
←, → to view iQC,
ENTER to print.
```

```
Control level XX
xx/xx/xx    xx:xxXM
←, → to view flags,
ENTER to print.
```

NOTE: If the analyzer has no records in memory, one of the following appears instead. Press ENTER to return to Step 1.

```
No control
results found.

Press ENTER.
```

```
No control
iQC found.

Press ENTER.
```

```
No control
flags found.

Press ENTER.
```

Step 6. View or search for control records.
Control records can be viewed sequentially, or located by date.

- **To view records sequentially:**

  Use ← → to view the records. The records are stored in reverse chronological order, so ← shows older records, and → shows newer records. The analyzer beeps twice when there are no more records to view.

  Find the record to be printed, then proceed with Step 7. To exit without printing, press EXIT.

- **To search for records by date:**

  Press RECALL.

  ```
  Search for control
  results on xx/xx/xx
  Edit date,
  ENTER to search.
  ```

  Use the numeric keys to enter the date. Use ← to erase displayed characters, and → to enter a dash (–). Press ENTER to search.

If any records have a matching date, the analyzer displays the control level, date, and time of the most recent matching record, along with the number of the record displayed (nnn, below), and the total number of records found (ttt). Use ← → to find the record of interest.

```
Control level XX
xx/xx/xx   xx:xxXm
nnn of ttt, ←,→ to
view, ENTER to print.
```

If no matching records are found, the following is displayed.

```
No control results
found on xx/xx/xx

Press ENTER.
```

If this occurs, press ENTER, make sure the date is correct (or choose another date), and search again.

Step 7. Print the control record.
Press ENTER, and follow the displayed instructions. (If a computer is connected to the analyzer, the records is automatically transmitted to the computer. Refer to **1.11**.)

```
Insert card to
print results.
```

```
Printing results...
```

```
Remove card.
```

Step 8. Print additional records.
To print additional records, return to Step 6 on page 4-5.

Step 9. Return to standby mode.
Press EXIT repeatedly until "Open drawer to run a disc" is displayed.

4.3 Viewing or printing error records

Use the following procedure to print errors record.

Step 1. Access the Recall Errors function.
From standby mode, press RECALL, then press MENU twice.

```
Press ENTER to
Recall Errors
MENU for next option
EXIT to leave.
```

Step 2. Recall a single error record.
Press ENTER.

```
Recall:1 Single
1-Single error card
2-All errors
ENTER to accept.
```

Step 3. Choose to print a single error.
Press 1, ENTER.

```
Select:1 Print
1-Print error card
2-Transmit errors
ENTER to accept.
```

Step 4. Accept the print option.
Press 1, ENTER. By default, the error level, date, and time of the most recent record are displayed.

```
Pt. # LEVEL XX
xx/xx/xx    xx:xxXM
←, → to view results,
ENTER to print.
```

NOTE: If the analyzer has no records in memory, the following appears instead. Press ENTER to return to Step 1.

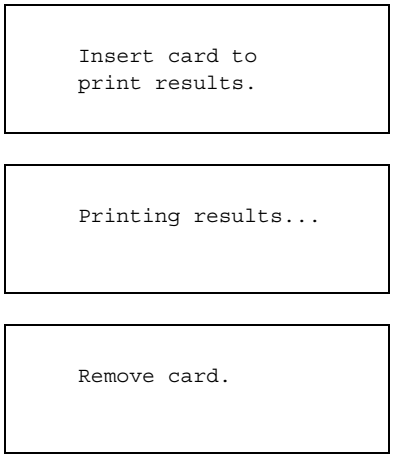
```
No error
results found.

Press ENTER.
```

Step 5. View the error records.

Use the ← → keys to view the records. The records are stored in reverse chronological order, so ← shows older records, and → shows newer records. The analyzer beeps twice when there are no more records to view.

Find the record to be printed, then proceed with Step 6. To exit without printing, press EXIT.

Step 6. Print the error record.
Press ENTER, and follow the displayed instructions. (If a computer is connected to the analyzer, the record is automatically transmitted to the computer. Refer to **1.11**.)



Step 7. Print additional records.
To print additional records, return to Step 5, above.

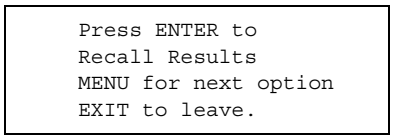
Step 8. Return to standby mode.
Press EXIT repeatedly until "`Open drawer to run a disc`" is displayed.

4.4 Transmitting patient records

Use the following procedure to transmit patient result records, quality control records, or error flag records to a connected computer.

NOTE: Transmitting all records is recommended before reinitializing the analyzer's software, or before returning the analyzer to Abaxis for service.

Step 1. Access the Recall Results menu.
From standby mode, press RECALL.



Step 2. Access the Recall Patient Records function.
Press ENTER.

```
Recall
patient results
←, → to change,
ENTER to accept.
```

Step 3. Select the type of patient records to transmit.
Use the ← → keys to select patient result records, iQC records, or flag records.

```
Recall
patient results
←, → to change,
ENTER to accept.
```

```
Recall
patient iQC
←, → to change,
ENTER to accept.
```

```
Recall
patient flags
←, → to change,
ENTER to accept.
```

Press ENTER to accept. One of the following appears, depending on the selection

```
Recall:1 Single
1-Single result card
2-All patients
ENTER to accept.
```

```
Recall:1 Single
1-Single iQC card
2-All patient iQC
ENTER to accept.
```

```
Recall:1 Single
1-Single flag card
2-All patient flags
ENTER to accept.
```

Step 4. To transmit *a single patient record*:

NOTE: To transmit all patient records, go to Step 5 on page 4-10.

a. Press 1, ENTER.

```
Select:1 Print
1-Print result card
2-Transmit patient
ENTER to accept.
```

```
Select:1 Print
1-Print iQC card
2-Transmit patient
ENTER to accept.
```

```
Select:1 Print
1-Print flag card
2-Transmit patient
ENTER to accept.
```

b. Press 2, ENTER. By default, the patient ID, date, and time of the most recent record are displayed.

```
Pt # XXXXXXXXXXXXXX
xx/xx/xx    xx:xxXM
←, → to view results,
ENTER to transmit.
```

```
Pt # XXXXXXXXXXXXXX
xx/xx/xx    xx:xxXM
←, → to view iQC,
ENTER to transmit.
```

```
Pt # XXXXXXXXXXXXXX
xx/xx/xx    xx:xxXM
←, → to view flags,
ENTER to transmit.
```

NOTE: If the analyzer has no results in memory, one of the following appears instead. Press ENTER to return to Step 1.

```
No patient
results found.

Press ENTER.
```

```
No patient
iQC found.

Press ENTER.
```

```
No patient
flags found.

Press ENTER.
```

c. View the records sequentially, or search for a particular record by patient ID.

- **To view records sequentially:**

  Use ← → to view the records. The records are stored in reverse chronological order, so ← shows older records, and → shows newer records. The analyzer beeps twice when there are no more records to view.

  Find the record to be transmitted, then proceed with Step 6. To exit without transmitting, press EXIT.

- **To search for records by patient ID:**

  Press RECALL.

```
Search for patient #
_ _ _ _ _ _ _ _ _ _ _ _ _

ENTER to search.
```

  Use the numeric keys to enter the patient ID. Use ← to erase displayed characters, and → to enter a dash (–). Press ENTER to search.

  If any records have a matching patient ID, the analyzer displays the patient ID number, date, and time of the most recent matching result, along with the number of the record displayed (`nnn`, below), and the total number of records found (`ttt`). Use ← → to find the record of interest.

```
Pt.# XXXXXXXXXXXXXX
xx/xx/xx   xx:xxXm
nnn of ttt, ←,→ view
ENTER to transmit.
```

  If no matching records are found, the following is displayed.

```
Pt.# XXXXXXXXXXXXXX
not found.

Press ENTER.
```

  If this occurs, press ENTER, make sure the patient ID is correct, and search again.

d. Go to Step 6, below.

Step 5. To transmit *all patient records*:

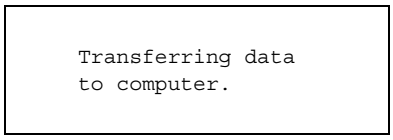
a. Press 2, ENTER.

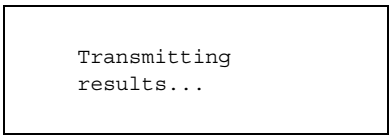
```
Transmit all
patient results
ENTER to transmit
EXIT to leave.
```

```
Transmit all
patient iQC
ENTER to transmit
EXIT to leave.
```

```
Transmit all
patient flags
ENTER to transmit
EXIT to leave.
```

Step 6. Transmit the record or records.
Press ENTER. One of the following appears while the record is being transmitted.





Step 7. Transmit additional records.
To transmit additional records, return to Step 4 on page 4-9.

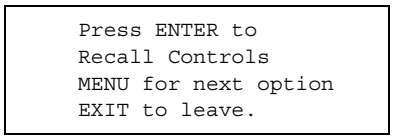
Step 8. Return to standby mode.
Press EXIT repeatedly until "`Open drawer to run a disc`" is displayed.

4.5 Transmitting control records

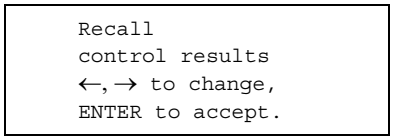
Use the following procedure to transmit control results records, iQC records, or flag records to a connected computer.

NOTE: Transmitting all records is recommended before reinitializing the analyzer's software, or before returning the analyzer to Abaxis for service.

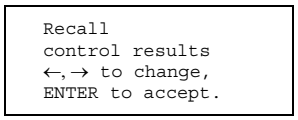
Step 1. Access the Recall Controls menu.
From standby mode, press RECALL, MENU.

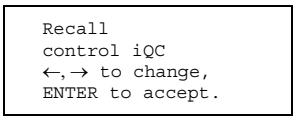


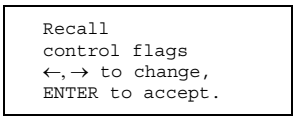
Step 2. Access the Recall Control Results function.
Press ENTER.



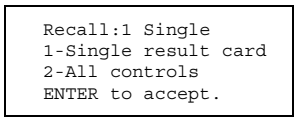
Step 3. Select the type of control records to transmit.
Use the ← → keys to select control result records, iQC records, or flag records.

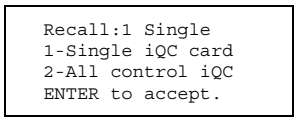


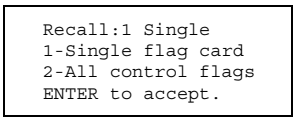




Press ENTER to accept. One of the following appears, depending on the selection



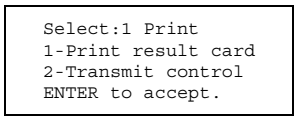


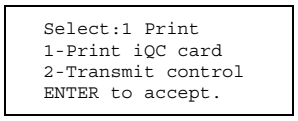


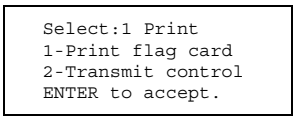
Step 4. To transmit *a single control record*:

NOTE: To transmit all control records, go to Step 5 on page 4-13.

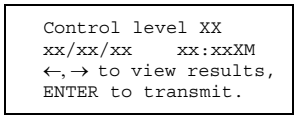
a. Press 1, ENTER.

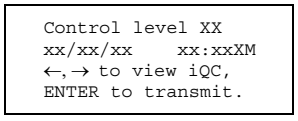


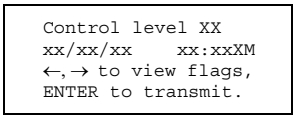




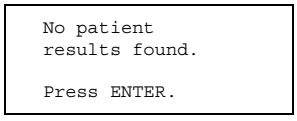
b. Press 2, ENTER. By default, the control level, date, and time of the most recent record are displayed.

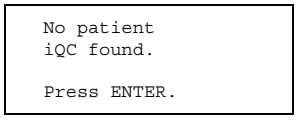


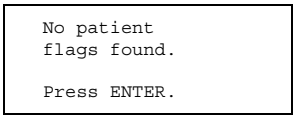




NOTE: If the analyzer has no records in memory, one of the following appears instead. Press ENTER to return to Step 1.







c. View the records sequentially, or search for a particular record by date.

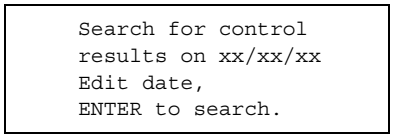
- **To view records sequentially:**

  Use ← → to view the records. The records are stored in reverse chronological order, so ← shows older records, and → shows newer records. The analyzer beeps twice when there are no more records to view.

  Find the record to be transmitted, then proceed with Step 6. To exit without transmitting, press EXIT.

- **To search for records by date:**

  Press RECALL.



Use the numeric keys to enter the date. Use ← to erase displayed characters, and → to enter a dash (–). Press ENTER to search.

If any records have a matching date, the analyzer displays the control level, date, and time of the most recent matching result, along with the number of the record displayed (`nnn`, below), and the total number of records found (`ttt`). Use ← → to find the particular record of interest.

```
Control level XX
xx/xx/xx   xx:xxXm
nnn of ttt, ←,→ view
ENTER to transmit.
```

If no matching records are found, the following is displayed.

```
No control results
found on xx/xx/xx

Press ENTER.
```

If this occurs, press ENTER, make sure the date is correct (or enter another date), and search again.

d. Go to Step 6, below.

Step 5. To transmit *all control records*:

a. Press 2, ENTER.

```
Transmit all
control results
ENTER to transmit
EXIT to leave.
```

```
Transmit all
control iQC
ENTER to transmit
EXIT to leave.
```

```
Transmit all
control flags
ENTER to transmit
EXIT to leave.
```

Step 6. Transmit the record or records.
Press ENTER. One of the following appears while the record is being transmitted.

```
Transferring data
to computer.
```

```
Transmitting
results...
```

Step 7. Transmit additional records.
To transmit additional records, return to Step 4 on page 4-12.

Step 8. Return to standby mode.
Press EXIT repeatedly until "`Open drawer to run a disc`" is displayed.

4.6 Transmitting error records

Use the following procedure to transmit error records to a connected computer.

NOTE: Transmitting all records is recommended before reinitializing the analyzer's software, or before returning the analyzer to Abaxis for service.

Step 1. Access the Recall Errors function.
From standby mode, press RECALL, then press MENU twice.

```
Press ENTER to
Recall Errors
MENU for next option
EXIT to leave.
```

Step 2. Recall the error records.
Press ENTER.

```
Recall:1 Single
1-Single error card
2-All errors
ENTER to accept.
```

Step 3. To transmit *a single error record*:

NOTE: To transmit all error records, go to Step 4 on page 4-16.

a. Press 1, ENTER.

```
Select:1 Print
1-Print error card
2-Transmit errors
ENTER to accept.
```

b. Press 2, ENTER. By default, the error level, date, and time of the most recent record are displayed.

```
Pt.#  LEVEL XX
xx/xx/xx  xx:xxXM
←,→ to view results,
ENTER to transmit.
```

NOTE: If the analyzer has no records in memory, the following appears instead. Press ENTER to return to Step 1.

```
No error
results found.

Press ENTER.
```

c. View the records sequentially, or search for a particular record by date.

- **To view records sequentially:**

  Use the ← → keys to view the records. The records are stored in reverse chronological order, so ← shows older records, and → shows newer records. The analyzer beeps twice when there are no more records to view.

  Find the record to be transmitted, then proceed with Step 5 on page 4-16.
  To exit without transmitting, press EXIT.

- **To search for records by date:**

  Press RECALL.

```
Search for errors
results on xx/xx/xx
Edit date,
ENTER to search.
```

  Use the numeric keys to enter the date. Use ← to erase displayed characters, and → to enter a dash (–). Press ENTER to search.

  If any records have a matching date, the analyzer displays the error level, date, and time of the most recent matching result, along with the number of the record displayed (`nnn`, below), and the total number of records found (`ttt`). Use ← → to find the particular record of interest.

```
Pt.# LEVEL XX
xx/xx/xx   xx:xxXm
nnn of ttt, ←,→ view
ENTER to transmit.
```

  If no matching records are found, the following is displayed.

```
No error results
found on xx/xx/xx

Press ENTER.
```

  If this occurs, press ENTER, make sure the date is correct (or enter another date), and search again.

d. Go to Step 5, below.

Step 4. To transmit *all error records*:
Press 2, ENTER.

```
Transmit all
errors
ENTER to transmit
EXIT to leave.
```

Step 5. Transmit the record or records.
Press ENTER. One of the following appears while the data is being transmitted.

```
Transferring errors
to computer.
```

```
Transmitting
results...
```

Step 6. Transmit additional records.
To transmit additional records, return to Step 3 on page 4-14.

Step 7. Return to standby mode.
Press EXIT repeatedly until "`Open drawer to run a disc`" is displayed.

Section 5: Maintenance and Troubleshooting

5.1 Routine maintenance

The Piccolo® Point-of-Care Chemistry Analyzer requires no scheduled servicing. Maintenance of the analyzer is limited to:

- cleaning the exterior weekly, or as needed
- cleaning the printer and results card slot every 3 months
- cleaning the air filter every 6 months

Biohazard: The interior of the analyzer should be considered contaminated after the first sample or control has been run.

5.1.1 Cleaning the exterior

Clean the outside surface of the analyzer at least every week and immediately after sample, reagent, or other material has been spilled on it. Clean the analyzer with a soft cloth dampened with a mild detergent or cleaning solution, or a 10% bleach solution (1 part bleach to 9 parts water), or a 30% isopropyl alcohol solution. Do not spray or pour detergents or other solution directly onto the analyzer. Wipe the entire surface of the analyzer, including the keypad. Observe Universal Precautions when cleaning spills.

5.1.2 Cleaning the printer

The printer should be cleaned at least once every 3 months to avoid paper jams and printer malfunctions. Dust, debris, hair, or objects may become deposited in the result card slot during the course of operation. If more than one attempt is required to feed a card into the slot, the printer may require cleaning.

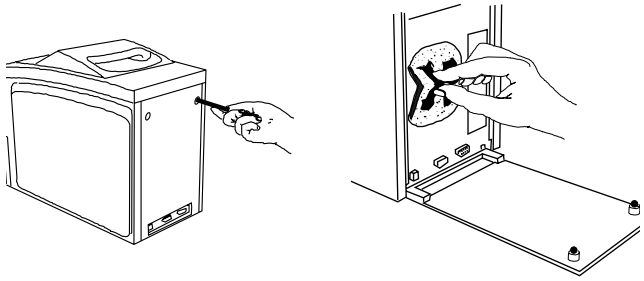
Procedure: Expel a steady stream of compressed air directly into the results card slot, sweeping from right to left, pausing momentarily, then sweeping back to the right. It is important to direct a stream of air into the left side of the slot to clear any debris from the print sensor.

If the problem persists, a more thorough cleaning may be required. Access the printer follow the instructions for clearing a paper jam; then expel compressed air directly into the printer. For further assistance, call Abaxis Technical Support at 800-822-2947.

5.1.3 Cleaning the air filter

The air filter should be cleaned at least once every 6 months. Check the air filter more frequently if the analyzer is in a dusty environment. To clean the air filter:

Step 1. Remove the filter.
Power down the analyzer and unplug the power cord from the back panel. Remove the back panel by removing the two Phillips screws at the top of the panel. Grasp the black mesh filter in the circular opening and pull the filter free.



Step 2. Wash the filter.
Use warm soapy water. Dry the filter thoroughly before replacing it in the analyzer.

Step 3. Replace the filter.
Tuck the sides in behind the edges of the circular opening. Replace the rear panel.

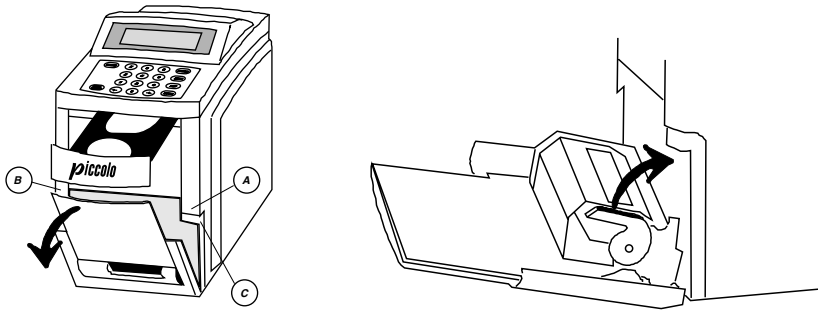
Step 4. Power up the analyzer.
Reconnect the analyzer to the power supply and plug it in. The analyzer returns to standby mode.

If the analyzer reports an error, repeat the installation procedure. If the error persists, call Abaxis Technical Support at 800-822-2947.

5.2 Clearing a paper jam

If a results card becomes jammed in the printer, you can open the analyzer front panel and remove the card.

Step 1. Access the printer.
Open the disc drawer. Power down the analyzer and unplug the power cord from the back panel. Open the front panel by placing your thumbs at points A and B shown in the figure below. Grasp slot C on both sides of the front panel with your fingers and pull the panel toward you. (The panel is hinged at the bottom.) The printer is visible when the front panel is open.



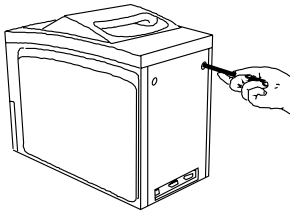
Step 2. Remove the jammed card.
Lift the printer-head lever located on the right side of the printer, as shown in the figure above. Carefully remove the jammed result card. Push the printer-head lever back down to its normal position. Press the front panel firmly into the closed position.

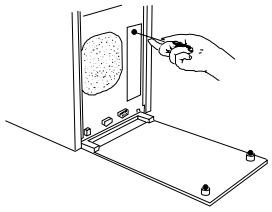
Step 3. Power up the analyzer.
Reconnect the analyzer to the power supply and plug it in. The analyzer returns to standby mode.

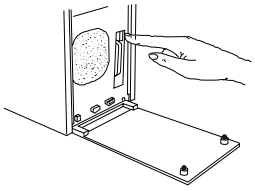
5.3 Installing a software card

From time to time, Abaxis will provide software cards to update and add functionality to the analyzer. To install a software card:

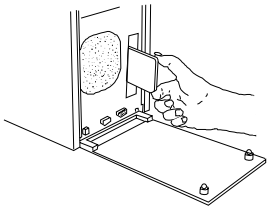
Step 1. Remove the existing software card.
Power down the analyzer and unplug the power cord from the back panel. Remove the back panel by removing the two Phillips screws at the top of the panel. Remove the software card retaining bracket by removing the Phillips screw. Take care to avoid losing this very small screw. To eject the card, push the black button at the top of the access slot. Refer to the figures below.







Step 2. Insert the new software card.
Insert the new card with the printed label facing toward the center of the analyzer. Refer to the figure to the right. Push the card in firmly until it clicks into place. Replace the retaining bracket and back panel.



Step 3. Automatic reprogramming.
Power up the analyzer. It performs the self-test and reprogramming in about 10 minutes. Additional time may be required for the analyzer to reach operating temperature. The procedure is complete when the analyzer returns to standby mode.

If the analyzer reports an error, repeat the installation procedure, verifying that the new card is seated properly. If the error persists, call Abaxis Technical Support at 800-822-2947.

5.4 Reinitializing the analyzer

Reinitializing the analyzer may become necessary if the memory becomes corrupted. A Code 28 error message is a warning that the memory has become corrupted and must be reinitialized.

The reinitializing process clears all results from memory and deletes all customized reference ranges. After receiving a Code 28 message, check the status of the patient and control results in memory following the procedures in **4.1** and **4.2**. If results remain in memory, and the analyzer is linked to an external computer, follow the instructions to transmit all patient records, control records, and system QC data (see **4.4** and **4.5**), respectively, to the external computer before reinitializing the software. If results remain in memory, and the analyzer is not linked to an external computer, print all records (patient, control, and system QC results) that you wish to retain, following the procedures in **Section 4**. Follow the procedure in **3.7** or **3.8** to print or transmit reference ranges.

Reinitializing restores all defaults. Refer to **Section 3** for procedures for changing the date and time, selecting units, and customizing reference ranges.

Step 1. Access the Reset function.
From standby mode, press 0.

```
RESET
Internal Clock
CLEARING memory
ENTER to accept
```

Step 2. Verify intention to reset.
Press ENTER. The display reads:

```
Are you sure you want
to reset?
ENTER for yes
EXIT for no
```

Step 3. Begin reinitialization.
Press ENTER again. During the reinitialization process, the display reads:

```
Resetting clock ...
Clearing Memory ...
```

5.5 Returning the analyzer to Abaxis for service

If the procedures in Maintenance and Troubleshooting fail to resolve a problem with the operation of the analyzer, call Abaxis Technical Support at 800-822-2947. Authorization from Technical Support is required before returning an analyzer for repairs.

5.6 Error messages

The following list of warnings and error messages is in order by error code number. Some error codes include an internal error code number displayed flush left on the 4th line of the display. Record this internal error code number before pressing EXIT or calling Abaxis Technical Support at 800-822-2947. The number helps Technical Support to diagnose the problem. All error messages generate a cancellation report in addition to the error code. Insert a result card to print the report before pressing EXIT. Have any error codes and the report, if applicable, at hand when calling Abaxis Technical Support.

Error Message	Explanation and Solution

Code 10
`Run canceled: Barcode error. Repeat run with new disc.`
`xxxx See Code 10`
	The disc bar code is unreadable because of scratches, spills, or other problems; or an outdated version of the software is installed on the analyzer.
	Record the internal error code (`xxxx`). Press EXIT to acknowledge the message and open the drawer. Remove and discard the disc. Prepare a new disc using the sample or control and proceed with testing.
	If this error message appears again during testing of the second disc, record the second internal error code. Insert a result card to print a troubleshooting report. When printing is complete, press EXIT. Remove and discard the disc. Call Abaxis Technical Support at 800-822-2947 with both internal error codes and the troubleshooting report at hand.

Code 11
`Ambient temperature outside operational range of analyzer.`
`See Code 11`
	The ambient temperature is outside the analyzer operating range (15-32°C; 59-90°F).
	Press EXIT to acknowledge the message. Adjust the room temperature, or power down the analyzer and move it to a warmer or cooler environment.

Error Message	Explanation and Solution
Code 12 `Run canceled. Analyzer temperature outside operating range. See Code 12`	The analyzer temperature is too high or too low to run the disc. Insert a result card to print the cancellation report. Press EXIT to acknowledge the message and open the drawer. Remove and discard the disc. Temperature too low: If you are running the first disc after powering up, allow the analyzer more warm-up time. If the ambient temperature is below 15°C (59°F), adjust the room temperature or move the analyzer to a warmer environment. Use a new disc to run the sample or control. Temperature too high: If the analyzer has run several discs, open the drawer and allow it to cool down for about 15 minutes. Use a new disc to run the sample or control.
Code 13 `Run canceled. Disc out of date. Repeat run with new disc. See Code 13.`	The disc expiration date has passed. Insert a result card to print the cancellation report. Press EXIT to acknowledge the message and open the drawer. Remove and discard the disc. Verify that the analyzer is using the correct date. Refer to **3.2**. Use a within-date disc to run the sample or control.

Error Message	Explanation and Solution

Code 14
`Run canceled. Repeat run with new disc.`
`xxxx See Code 14`
	The problem may be with the sample, the disc, or the analyzer hardware or software.
	Record the internal error code (`xxxx`). Insert a result card to print the cancellation report. Press EXIT to acknowledge the message and open the drawer. Remove and discard the disc. Use a new disc to run the sample or control. There may be a brief delay (10-15 seconds) before testing begins.
	If this error message appears again during testing of the second disc, record the second internal error code. Insert a result card to print the cancellationreport. Press EXIT to acknowledge the message and open the drawer. Remove and discard the disc. Call Abaxis Technical Support at 800-822-2947 with both internal error codes and the troubleshooting report at hand.

Code 15 `Run canceled. Insufficient sample. Repeat run with new disc. See Code 15`	The run has been canceled due to one of the following: • Insufficient sample or control is in the disc. • The whole blood sample has clotted. • A used disc has been left in the analyzer. Insert a result card to print the cancellation report. Press EXIT to acknowledge the message and open the drawer. Check the disc for insufficient or coagulated sample. Discard the disc. Use a new disc to run the sample or control.

Error Message	Explanation and Solution
Code 21 `Analyzer overheated. Refer to manual. See Code 21`	This message may be displayed at the end of a run. The results of that run are not affected and may be reported. However, unless the analyzer is allowed to cool down, the next run may be aborted. Insert a result card to print the cancellation report. Press EXIT to acknowledge the message and open the drawer. Remove and discard the disc. Leave the drawer open and allow the analyzer to cool down for about 15 minutes. If necessary, adjust the room temperature to 32°C (90°F) or less, or move the analyzer to a cooler environment.
Code 22 `Faulty software card. Refer to manual for card replacement. xxxx See Code 22`	This message may be displayed after powering up the analyzer. The software card may not be seated properly or may be faulty. Record the internal error code (`xxxx`). Insert a result card to print the cancellation report. Press EXIT to acknowledge the message. The analyzer automatically shuts down. Refer to **5.3** for the procedure to reinstall the software card. If the problem persists, call Abaxis Technical Support at 800-822-2947.
Code 24 `Paper jammed in printer. Refer to manual to clear. See Code 24`	Refer to **5.2** for instructions on clearing a paper jam.

Error Message	Explanation and Solution
Code 25 `Drawer malfunction. Refer to manual to clear. See Code 25`	The drawer motor has shut down because the drawer cannot completely close or open. **Drawer does not close:** Press EXIT to acknowledge the message. Inspect the disc to see if the bar code ring has separated from the disc. If no separation is visible, reposition the disc and press close. If separation is visible, prepare a new disc and load it. **Drawer does not open:** Call Abaxis Technical Support at 800-822-2947.
Code 26 `Analyzer failure. Remove from service. xxxx See Code 26`	The analyzer has been exposed to very cold temperatures or there is a problem with the analyzer hardware that cannot be corrected by resetting the analyzer (powering down and up).Record the internal error code (`xxxx`). Press EXIT to acknowledge the message. Power down the analyzer and allow it to sit for 15-30 minutes at an ambient temperature of 15-32°C (59-90°F). Power up the analyzer and allow adequate warm-up time before running a disc. If the analyzer has not been exposed to cold temperatures, there may be a hardware problem. Record the internal error code (`xxxx`). Press EXIT to acknowledge the message and shut down the analyzer. Call Abaxis Technical Support at 800-822-2947.

Error Message

Code 27

```
Run canceled.
Disc rubbing. Repeat
run with new disc.
xxxx See Code 27
```

The disc is not spinning properly or is rubbing against the walls of the drawer.

Record the internal error code (xxxx). Insert a result card to print the cancellation report. Press EXIT to acknowledge the message and open the drawer. Remove and discard the disc. Use a new disc to run the sample or control.

If this error appears again during testing of the second disc, record the second internal error code. Call Abaxis Technical Support at 800-822-2947 with both internal error codes at hand.

Code 28

```
Internal clock error
corrected. Check ana-
lyzer time and date!
See Code 28
```

The memory may have become corrupted and may require reinitialization. Press EXIT to acknowledge the message. Refer to 5.4.

Code 31

```
No results found in
memory. Run a disc
before printing.
See Code 31.
```

This message appears only before the first use of the analyzer or if the memory was cleared when the analyzer was serviced.

Press EXIT to acknowledge the message. Run a sample or control before printing or recalling results.

Code 33

```
Reference ranges are
corrupt. Ranges will be
reset to factory val-
ues!
See Code 33
```

There is a problem with the customized reference ranges stored in memory. All the ranges have been reset to the default value. Press EXIT to acknowledge the message. Refer to **3.6** for directions on customizing reference ranges.

Error Message	Explanation and Solution
Code 34 `Memory error. All results and settings cleared from memory. See Code 34.`	A memory error has been automatically corrected. All patient and control results stored in the analyzer have been lost. Menu functions have been restored to their default settings. Results cannot be restored. Press EXIT to acknowledge the message. Refer to **Section 3** for instructions on resetting date, time and units, if necessary.
Code 35 `Improper date set in analyzer. Correct date and repeat run. See Code 35`	The internal clock is set to a date that is earlier than the manufacture date of the reagent disc. Press EXIT to acknowledge the message and open the drawer. Remove and discard the disc. Refer to **3.2** for instructions on resetting the date. Use a new disc to run the sample or control.
Code 36 `Wrong disc type used (not Piccolo). Repeat run with new disc. See Code 36`	The wrong disc type is being used (VetScan rotor in stead of Piccolo disc), or the analyzer has the wrong software installed. Use a Piccolo disc and repeat the run. If the problem persists, call Abaxis Technical Support at 800-822-2947.
Code 37 `Run canceled. Sample Quality Check Serum See Code 37`	Unacceptably low transmission occurred at the wavelengths used to check for endogenous substances (HEM, LIP, ICT). Insert a result card to print the cancellation report. If the sample distributed properly on the disc (beads dissolved), then the sample is likely hemolized (HEM). If the sample contains whole blood, separate the red blood cells out, and check whether the serum sample is hemolized (HEM), lipemic (LIP), or icteric (ICT).