

Piccolo Xpress chemistry analyzer Operator's Manual

for In-Vitro Diagnostic Use Only

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*The Information in the manual is relevant for analyzer part numbers 1100-1001 and 1100-1001R.
Analyzers 1100-1001 and 1100-1001R report to catalog numbers 1100-0000, 1100-0000E,
1100-0000R and 1100-0000ER.*

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General Information

This section provides an overview of the Piccolo Xpress chemistry analyzer.

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1.1 Intended Use

The Piccolo Xpress chemistry analyzer provides quantitative in-vitro determinations of clinical chemistry analytes in lithium-heparinized whole blood, heparinized plasma, or serum. The Piccolo Xpress will be referred to as the “analyzer” throughout this manual.

CAUTION: *The analyzer may not operate as intended if used other than described in this manual. It may produce inaccurate or no results and may pose a safety hazard.*

Note: *Use only Piccolo reagent discs with this analyzer.*



Applicable to U.S. Customers Only:

CLIA WAIVED: The Lipid Panel, Lipid Panel Plus, Liver Panel Plus, General Chemistry 6, General Chemistry 13, Kidney Check, Comprehensive Metabolic Panel, Basic Metabolic Panel, Electrolyte Panel, MetLyte 8, and Renal Function Panel Reagent Discs are CLIA Waived. These discs are waived under CLIA '88 regulations. For CLIA waived labs, only lithium heparin whole blood may be tested. For use in moderate complexity labs, lithium heparinized whole blood, lithium heparinized plasma, or serum may be used. A CLIA Certificate of Waiver is needed to perform CLIA waived testing. A Certificate of Waiver can be obtained from the Centers for Medicare & Medicaid Services (CMS). If a waived laboratory modifies the test system instructions, then the test is considered high complexity and subject to all CLIA requirements.

1.2 Universal Precautions

Operator health and safety regulations require that Universal Precautions be observed at all times while handling human blood samples or working with this analyzer. For details, see *OSHA 29 CFR Part 1910 (“Occupational Safety and Health Standards”), Standard Number 1910.1030 (“Toxic and Hazardous Substances: Bloodborne Pathogens”)*, which can be found by visiting <http://www.osha.gov> and searching for “1910.1030.”

For further guidelines on handling and disposing of hazardous laboratory wastes, refer to *Clinical Laboratory Waste Management; Approved Guideline — Second Edition (GP5-A2)*, from the Clinical and Laboratory Standards Institute (formerly NCCLS). This can be found at <http://www.clsi.org>.

1.3 Introduction

This system consists of a portable analyzer and single-use disposable reagent discs – it is compact and easy to transport. The analyzer contains the following:

- a variable-speed motor to spin the reagent disc
- a photometer to measure analyte concentrations
- two microprocessors to control testing and analytical functions
- a thermal line printer for results
- a WVGA color touchscreen for communicating with the analyzer
- optional data functions for more detailed analysis information

Each reagent disc is self-contained clear plastic, 8 cm in diameter and 2 cm thick. It contains a liquid diluent in its center and dry reagent beads in clear containers (cuvettes) around its edge. All blood separation and sample diluent mixing is performed within the disc itself.

To perform an analysis, the operator needs only to:

1. collect a blood sample (lithium-heparinized whole blood or plasma, serum)
2. place it in the reagent disc
3. put the disc into the analyzer drawer on the front of the analyzer
4. input patient information

When analysis is finished, the results print automatically on an adhesive-backed thermal paper, which is placed in the patient's medical record. The device has one Ethernet port and five USB ports to send data to an external printer, computer, memory stick, or laboratory information systems/electronic medical record systems (LIS/ EMR).

The entire analysis requires ~100 µL of sample and can provide results in about 12 minutes.

Note: *The analyzer screens and computer screen capture in this manual are illustrations only, not exact duplications. All screens represent typical use and installations and may differ in some minor details from the screens on your system.*

Note: *Operators shall report any serious incident that has occurred in relation to the device to the manufacturer and if applicable also to the competent authority of the EU Member State in which the user and/or the patient is established.*






1.4 Technical Support

Abaxis Technical Support personnel are trained to answer questions regarding the operation of the Piccolo Xpress chemistry analyzer. For technical support, call or contact:

- USA: 1-800-822-2947
USA: AB-PiccoloTechSupport@zoetis.com
- Europe: int.piccolosupport@zoetis.com

1.5 Symbols Used in Labeling

The following symbols are found on the back of the analyzer, on the Piccolo Xpress label and above the connectors.

Symbol	Explanation
	Direct current Caution
	Caution Refer to any accompanying documents.
	Biological Risk Indicates that there are potential biological risks associated with the medical device.. See “Universal Precautions” on page 1-2.
	USB connection
	Network connection

Symbol	Explanation
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Manufacturer



Date of Manufacturing in the USA



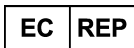
In Vitro Diagnostics Medical Device



Serial Number



Catalogue Number



European Authorized Representative



Importer Contact (EU)



Device may be used for Near-Patient- Testing



Do not dispose as household waste. Separate collection and recycling.



Unique Device Identification



Barcode in Health Industry Barcode Council format



Use By



Batch Code

Symbol	Explanation
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Consult Instructions for Use



Do Not Reuse



X Number of Test Devices in Kit



Manufacturing Sequence



Temperature Limitation

PN:

Part Number



Denotes conformity to specified European directives and regulations

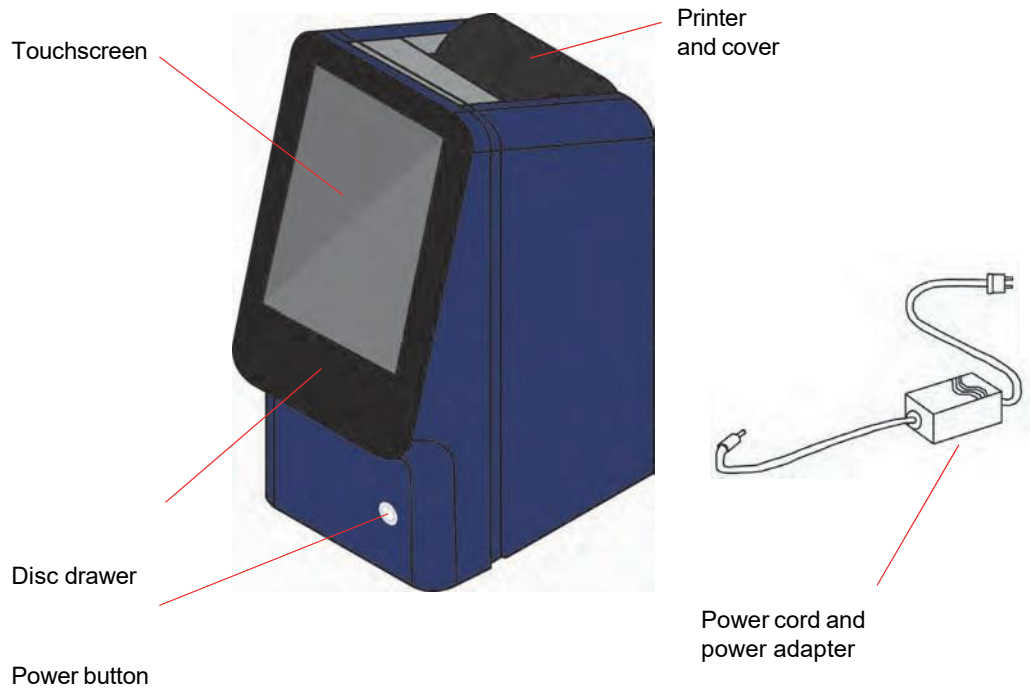
Setup and Description

This section describes how to unpack the Piccolo Xpress analyzer, and how to set it up in a suitable environment. This section also introduces the analyzer's front panel and touchscreen user interface.

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2.1 Unpacking

1. Remove the analyzer from its shipping carton.
2. Place the analyzer on a level surface that is free of hair, dust, and other contaminants. Do not place the analyzer near a sunny window or any other heat source.
3. Check the components received with the Piccolo Xpress against the following figure to make sure everything required to set up the analyzer is included.



Note: The shipping carton also includes these items, not shown above: a USB cable, Abaxis Driver CD, Piccolo Xpress Operator's Manual (this manual), warranty card, and Startup kit.

4. After setup, complete the warranty card and mail it to Abaxis within 10 days to start the warranty period. You will be placed on the customer mailing list to receive any information pertaining to the Piccolo Xpress and ancillary products, such as software upgrades.

2.2 Physical & Environmental Specifications

Dimensions	Height:	32.5 cm (12.80 inches)
	Width:	14.9 cm (5.87 inches)
	Depth:	21.0 cm (8.27 inches)
Weight	Analyzer:	5.3 kg (11.6 pounds)
	Power adapter:	1.0 kg (2.3 pounds)
Mode of operation		Continuous
Protection against fluid ingress		Ordinary equipment (IPXO)
Altitude		2000 m (6562 ft)
Ambient operating temperature		15–32 °C (59–90 °F), indoor use
Humidity		8–80% relative humidity noncondensing
Reaction temperature		37 °C (98.6 °F)
Thermal protection rating		70 °C (158 °F)
Power requirements		100–240 volts AC, 50–60 Hz or 16 volts DC, 5.0 A
		Main unit: 1.1–0.45 amps, 16 volts DC, 5.0 A
Main supply voltage		Fluctuations not to exceed $\pm 10\%$ of the nominal voltage
Transient overvoltages		Installation Category II in accordance with UL 61010A-1 second edition Annex J
Pollution		Degree 2 in accordance with IEC 664

If the Piccolo Xpress® chemistry analyzer is used in any way other than described in the Instructions for Use, the analyzer may not operate as intended, may produce inaccurate or no results, and may pose a safety hazard. Locate in an ambient operating temperature of 15-32°C (59-90°F), indoor use Humidity: 8-80% relative humidity noncondensing.

EMC Notice:

The Piccolo Xpress® chemistry analyzer meets the electromagnetic emissions requirements of EN 61326-2-6 and EN 60601-1-2. Interference from other electrical equipment is not expected.

CAUTION: To avoid electrostatic discharge, do not use the product in a very dry environment, especially one in which synthetic materials are present.

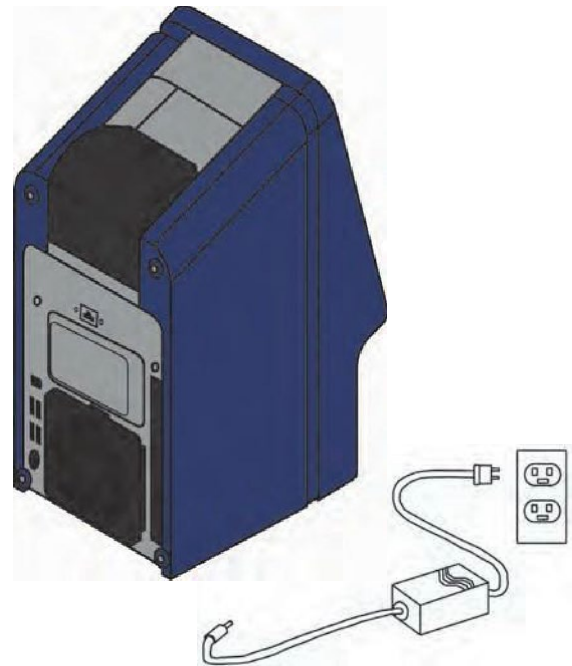
CAUTION: This product should not be used in close proximity to sources of strong electromagnetic radiation, e.g., mobile phones, electrocautery, MRI, electrosurgical units, diathermy devices or other medical emitters as these may cause potential electromagnetic disturbances that could prevent the product from functioning correctly.

No claims on the functionality of the device outside of a clinical laboratory or point of care setting are made.

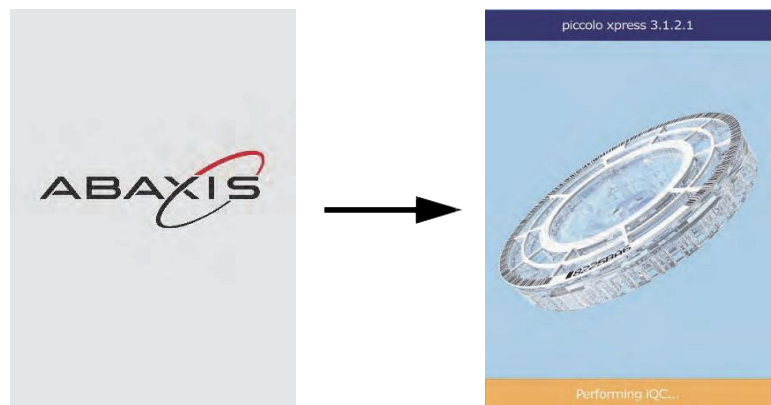
2.3 Setup

1. Set up the Piccolo Xpress on a surface that is:
 - Level
 - Free of vibration and sudden jolts
 - Free of hair, dust, and other contaminants
 - Located in an ambient operating temperature of 15–32 °C (59–90 °F)
 - Away from sunny windows and all other potential heat sources
 - At least six inches from any wall to provide adequate ventilation and access to the power connection and USB ports
2. Plug the power jack into the analyzer, then plug the detachable power supply cord into the power adapter and into a grounded electrical outlet.

CAUTION: To prevent power surges or drain, **do not** plug the analyzer into the same circuit as a centrifuge or any other high-current device. If this is not possible, use an ancillary power conditioner or battery backup (UPS) for the analyzer.



3. Press the Power button to turn on the analyzer.
The display will show the following:

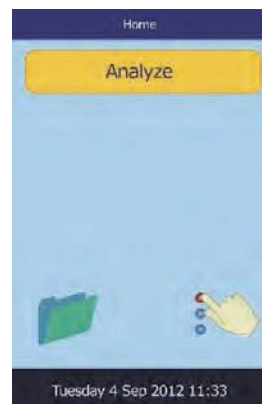


Note: If the display is blank (shows no message), remove the plug from the power adapter, then re-insert the plug and press firmly to make sure it seats correctly.

4. After passing the self test and reaching operating temperature, the analyzer is ready to run the first reagent disc. The display will read **Analyze**.

See “[Quality Control Features](#)” on page 6-1 for details about the analyzer self test. The analyzer may require additional time to reach operating temperature.

5. Check the analyzer date and time to be sure they are correct. See “[Changing Date and Time](#)” on page 4-15 for directions.
6. The analyzer can be connected to an external computer or printer to send/print patient and control results. See “[Connecting a Computer/Printer](#)” on page 10-1 for instructions.
7. Reference ranges are preset when the analyzer is shipped from the factory. The range values can be changed using the Customizing Reference Range feature described in “[Customizing Reference Ranges](#)” on page 4-2.



2.4 Piccolo Xpress System Description

This system is made up of a portable analyzer and disposable single-use reagent discs. Each disc has all the reagents needed to perform a panel of tests on a single sample.

Be sure to become familiar with the system before running samples.

The analyzer uses both centrifugal and capillary forces to process heparinized whole blood samples. It distributes the diluted plasma to the reaction chambers (cuvettes), which are inside the disc. Serum and plasma are processed the same way.

The analyzer uses light to measure chemical reactions. It calculates the concentrations of materials to be measured from the results, and from calibration data coded into the bar code ring on the disc.



Results are stored in memory, and can be printed using the built-in thermal printer or downloaded to an external computer for data management.

The touchscreen display shows procedural instructions, indicates analyzer status, and presents any error messages. For details, see “[Touchscreen and Front Panel](#)” on page 2-6.

The reagent disc drawer slides out from the front of the analyzer, transports the reagent disc (see

“Reagent Discs” on page 2-7) into the analyzer, and automatically positions it for analysis.

The internal printer provides results on adhesive-backed thermal paper tape.

An external power adapter and two power supply cords are provided — one connects the adapter to the back of the analyzer, and the other connects it to a surge protector for use with a computer. The analyzer also has several USB connectors — use the top connector for an external computer (see “Connecting a Computer/Printer” on page 10-1 for details).

The analyzer has a recessed handle on the top of the unit and is easy to carry.

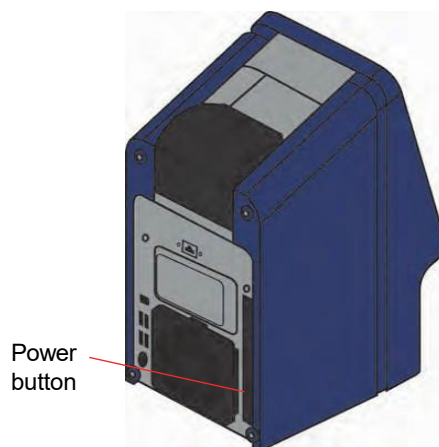
2.5 Touchscreen and Front Panel

The touchscreen display is used to operate the analyzer.

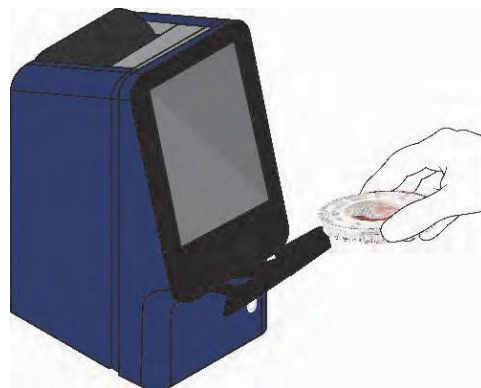
- Use the on-screen keyboard and numerical keypad to input patient information.
- To enter accented letters, select and hold the letter key on the keyboard, then select the accented version from the choices.
- The left and right arrow touchscreen keys move the display cursor forward or backward to change a number on the display. The right arrow key (\triangleright) functions as a dash (-) when entering a patient identification number. The left arrow key (\triangleleft) functions as a backspace.
- Use the up (\triangle) and down (∇) arrow keys to scroll through a displayed list of items, or to increase or decrease a displayed value.
- Operating functions are available through various icons on the touchscreen, as well as specific keys that appear on the touchscreen according to the actions performed.
- Select **Back** on the touchscreen to cancel a choice and return to the previous screen, or to move backward through a series of screens.

Turn power on and off by pressing the Power button on the front of the analyzer.

Note: *The Power button works only when the disc drawer is empty and closed.*





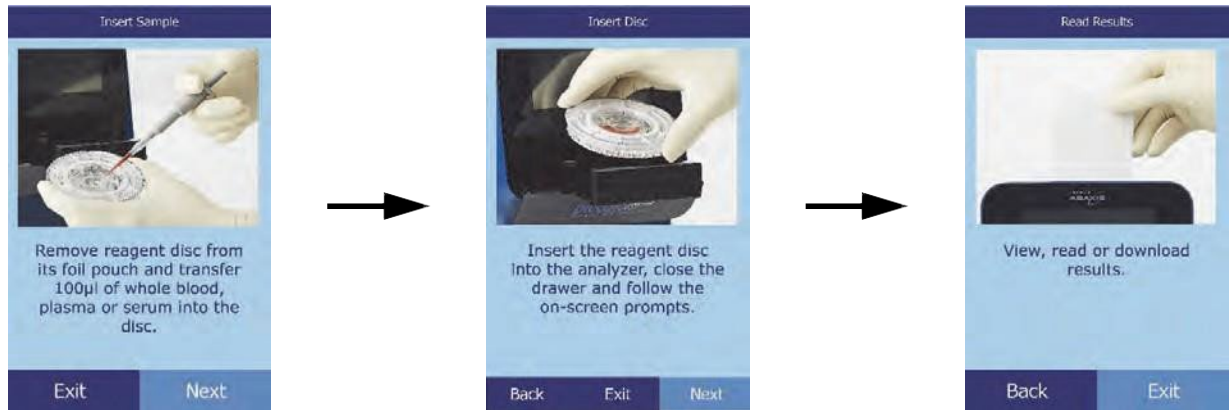
To open or close the disc drawer, select **Analyze** or **Close** on the touchscreen. Closing a drawer containing a reagent disc initiates an analysis.



Results for previously analyzed samples can be accessed using the Recall function. See “[Recalling Results](#)” on page 5-1 for instructions.

2.5.1 Information Icons

Among the touchscreen displays is an icon  to access additional information about the procedure being performed. For example, on the screen that appears when a disc is loaded, pressing  displays the following screens that outline basic analysis procedure:



Select **Next** and **Back** to move through the information screens, and **Exit** to close them.

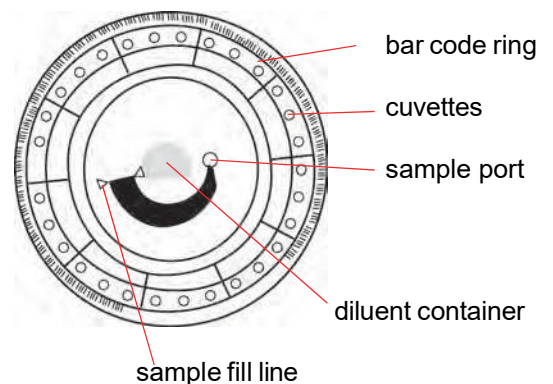
2.6 Reagent Discs

2.6.1 Disc Structure and Function

All chemistry reactions are performed inside clear plastic reagent discs, specially designed to convert a few drops of whole blood, plasma, or serum into a panel of test results. Each disc contains all components and reagents needed to perform one or more tests on a single sample.

A total of 30 cuvettes are located around the outer edge:

- four system cuvettes contain QC reagent beads for instrument and chemistry quality control
- minimum and maximum absorbance cuvettes are used for calibration
- a specially designed cuvette detects whether sample volume was sufficient
- a cuvette verifies that sufficient diluted sample was delivered to the reaction cuvettes
- an empty cuvette collects excess fluids
- 21 cuvettes contain test-specific lyophilized reagent beads



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

The **sample port** provides access to the **sample chamber**. It is marked by an arrow pointing to a molded circle on the upper disc surface. When enough sample has been loaded, the **sample fill line** forms between two molded arrows 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 this container and releases the diluent.

The analyzer separates a lithium-heparinized whole blood sample by centrifugation (high-speed spinning) inside the disc. Plasma and serum samples are unaffected. Precisely measured quantities of sample and diluent are delivered to the **mixing chamber**. Centrifugal and capillary forces then deliver the diluted sample to the cuvettes, where it dissolves the reagent beads and initiates the chemical reactions. Reaction products in the cuvettes are then measured photometrically (using the properties of light).

2.6.2 Disc Storage and Handling

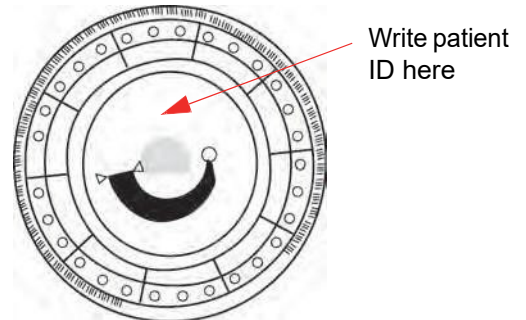
CAUTION: *Discs are fragile — always handle with care. Do not tap discs on the table or work bench to empty the sample port. Never use a disk that has been dropped.*

Inspect every reagent disc for damage before use. Never use a damaged disc.

- Store the disc as described on the label to keep reagents stable until the expiration date (printed on the foil pouch and encoded in the bar code ring). The analyzer automatically rejects any expired disc.
- The disc can be used directly from the refrigerator (stored at 2–8°C [36–46°F]) without warming.
- The disc can remain in its sealed pouch at room temperature for a *cumulative* period of 48 hours. Any longer may cause it to become ineffective or unusable (for example, chemical suppression and disc cancellations).
- Do not expose the disc (in or out of foil pouch) to direct sunlight or to temperatures above 32°C (90°F).
- Inspect the unopened foil pouch for tears and/or holes. A damaged pouch can 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.

Note: *You must use the disc within 20 minutes of opening the pouch.*

- Once the pouch is opened, do not place the disc back in the refrigerator for later use.
- Keep the disc clean. Handle only by the edges to avoid smudges on the optical surfaces. Use a lint-free tissue to remove any spilled blood from disc surfaces.
- **Optional:** Write the patient identification number on the disc surface in the space shown at right. Do not write anywhere else on the disc or on the bar code ring.
- Hold the disc flat after adding the sample or control to avoid spills.



WARNING: 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. FOR MORE INFORMATION, SEE “UNIVERSAL PRECAUTIONS” ON PAGE 1-2.

2.7 Installing a Printer Paper Roll

1. Open the printer cover. If the printer contains a roll of paper, remove it.
2. Remove the wrapper from the new paper roll, then unroll several inches of paper.
3. Put the paper roll into the printer so that it unrolls from the bottom and out toward the front of the analyzer, as shown.
4. Make sure several inches of paper extend out of the printer slot.
5. Press the cover closed until it locks into place.
6. Pull gently on the end of the paper until it is taut.



2.8 Ancillary Products

To order consumables or supplies such as reagent discs, pipettes, tips, printer paper, or control samples, contact your authorized distributor or Abaxis Customer Service.

Operational Materials	Catalog Number
Pipette tips, disposable, pack of 96	Abaxis #500-9007
Mini pipette, 100 ml, gray	Abaxis #500-9006
Internal printer paper rolls, box of 6	Abaxis #1100-4410
Fan filter, covered	Abaxis #1987-0009

2.9 Optional Accessories

These items can be attached to the analyzer using its USB ports:

- USB keyboard
- External printers: contact Abaxis Technical Support for specific models
- Barcode scanners: contact Abaxis Technical Support for specific models

Testing and Results

This section provides general introductory information about the Piccolo Xpress analyzer, reagent discs, test procedures, and test results.

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3.1 Sample Requirements

- The analyzer accepts **lithium-heparinized** whole blood, plasma, or serum samples.
- **Lithium heparin** is the only anticoagulant recommended for use with this analyzer.

Note: *When collecting the sample in lithium heparin collection tubes, fill the tube at least halfway so that it does not become too concentrated in the sample.*

- **If using CLIA '88 Waived reagent discs:** only lithium-heparinized whole blood can be used as a sample.
- **If performing a Basic Metabolic Panel Plus:** only lithium-heparinized plasma or serum can be used as a sample. Heparinized whole blood cannot be used.
- 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 damage to red blood cells (hemolysis), do not refrigerate or shake whole blood.
- Plasma or serum can be stored at room temperature for no longer than five hours after centrifugation. If storage for more than five hours is required, refrigerate the sample in the stoppered tube at 2–8°C (36–46°F) for no longer than 48 hours, or store it at -10°C (14°F) for up to five weeks in a freezer with no self-defrost cycle. This will avoid clinically important changes in most analyte concentrations.
- For accurate glucose and lipid results, the patient should not eat or drink (fast) for at least 12 hours before the sample is collected.

WARNING: *OPERATOR HEALTH AND SAFETY REGULATIONS REQUIRE THAT UNIVERSAL PRECAUTIONS BE OBSERVED AT ALL TIMES WHILE HANDLING HUMAN BLOOD SAMPLES OR WORKING WITH THE PICCOLO XPRESS CHEMISTRY ANALYZER IN ANY WAY.*

FOR DETAILS, PLEASE REFER TO OSHA 29 CFR PART 1910 (“OCCUPATIONAL SAFETY AND HEALTH STANDARDS”), STANDARD NUMBER 1910.1030 (“TOXIC AND HAZARDOUS SUBSTANCES: BLOODBORNE PATHOGENS”), WHICH CAN BE FOUND BY GOING TO [HTTP://WWW.OSHA.GOV](http://www.osha.gov) AND SEARCHING FOR “1910.1030.”

WARNING: *OPERATORS MUST ALSO BE AWARE OF STATE AND LOCAL OSHA BIOHAZARD REGULATIONS THAT MAY SPECIFY REQUIREMENTS IN ADDITION TO THE FEDERAL REGULATIONS, AND MUST ALSO ENSURE COMPLIANCE PROCEDURES ARE IN PLACE.*

3.1.1 Test Tube Order (ISO 6710:2017)

To prevent contamination, always fill test tubes in this order:

1. **Light blue top:** Sodium citrate for coagulation determinations
2. **Gold top:** SST tube with clot activator
3. **Red top:** Serum only, no anticoagulant
4. **Green top:** Lithium heparin – anticoagulant for chemistry only
5. **Lavender top:** EDTA – anticoagulant for hematology only

CAUTION: *Do not remove a sample from the disc and try to reintroduce it to the disc.*

Never place green top tubes in a test tube rocker.

Store samples at room temperature, and use within 60 minutes.

EDTA contamination severely affects results, especially Ca and K⁺.

Use of a sodium heparin tube will falsely elevate Na⁺ results.

3.1.2 Venipuncture Using Vacutainer or Syringe

Whole blood samples must be collected using lithium heparin. Excess heparin can interfere with certain chemistries and can cause dilution. To prevent this, fill the vacutainer tube at least halfway with sample, then mix well by gently inverting two or three times.

The following venipuncture methods are available:

- **Preferred method: collect samples directly into a lithium heparin vacutainer tube (green top).** If additional tubes will be filled, collect in the following order to prevent adverse effects on results: (1) light blue, (2) gold, (3) red, (4) green, (5) lavender.
- **Syringe with no anticoagulants.** Draw the sample, remove the needle, remove the tube top, then immediately add the sample to lithium heparin (green top). Gently invert the tube two or three times to mix.

Note: *Do not shake the tube or hemolysis will result.*

3.2 Preparing the Reagent Disc

- See “Reagent Discs” on page 2-7 for complete information on reagent discs, including handling instructions. Make sure you are thoroughly familiar with this information before using the analyzer.
- See “Sample Requirements” on page 3-2 for sample handling and storage requirements.

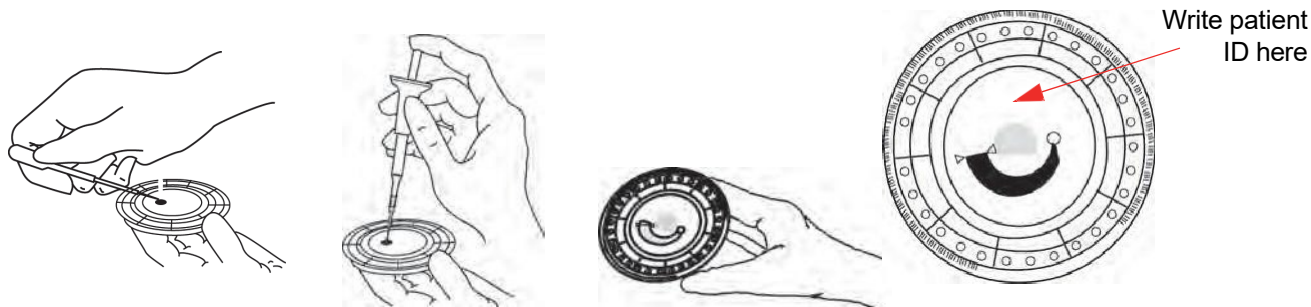
CAUTION: Analysis must begin immediately (no more than 10 minutes) after placing the sample into the reagent disc.

CAUTION: Discs are fragile – always handle with care. Do not tap discs on the table or work bench to empty the sample port. **Never use a disk that has been dropped.**

CAUTION: Inspect every reagent disc for damage before use. **Never use a damaged disc.**

3.2.1 Step 1 — Dispense the Sample

Use a micropipette (one is included with the analyzer) or other transfer device to dispense approximately 100 μ L of sample into the disc through the sample chamber.



CAUTION: Wear powder-free gloves while handling reagent discs or operating the analyzer. Powder can interfere with the analyzer's optical components.

1. Fill the sample chamber.
 - a. Firmly attach a new tip to the end of the Piccolo 100 μ l pipette.

- b. With the index finger or thumb, push the pipette button to the stop position and hold it down for sample pickup.
- c. Immerse the tip 2-3 mm below the surface of the sample, as shown.
- d. *Slowly* release the button to pick up the sample. Pause, then remove the pipette from the sample tube.
- e. Make sure there are no air bubbles or air gaps in the pipette tip.



- f. Place the pipette tip into the disc sample chamber, and tilt the disc to 45° with the sample port above the fill line, so that the entire sample flows into the sample chamber. The tip should touch the sample chamber, as shown.
- g. Push the plunger down with a slow, continuous motion. Take care not to overfill the sample chamber. A 90 µL sample will fill the sample chamber and form a line between the two arrows molded on the disc. More than 120 µL will overfill the chamber, which can cause analyzer contamination and contribute to component failures.




- h. Keep the pipette plunger pressed down until the tip is removed from the sample port.
- i. Discard the pipette tip into a biohazard container.
- j. Clean the 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.

- 2. **Optional:** Label the disc. Write the patient ID on the disc surface, in the space as shown on [page 3-4](#). Do not write anywhere else on the disc or on the bar code ring.
- 3. Carry the disc to the analyzer. Hold it by the edges and keep it level to avoid spills.

CAUTION: Do not remove the sample and then try to reintroduce it to the disc.

3.3 Running a Patient Sample

This section includes detailed, step-by-step instructions for performing analyses.

Note: The analyzer includes a number of optional data functions that can be used to enter more detailed information about samples. In this manual, the steps for these functions are marked with the Advanced Setting icon:  The screens for these functions appear only if the functions are enabled.

If a screen shown in a procedure step in this manual does not appear on the analyzer screen, skip that step. (For details about these functions, see “Using Optional Data Functions” on page 4-29.)

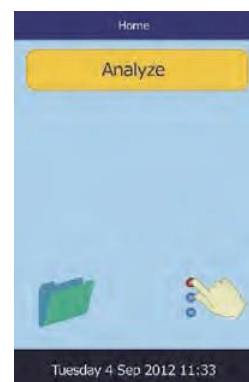
1. Turn on the analyzer by pressing the Power button on the front of the analyzer. *Do this before taking discs from the refrigerator.*



The analyzer will start up, then perform a self test. (For information about the analyzer self test, see “Quality Control Features” on page 6-1.)

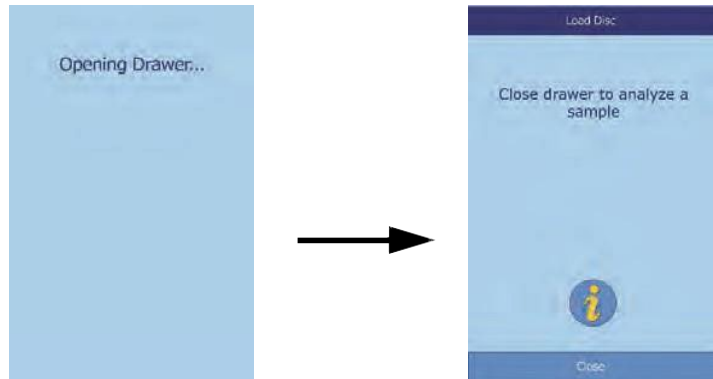
The display will show **Warming** if the analyzer needs time to warm the disc chamber to operating temperature.

When the analyzer reaches operating temperature, **Analyze** will show on the Home screen.



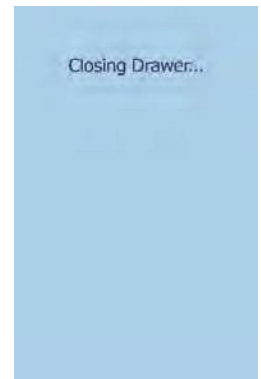
2. Select **Analyze** on the touchscreen to open the disc drawer.


The following messages will appear.





Note: Select the information icon  in the Load Disc screen to see an outline of the basic analysis procedure. Select **Next** and **Back** to move through the screens, and **Exit** to close.

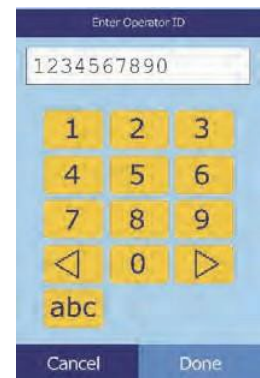
3. Place the disc in the recessed area in the drawer.
4. Select **Close** to close the drawer.



5.  **Optional:** Enter the operator ID, then select **Done**.

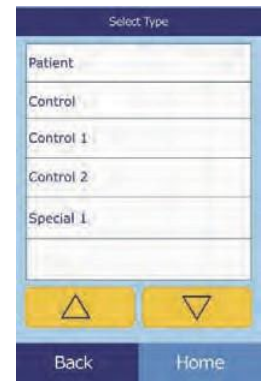
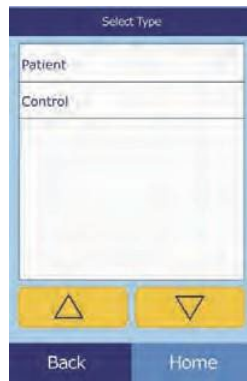
The operator ID is a string of up to 14 numbers and/or characters.

The right arrow key () functions as a dash (-), and the left arrow key () functions as a backspace.



6. Select the sample type from the display.


The example figure on the left shows the default selections: **Patient** and **Control**. The choices you see depend on the analyzer's configuration. (See "Using Optional Data Functions" on page 4-29.)



Note: *The correct sample type is necessary for results to be interpreted correctly.*

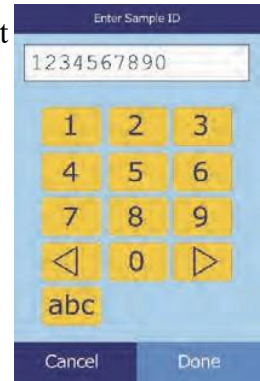
7.  **Optional:** Select the patient's gender.




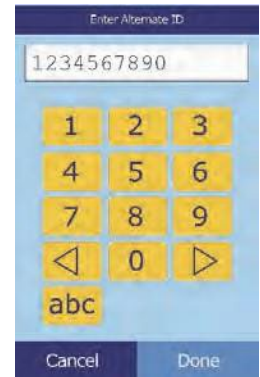
8.  **Optional:** Enter the patient's age using the up (\triangle) and down (∇) arrow keys. Adjust the units as needed, then select **Done**.



9. Enter an ID number for the sample (up to 14 characters), then select **Done**.



10.  **Optional:** Enter an alternate ID (up to 14 characters), then select **Done**.

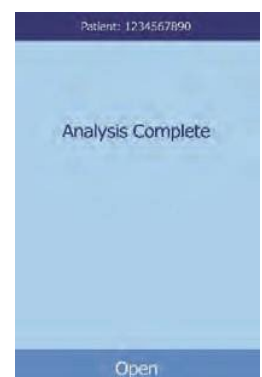


11. The analyzer will then check the disc type and begin processing the sample.



Note: *An error will appear if the disc is the wrong type or has expired. Repeat with an unexpired disc of the correct type.*

12. When the sample is finished processing, the analyzer will store the results and show that the analysis is complete.

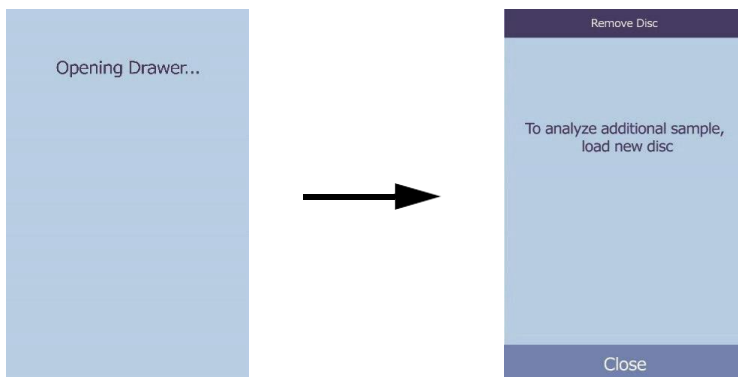


13. The analyzer will automatically print analysis results.

If the results do not print automatically, they can be recalled from memory and printed. (See “Searching for Results” on page 5-3.)

Note: Be sure to check the printout for any suppressed results, marked with these symbols: ~~~

14. Select **Open** to open the disc drawer.

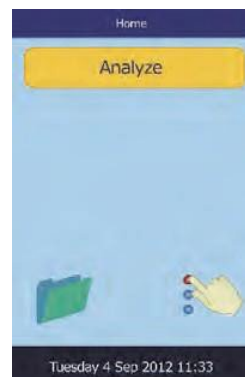


15. Remove the disc from the drawer.

WARNING: 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. FOR MORE INFORMATION, SEE “UNIVERSAL PRECAUTIONS” ON PAGE 1-2.

16. To analyze another sample, insert a new disc and repeat the above procedure.

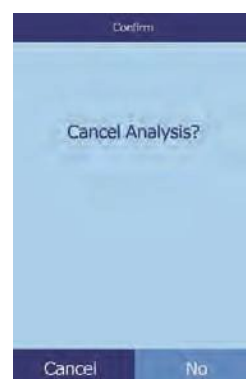
17. When finished, select **Close** to close the drawer and return the analyzer to standby mode.



3.4 Canceling Analysis

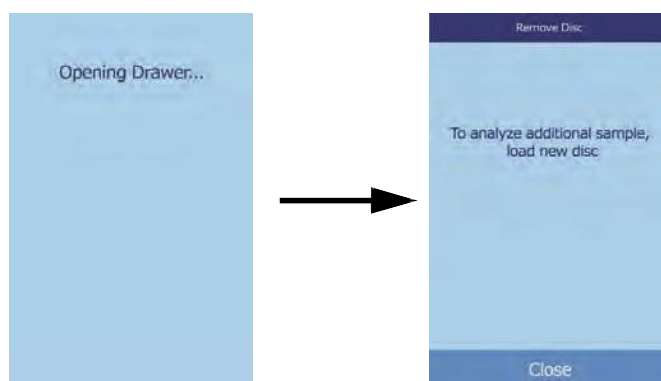
Occasionally you may need to cancel an analysis in progress.

1. Select **Cancel** on the touchscreen.



2. Select **Cancel** again to confirm.

The analysis is canceled and the disc drawer will open.



3. Remove the disc from the drawer. Select **Close** to close the drawer.

The analyzer is now ready to perform another analysis.

3.5 Results

Analysis results are stored in memory and printed automatically, and can also be recalled and printed later as needed. If the analyzer is connected to an external computer, the results are automatically transmitted as soon as they are calculated (see [“Connecting a Computer”](#) on page 10-2). (See [“Principles of Operation”](#) on page 8-2 for the basic procedure and equations used to calculate analyte concentrations.)

This figure shows a typical results printout. The heading includes information such as the reagent disc type, test date and time, sample type, patient or control ID number, alternate ID number, gender, age, operator ID number, disc lot number, and analyzer serial number. Results are printed in four columns: chemistry name, analyte concentration, reference range, and specified units. The printout has an adhesive backing so it can easily be placed into the patient's file.

Each disc contains reagents to detect exposure to extreme conditions such as temperature and humidity. The message **QC OK** is printed near the bottom when results are within the expected ranges. If they are not, the results will not print and the disc drawer will open.

PICCOLO XPRESS DEMONSTRATION SOFTWARE COMPREHENSIVE METABOLIC PANEL			
11 MAR 2013		01:15 PM	
SAMPLE TYPE:		PATIENT	
PATIENT ID:		77752	
ALTERNATE ID:		14789	
GENDER:		FEMALE	
AGE:		27 YEARS	
RACE:		BLACK	
DISC LOT NUMBER:		2347E	
SERIAL NUMBER:		0000P03015	
.....			
NA+	137	128-145	MMOL/L
K+	4.0	3.6-5.1	MMOL/L
TCO2	26	18-33	MMOL/L
CL-	103	98-108	MMOL/L
GLU	96	73-118	MG/DL
CA	9.2	8.0-10.3	MG/DL
BUN	15	7-22	MG/DL
CRE	0.9	0.6-1.2	MG/DL
EGFR	60 C		ML/MIN
ALP	91	42-141	U/L
ALT	29	10-47	U/L
AST	25	11-38	U/L
TBIL	0.9	0.2-1.6	MG/DL
ALB	4.4	3.3-5.5	G/DL
TP	7.3	6.4-8.1	G/DL
.....			
QC	OK		
MEM 1	LIP 0	ICT 0	

3.5.1 Interpreting Results

Note: *As with any diagnostic test procedure, all other test procedures — including the clinical status of the patient — should be considered prior to final diagnosis.*

- Results falling outside the reference range are indicated in the results by an asterisk (*) printed next to the analyte concentration.
- Results falling outside the dynamic range are indicated in the results by a less-than symbol (<) printed next to the lowest value of the dynamic range, or a greater-than symbol (>) printed next to the highest value of the dynamic range.

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**, and a concentration above this range would be printed as **>700 mg/dL**. Results outside the dynamic range should be reported as being below or above the value indicated.

Note: *If any result for a particular test exceeds the dynamic range, analyze the sample by another approved test method or send it to a referral laboratory for analysis. **Do not attempt to dilute the sample and re-run it on the analyzer.***

*Extensive analyzer testing has shown that in very rare instances, a sample may not flow smoothly into the sample chamber, and not enough sample is analyzed. **This can cause several results to unexpectedly fall outside the reference ranges. If this happens, run the sample using a new disc.** (For details, see “Instrument and Result Messages” on page 7-2, and especially the table on page 7-3.)*

- The sample indices are included at the bottom of the results printout. These indices indicate the degree of hemolysis (HEM), icterus (ICT), and lipemia (LIP) found in the sample, measured on a scale of 0 (clear), 1+ (slight), 2+ (moderate), and 3+ (gross).

3.5.2 Troubleshooting Problem Results

- The symbols ~~~ are printed in place of numbers when a result cannot be determined — that is, when the result is suppressed. This may happen due to improper mixing of a reagent bead with diluted sample, a nonlinear reaction, an endpoint of a particular reaction not reached, or a concentration outside the analyzer’s capabilities. When a chemistry is suppressed (~~~), the analyzer will prompt to print an error report.
- **CONFIRM LOW RECOVERIES** with an exclamation point (!) next to every analyte indicates that at least one of the analytes has a lower concentration that would normally be expected. If this occurs, re-run the sample. If it happens again, the sample may be problematic.
- **HEM**, **LIP**, or **ICT** is printed in place of the analyte concentration if the interferent has adversely affected the results. **LIP** is also printed if both lipemia and icterus have been affected. **HEM** is also printed if hemolysis and icterus, hemolysis and lipemia, or hemolysis, lipemia, and icterus have affected a particular analyte. Examine the sample indices to determine if more than one interferent is affecting a particular result.

3.5.3 Lactate Dehydrogenase (LD) Assay

- Blood cells contain significant levels of LD, and therefore all LD assays are sensitive to hemolysis caused by release of LD from red blood cells. In the following circumstances, the results are annotated to help interpret LD activity in the presence of small amounts of hemolysis.
- If HEM is greater than 50 and less than or equal to 100 mg/dL, the printed LD value is followed by an **H**, indicating additional influence from hemolysis.
- If HEM is greater than 100 and less than or equal to 150 mg/dL, the LD value is preceded by **<** and followed by **H**, indicating that the true LD recovery is less than reported.
- If HEM is greater than 150, no result will be indicated, and only **HEM** will be printed.

3.5.4 Endogenous Substances

The analyzer judges the quality of each sample, and uses light (spectrophotometrically) to measure the concentrations of endogenous substances for each run. The levels of HEM, LIP, and ICT are shown at the bottom of each result tape or on the touchscreen.

Levels are scored as 0, 1+, 2+, or 3+ depending on levels of each interferent. The following table shows the relationship between these scores and the approximate concentration of each endogenous substance in the sample.

Correlation of Sample Index vs Endogenous Substance Concentration

	Index	Endogenous Substance Concentration (mg/dL)
HEM	0	< 20
	1+	≥ 20 to < 45
	2+	≥ 45 to ≤ 181
	3+	> 181
LIP	0	< 150
	1+	≥ 150 and < 221
	2+	≥ 221 and ≤ 301
	3+	> 301
ICT	0	< 2.8
	1+	≥ 2.8 and < 5.5
	2+	≥ 5.5 and ≤ 10.5
	3+	> 10.5

The effects of endogenous substances have been characterized for each of the Abaxis analyte test methods, and cut-off levels have been set for each. The result will be automatically suppressed, and in its place **HEM**, **ICT**, or **LIP** will be indicated if the test results will be negatively affected. The table below lists the concentration above which an analyte might be negatively affected.

Endogenous Substance Cut-off for Abaxis Analyte Test Methods

Analyte	HEM (mg/dL)	LIP (mg/dL)	ICT (mg/dL)
ALB	2580	4200	37
ALP	1000	1600	37
ALT	1300	2200	17
AMY	1300	1600	26
AST	430	1436	17
BUN	2580	4200	37
CA	2000	1500	26
CHOL	1400	3900	25
CK	1000	1600	42
CL-	1300	2000	34
CRE	688	3000	7
DBIL	200	600	N/A
GGT	1300	1600	26
GLU	1790	750	37
HDL	400	1000	17
LAC	500	3000	15
LD	150	1720	64
K+	300	2000	17
MG	1000	1500	38
NA	2000	2600	25
PHOS	400	1100	42
TBIL	420	1500	N/A
TCO2	1300	2200	17
TP	2580	1000	14
TRIG	750	1000	42
UA	1100	1500	6.5

If the sample is identified as hemolytic, collect a new sample and run another disc. 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 appear on the result card as **HEM**. Follow the instructions above for retesting hemolyzed samples.

High lipemia may be due to diet. Have the patient fast for at least 12 hours before collecting another sample. For suggestions on testing grossly lipemic or icteric samples, see “[Troubleshooting](#)” on page 7-1. For grossly lipemic samples from fasting patients or for icteric samples, use an alternative testing method or send the sample to a reference laboratory.

3.6 Testing Procedure Summary

3.6.1 Piccolo Xpress Chemistry Analyzer

- Make sure the electrical outlet used for the analyzer is grounded.
- Make sure the ambient temperature in the analyzer’s location is 15–32°C (59–90°F).
- Do not disconnect the power to the analyzer while running a sample.
- Keep the analyzer drawer closed when not in use.
- Do not attempt to repair the analyzer, as this may void the warranty.
 - See “[Troubleshooting](#)” on page 7-1 for troubleshooting procedures.
 - See “[Maintenance and Service](#)” on page 9-1 for regular maintenance tasks.

3.6.2 Reagent Discs

CAUTION: *Discs are fragile — always handle with care. Do not tap discs on the table or work bench to empty the sample port. Never use a disk that has been dropped.*

Inspect every reagent disc for damage before use. Never use a damaged disc.

- Do not use expired discs. The expiration date is printed on the foil pouch and is encoded in the bar code.
- Store all discs at 2–8°C (36–46°F) as described on their pouch labels. Discs may be used directly from the refrigerator.
- Keep reagent discs clean. Use powder-free gloves, and touch the discs only along the edges to avoid fingerprints on the cuvette optical surfaces. Remove sample spills on the outside of the disc with a lint-free tissue, and make sure the tissue does not withdraw any sample from the sample port.
- After adding the sample, hold the disc level to avoid spills.
- Never use a disc that has been dropped.
- Use the disc **within 20 minutes** of opening the foil pouch.
- Run the disc **within 10 minutes** of adding the sample.

3.6.3 Samples

- Analyze whole blood samples within 60 minutes of collection.
- Fill the lithium heparin specimen collection tube at least half-way to ensure the sample does not have a high concentration of anticoagulant.
- To prevent hemolysis, do not refrigerate or shake whole blood samples.
- When adding blood to evacuated collection tubes, remove the needle from the syringe and the stopper from the tube, and gently place the sample into the tube. (If sample is injected through the stopper, hemolysis may occur.)

CAUTION: *Do not remove a sample from the disc and then try to reintroduce it into the disc.*

Note: *Always fill evacuated collection tubes in this order (ISO 6710:2017):*


1. **Light blue top:** *Sodium citrate for coagulation determinations.*
2. **Gold top:** *SST tube with clot activator.*
3. **Red top:** *Serum only, no anticoagulant.*
4. **Green top:** *Lithium heparin. Anticoagulant for chemistry only.*
5. **Lavender top:** *EDTA. Anticoagulant for hematology only.*

Configuring the Analyzer

This section describes how to configure the Piccolo Xpress chemistry analyzer to achieve the best performance.

Here are the main analysis tasks:

- Review “Using the Settings Screen” on page 4-2 to see how to adjust analyzer settings.
- Change reference ranges to be specific to the patient population, and print, transmit, or archive these ranges:
 - “Customizing Reference Ranges” on page 4-2
 - “Printing and Archiving Reference Ranges” on page 4-11
 - “Transmitting Reference Ranges” on page 4-13
- Adjust analyzer general settings as needed:
 - “Viewing Analyzer Information” on page 4-15
 - “Changing Date and Time” on page 4-15
 - “Selecting the Language” on page 4-16
 - “Selecting Units” on page 4-17
 - “Setting Sound Volumes” on page 4-21
 - “Adjusting the Display” on page 4-22
 - “Printer Settings” on page 4-24
 - “Setting Communication Protocol” on page 4-28
 - “Using Optional Data Functions” on page 4-29
 - “Security Settings” on page 4-34
- Run control samples:
 - “Running Controls” on page 4-31.

Note: When available, select the information icon  for additional help.

4.1 Using the Settings Screen

The following shows the general path through analyzer menus to perform the procedures in this section. These procedures are available whenever the analyzer displays the Home screen.



1. In the Home screen, select the **Settings** icon.

The first Analyzer Settings screen is for adjusting the date and time, language, sound, display, and printer, or to view basic analyzer information.



2. Select the **More Settings** icon.

The second Analyzer Settings screen is the starting point to make additional settings, work with reference ranges, and update analyzer software.

3. Select **Home** to return to the Home screen.

4.2 Customizing Reference Ranges

The analyzer includes a number of factory-set analyte and demographic reference ranges for use in analysis. The ranges can be modified as needed, as well as create or remove custom ranges, or return all factory ranges to their default settings.

Note: *When modifying reference ranges, change the ranges in either Common units or SI units, not both. The analyzer automatically converts units.*



1. In the Home screen, select the **Settings** icon.



2. Select the **More Settings** icon.

3. Select the **Reference Range Settings** icon.



4. In the Include Reference Ranges screen:

- To modify the last reference range that was changed, select **Last Modified**, then skip to [step 5](#) on [page 4-4](#).
- To modify any reference range, select **All**, then continue with the next step below.



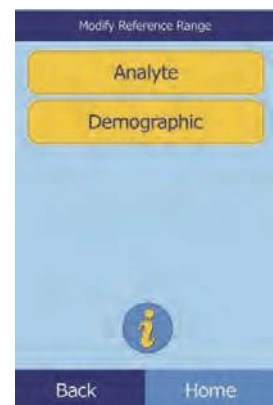
5. The Modify Reference Range screen will open with a list of the following procedures:

- Modify the reference ranges for a specific analyte — see below.
- Modify the reference ranges for a particular demographic — see [page 4-5](#).
- Add a reference range for a new demographic — see [page 4-6](#).
- Remove a reference range for a demographic — see [page 4-9](#).
- Restore all factory reference ranges to their default values — see [page 4-10](#).

4.2.1 Modifying Reference Ranges for an Analyte

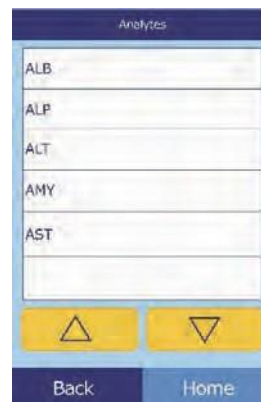
Change the reference ranges for a specific analyte as follows.

1. In the Modify Reference Range screen, select **Analyte**.



2. In the Analyte screen, select the analyte.

Use the up (\triangle) and down (∇) arrow keys to scroll through the list.



3. Select the patient's gender.

4. Select the reference range to modify.

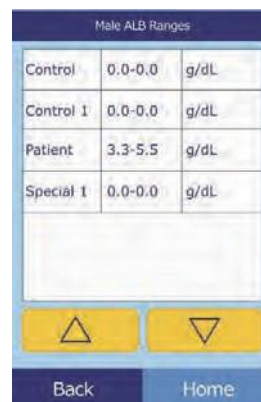
Use the up (\triangle) and down (∇) arrow keys to scroll through the list.



5. Use the controls to set the upper and lower limits for the range.

- Use the up (\triangle) and down (∇) arrow keys to adjust the values.
- Select **Clear** to set both limits to zero.
- Select **Default** to use the factory default values for the range.

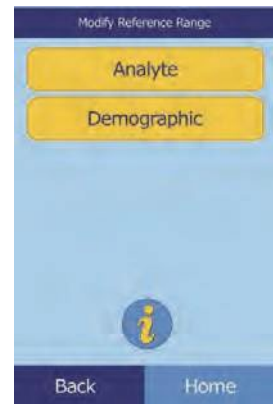
6. Select **Save** to store the changes.



4.2.2 Modifying the Reference Ranges for a Demographic

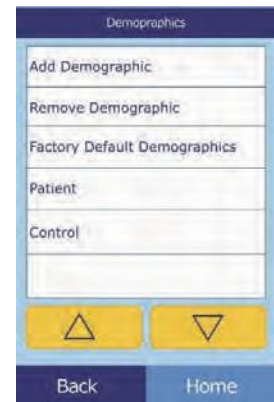
Use this procedure to modify the reference ranges for a particular demographic, patient type, or control.

1. In the Modify Reference Range screen, select **Demographic**.



2. In the Demographics screen, choose the patient or control demographic to modify.

Use the up (\triangle) and down (∇) arrow keys as needed to scroll through the list.



3. **Patient demographic only:** select the gender.



- The analyzer will display the ranges for the patient or control demographic.

Select the analyte to adjust. If needed, use the up (\triangle) and down (∇) arrow keys to scroll through the list.

Female Patient Ranges		
ALB	3.3-5.5	g/dL
ALP	42-141	U/L
ALT	10-47	U/L
AMY	14-97	U/L
AST	11-38	U/L

Control Ranges		
ALB	0.0-0.0	g/dL
ALP	0-0	U/L
ALT	0-0	U/L
AMY	0-0	U/L
AST	0-0	U/L

- Use the controls to set the upper and lower limits for the range.

- Use the up (\triangle) and down (∇) arrow keys to adjust the values.
- Select **Clear** to set both limits to zero.
- Select **Default** to use the factory default values for the range.

ALB Patient [g/dL]

Lower	Upper
3.3	5.5

\triangle ∇

Clear Default

Cancel Save



ALB Control [g/dL]

Lower	Upper
0.0	0.0

\triangle ∇

Clear Default

Cancel Save

- Select **Save** to store the changes.

4.2.3 Adding a Demographic

Use this procedure to add reference ranges for a particular demographic.

- In the Modify Reference Range screen, select **Demographic**.

Modify Reference Range

Analyte

Demographic

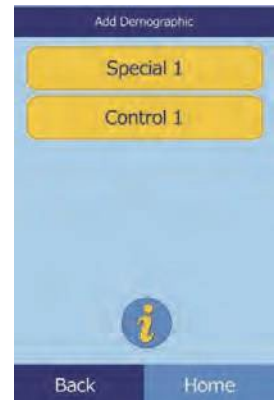
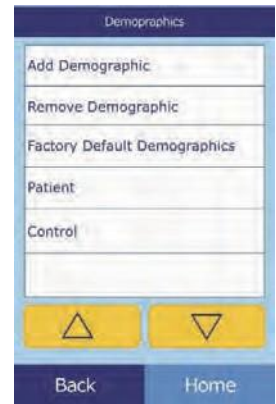
Back Home

2. In the Demographics screen, select **Add Demographic**.

❑ To create a reference range for a new, unnamed demographic:

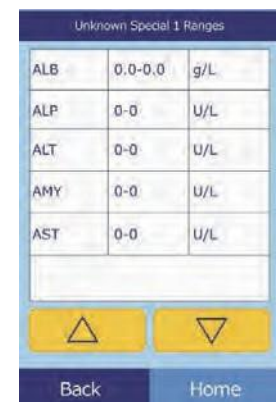
a. Select **Special #**.

Note: *The displayed number # depends on the number of special or control level demographics already added or deleted.*



b. Select the gender.

c. Select the analyte to adjust. If needed, use the up (Δ) and down (∇) arrow keys to scroll through the list.

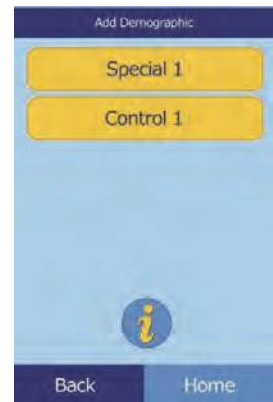


- d. Use the up (Δ) and down (∇) arrow keys to set upper and lower limits for the analyte.
- Select **Clear** to set both limits to zero.
 - Select **Default** to use the factory default values.

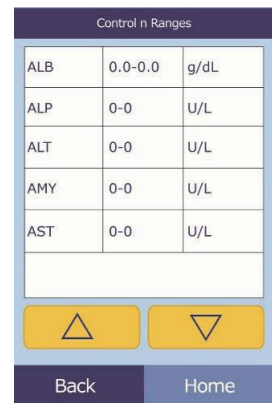


Note: *Entering zero for both values suppresses printing the ranges for this analyte in results (blanks appear instead), and also suppresses checking the recovered value against the range limits.*

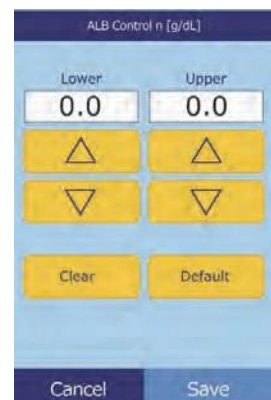
- e. Select **Save** to store the changes.
- ❑ To create a new control:
- a. Select **Control #**.



- b. Select the analyte to adjust from the list. Use the up (Δ) and down (∇) arrow keys to scroll through the list.



- c. Use the up (Δ) and down (∇) arrow keys to set upper and lower limits for the analyte.
- Select **Clear** to set both limits to zero.
 - Select **Default** to use the factory preset values.



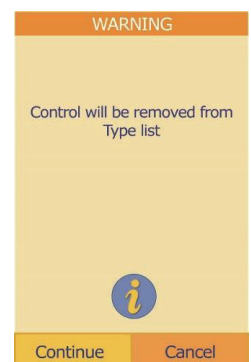
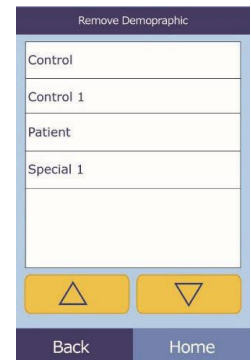
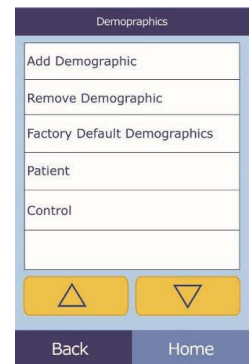
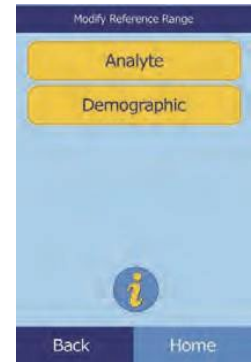
Note: *Entering zero for both values suppresses printing the ranges for this analyte in results (blanks appear instead), and also suppresses checking the recovered value against the range limits.*

- d. Select **Save** to store the changes.

4.2.4 Removing a Demographic

Use this procedure to remove the reference ranges for a particular demographic.

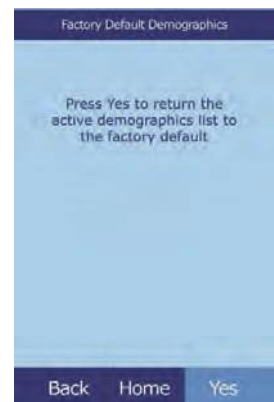
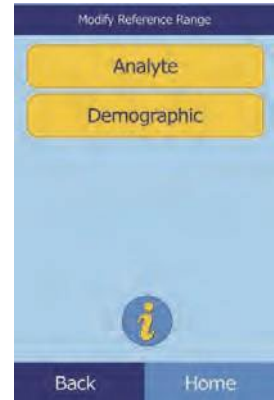
1. In the Modify Reference Range screen, select **Demographic**.
2. In the Demographics screen, select **Remove Demographic**.
3. Select the demographic to remove. Use the up (\triangle) and down (∇) arrow keys to scroll through the list.
4. When the warning screen appears, select **Continue** to permanently remove the demographic.



4.2.5 Restoring Factory Default Demographics

Use this procedure to restore all factory reference ranges to their default settings.

1. In the Modify Reference Range screen, select **Demographic**.
2. In the Demographics screen, select **Factory Default Demographics**.
3. Select **Yes**.



4.3 Printing and Archiving Reference Ranges

Reference ranges can be printed or stored in the analyzer as archive files for later use.

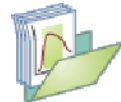
1. In the Home screen, select the **Settings** icon.



2. Select the **More Settings** icon.



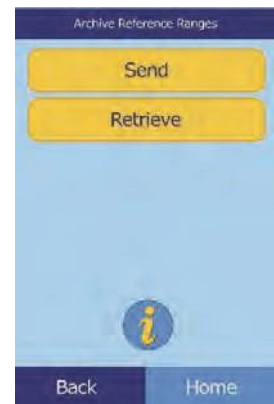
3. Select the **Archive Reference Ranges** icon.



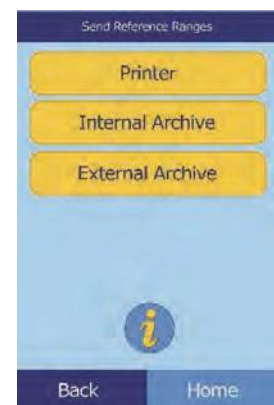
4. Select **Send**.

- To archive the reference ranges into the analyzer's internal memory: select **Internal Archive**.

The reference range is then stored in the analyzer under the current date and time.



Note: See *“Retrieving Reference Ranges”* on page 4-12 for instructions on retrieving stored archives.



- To archive the ranges onto a PC connected to the analyzer, see *“Transmitting Reference Ranges”* on page 4-13.

(See *“Connecting a Computer”* on page 10-2 for instructions on connecting a PC to the analyzer.)

❑ To print a range or ranges:

a. Select **Printer**.

b. Select the report type to print (the left diagram shows the default choices, the right shows typical customized choices).



All prints controls and patients.

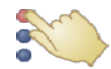
c. The reference range (or ranges) is then printed.

4.4 Retrieving Reference Ranges

Reference ranges can be retrieved from archives as follows.

Note: *Retrieving an archived reference range overwrites all reference range values currently in the analyzer. Consider archiving the current reference ranges before retrieving another set.*

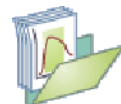
1. In the Home screen, select the **Settings** icon.



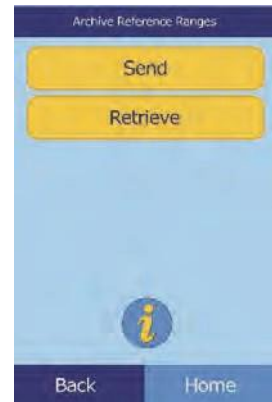
2. Select the **More Settings** icon.



3. Select the **Archive Reference Ranges** icon.



4. Select **Retrieve**.
5. Select the archive to retrieve. Use the up (\triangle) and down (∇) arrow keys as needed to scroll through the list.



6. When a warning screen appears, select **Continue** to retrieve the archived reference range.

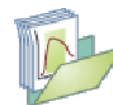


4.5 Transmitting Reference Ranges

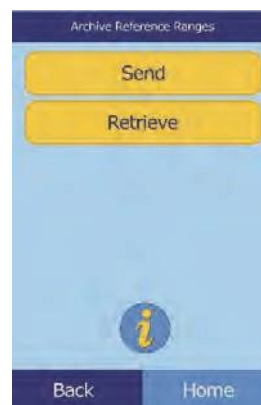
Reference ranges can be transmitted to a connected PC and stored for later use or review.

1. In the Home screen, select the **Settings** icon.
2. Select the **More Settings** icon.

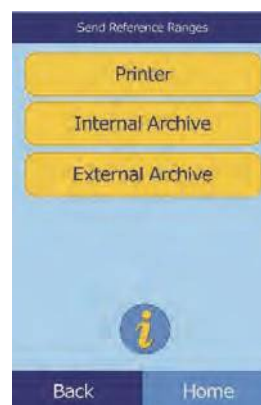




3. Select the **Archive Reference Ranges** icon.

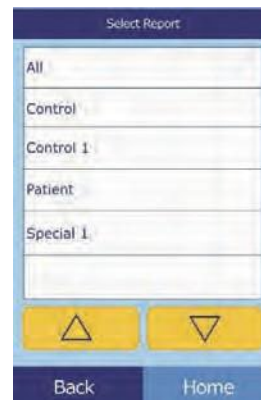
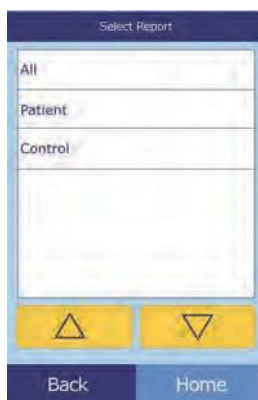


4. Select **Send**.



5. Select **External Archive**.

6. Select the report type (the type of ranges) to send to the PC.



The reference range is then sent to the PC and stored under the current date and time.

Note: See *“Retrieving Reference Ranges”* on page 4-12 for instructions on retrieving stored archives.

4.6 Viewing Analyzer Information

Use this function to verify information about the analyzer, such as its serial number, the version of the installed software, and information about the tests that have been run and printed.

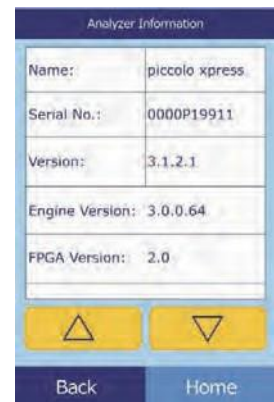
1. In the Home screen, select the **Settings** icon.



2. Select the **Analyzer Information** icon.



3. The display then shows the analyzer information.



4.7 Changing Date and Time

The date and time is factory preset to Pacific Time. Verify the date and time when the analyzer is removed from its shipping carton.

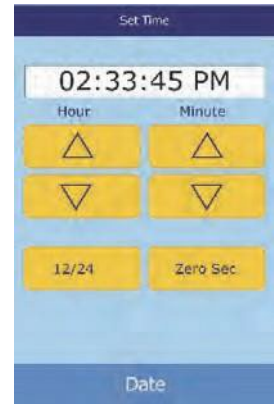
1. In the Home screen, select the **Settings** icon.



2. Select the **Date and Time** icon.



3. In the Set Time screen, use the controls to set the time:
 - Use the up (Δ) and down (∇) arrow keys to adjust the hour and minutes.
 - Select **12/24** to switch between 12- and 24-hour time formats.
 - Select **Zero Sec** to set the seconds to zero.
4. Select **Date** to save.



Note: *If the time entered is invalid, an error message appears — select **Continue**, set the correct time, then select **Done**.*

5. In the Set Date screen, use the up (Δ) and down (∇) arrow keys to adjust the day, month, and year.
6. Select **Done** to save.



Note: *If the date entered is invalid, an error message appears — select **Continue**, set the correct date.*

4.8 Selecting the Language

The analyzer provides several languages for menus, the keyboard, and printing (English USA is the default). Select the language to use as follows.

1. In the Home screen, select the **Settings** icon.
2. Select the **Languages** icon.



3. Select the display language from the list. If needed, use the up (Δ) and down (∇) arrow keys to view the entire list.



4. Select the keyboard type from the list. Use the up (Δ) and down (∇) arrow keys to scroll through the list.

Note: The selected keyboard affects **all** keyboards and barcode scanners connected to the analyzer USB ports.

Note: To add accented letters, select and hold the letter key in the onscreen keyboard, then select the accented version from the choices that appear.



4.9 Selecting Units

Use this procedure to set the units used by the analyzer and in results: Common units (mg/dL, etc.) or SI units (Systems International) (mmol/L, etc.).

1. In the Home screen, select the **Settings** icon.



2. Select the **More Settings** icon.



3. Select the **Units Settings** icon.



4. Set the units used for all analytes, a particular analyte, or a group of analytes as follows.

To set units for all analytes:

a. Select **All Analytes**.



b. Select the units to use for all analytes: **Non SI** or **SI**.



To set units for a particular analyte:

a. Select **Single Analyte**.

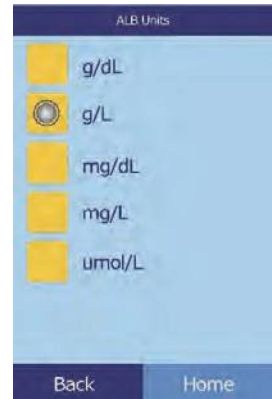


- b. Select the analyte from the list.

If needed, use the up (\triangle) and down (∇) arrow keys to view the entire list.



- c. Select the units to use for the analyte: **g/dL**, **g/L**, **mg/dL**, **mg/L**, or **umol/L**.

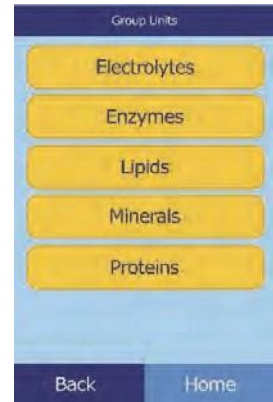


- ❑ To set units for a group of analytes (electrolytes, enzymes, lipids, minerals, or proteins):

- a. Select **Analyte Groups**.



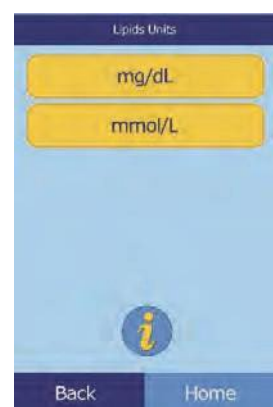
- b. Select to select an analyte group: **Electrolytes, Enzymes, Lipids, Minerals, or Proteins.**



- For electrolytes: select **mmol/L** or **mEq/L**.



- For enzymes: select **U/L** or **ukat/L**.
- For lipids: select **mg/dL** or **mmol/L**.



- For minerals: select **mg/dL**, **mmol/L**, or **mEq/L**.



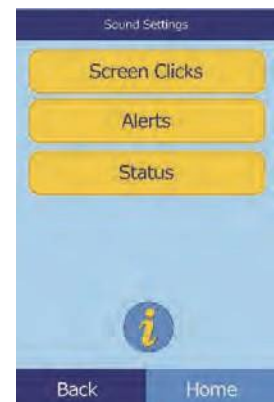
- For proteins: select **g/dL** or **g/L**.



4.10 Setting Sound Volumes

Adjust the volume of the analyzer's screen click, alert, and status notification sounds as follows.

1. In the Home screen, select the **Settings** icon.
2. Select the **Sound Settings** icon.
3. Select the sound to adjust.



4. Use the controls to set the selected volume.
 - Use the up (\triangle) and down (∇) arrow keys to adjust the volume.
 - Select **Off** to turn the sound off.
 - Select **Default** to set the sound to its factory default value.



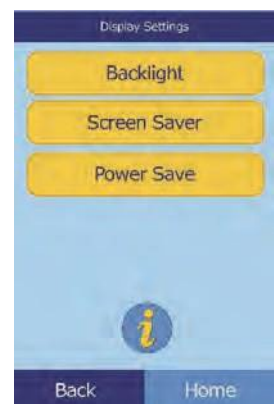
5. Select **Save** to store the new setting.

4.11 Adjusting the Display

The display brightness can be adjusted as needed, and the touchscreen can be calibrated for best performance. In addition, the time the analyzer must be inactive before it activates a screen saver or enters power-saving mode. (For either, touch the screen to wake the analyzer.)



1. In the Home screen, select the **Settings** icon.
2. Select the **Display Settings** icon.
3. Adjust or calibrate the display as follows:
 - To adjust the backlight brightness:
 - a. Select **Backlight**.



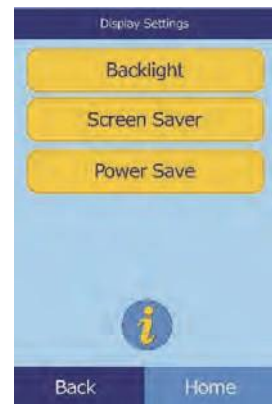
b. Use the controls to set the brightness:

- Use the up (Δ) and down (∇) arrow keys to adjust the brightness level.
- Select **Full** to select maximum brightness.
- Select **Default** to set the brightness to its factory default.



c. Select **Save** to store the new setting.

□ To adjust the screen saver delay:



a. Select **Screen Saver**.

b. Use the controls to set the delay:

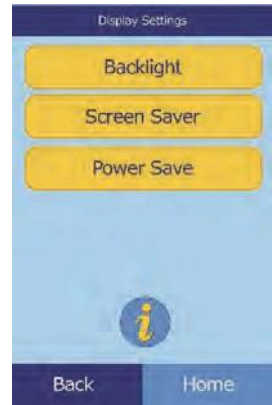
- Use the up (Δ) and down (∇) arrow keys to adjust the delay.
- Select **Never** to turn off the screen saver.
- Select **Default** to set the delay to its factory default.



c. Select **Save** to store the new setting.

- ❑ To adjust power-saving delay:

- Select **Power Save**.
- Use the controls to set the delay:
 - Use the up (\triangle) and down (∇) arrow keys to adjust the delay.
 - Select **Never** to prevent the analyzer from entering power-saving mode.
 - Select **Default** to set the delay to its factory default.
- Select **Save** to store the new setting.



4.12 Printer Settings

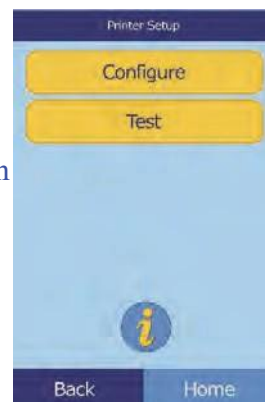
Use the following procedures to set up and configure the analyzer internal printer or an external printer connected to the analyzer.

- In the Home screen, select the **Settings** icon.
- Select the **Printer Settings** icon.



3. The Printer Setup screen then opens.

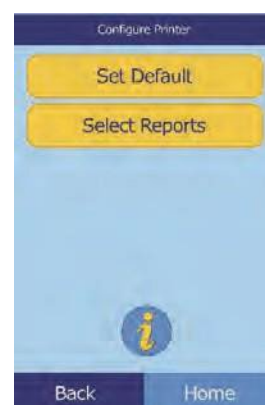
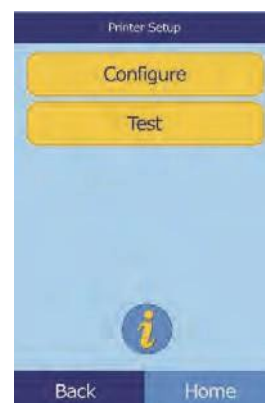
- ❑ To select the default printer to be used with the analyzer, see [“Setting the Default Printer,”](#) below.
- ❑ To test a printer for proper function, see [“Testing a Printer”](#) on [page 4-26](#).
- ❑ To select which reports can be printed automatically after an analysis, see [“Selecting Reports”](#) on [page 4-27](#).



4.12.1 Setting the Default Printer

Select the default printer for results and reports as follows.

1. In the Printer Setup screen, select **Configure**.
2. Select **Set Default**.



3. Select the **Analyzer Printer** or **External Printer**.

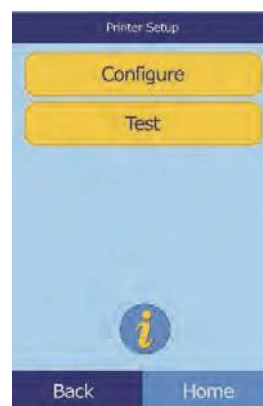


4. **External Printer only:** select the printer from the displayed list of available printers. The analyzer will automatically detect and configure the type of printer.

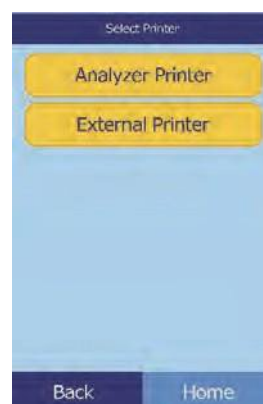
4.12.2 Testing a Printer

Test the function of the internal printer or connected external printer as follows.

1. In the Printer Setup screen, select **Test**.
2. Select the printer to test.



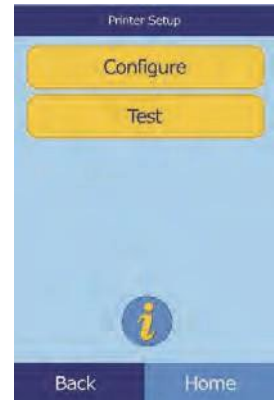
The selected printer then prints a test page.



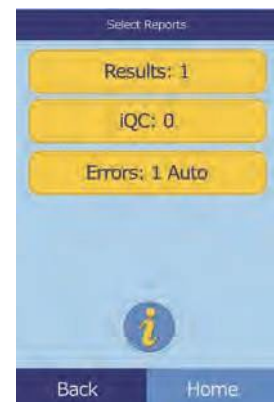
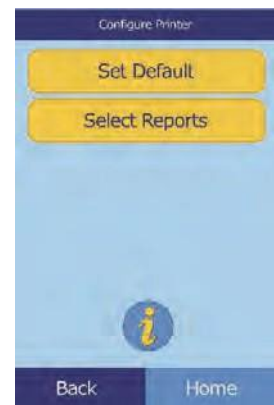
4.12.3 Selecting Reports

Use this procedure to set the type and number of reports that can be printed automatically after a sample is analyzed.

1. In the Printer Setup screen, select **Configure**.



2. Select **Reports**.
3. Select the **Report Type**.



4. Use the controls to set the number of copies to print:
 - Use the up (\triangle) and down (∇) arrow keys to adjust the number.
 - Select **Clear** to set the number to zero.
 - Select **Default** to set the delay to its factory default.

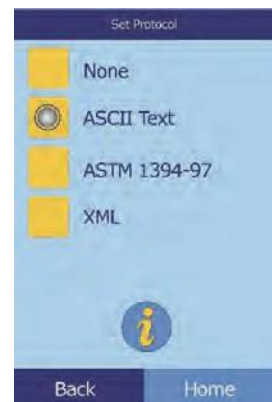


5. Select **Save** to store the new setting.

4.13 Setting Communication Protocol/Internet Connectivity

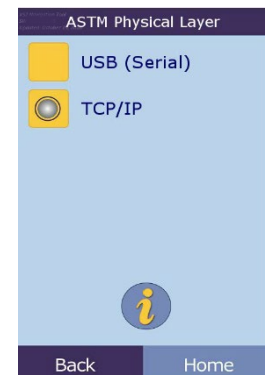
To transmit results and other information from the analyzer to an external computer, specify the communication protocol to be used.

1. In the Home screen, select the **Settings** icon.
2. Select the **More Settings** icon.
3. Select the **Communication Settings** icon.
4. Select a protocol: **None**, **ASCII Text**, **ASTM 1394-97**, or **XML**.

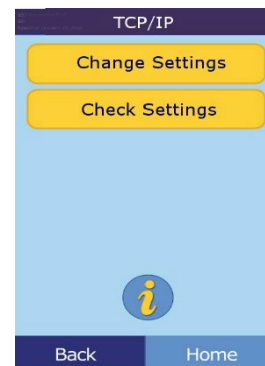


*Note: If the Analyze is Serial Number P0, P1 they will need a UGreen Adapter.
If the Analyze is Serial Number P2, P3 they will plug and play from
the port in the back.*

5. Click on **TCP/IP**



6. Select "**Change Settings**".



7. The following information will be provided by
the customers IT department.

ASTM TCP/IP Settings	
Analyzer IP	192.1.10.30
Subnet Mask	255.255.255.0
Gateway IP	10.1.1.1
Server IP	10.1.1.18
Server Socket	2398

At the bottom of the screenshot is a blue bar with "Back" and "Home" buttons.

4.14 Using Optional Data Functions

The analyzer includes a number of optional data-entry functions that can be used to enter more detailed information about samples, such as age and gender. The analyzer can be configured to use some or all of these functions as needed.

Note: *The analyzer includes a number of optional data functions that can be used to enter more detailed information about samples.*

*In this manual, the steps for these optional functions are marked with the **Advanced Setting** icon:*

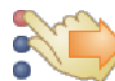


The screens for these optional functions appear on the analyzer only if the functions are enabled. If a screen shown in a procedure step in this manual does not appear on the analyzer screen, skip that step.

1. In the Home screen, select the **Settings** icon.



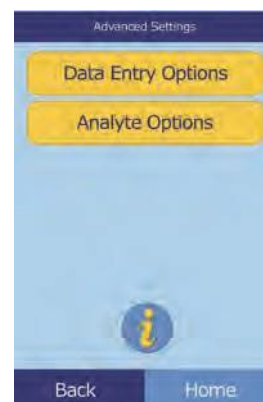
2. Select the **More Settings** icon.



3. Select the **Advanced Settings** icon.



4. Select **Data Entry Options**.

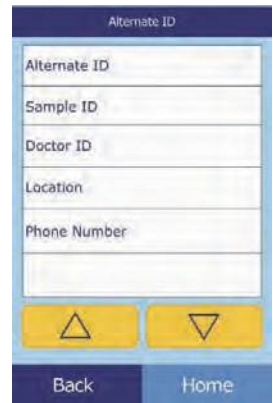


5. In the Advanced Settings screen, select the types of information that will be needed during analysis.



6. **Alternate ID only:** select an alternate ID item to be entered (such as Doctor ID, Phone #, DOB, Admission ID, or Patient ID).

Use the up (\triangle) and down (∇) arrow keys as needed to scroll through the list.



7. Enable the eGFR calculation (see “eGFR Xpress Operation” on page 4-31) as follows:

a. In the Home screen, select the **Settings** icon.



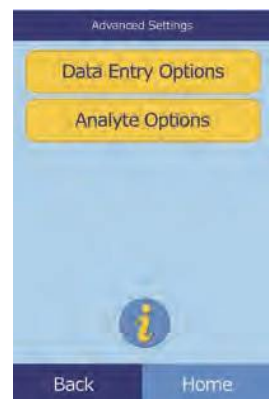
b. Select the **More Settings** icon.



c. Select the **Advanced Settings** icon.



d. Select **Analyte Options**.



e. Select **eGFR**.



eGFR Xpress Operation

eGFR (estimated Glomerular Filtration Rate) is turned off by default — it is enabled in the Advanced Settings screen (see [step 7, above](#)) under Analyte Options.

When eGFR is enabled, choosing Patient sample type will prompt for age, race, and gender whenever a disc includes CRE (creatinine). The analyzer requires information for these three items to perform the calculations. If no information or “unknown” is entered, the displayed result for eGFR will be **N/C** (Not Calculated) and an error report is printed automatically.

When eGFR is off, eGFR shows a result of **N/C** on the results printout, directly below **CRE**.

The official units for eGFR are mL/min/1.73 m². The analyzer uses mL/min to enable simpler printing.

4.15 Running Controls

A control is a biological sample or solution with a suitably contrived matrix that is analyzed for quality control (QC). The composition of the matrix must be such that the solution closely matches that of the biological specimen for characteristics of importance to the analyzer. Control materials need to be stable and available in sufficient volumes in multiple portions and over an extended period. Many control products are available commercially. Assayed controls also come with expected values of the analytes for guidance.

Abaxis recommends control testing as follows:

- at least every 30 days
- whenever laboratory conditions have changed significantly
- when training or retraining of personnel is needed
- when test results do not match patient symptoms or clinical findings
- with each new lot (CLIA waived tests in waived status labs)

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.

The analyzer runs samples and controls the same way. However, using the Run Controls option in the Menu function stores control results separately from patient results in the analyzer memory. The Recall function can be used to search for specific control results without searching through all patient results stored in memory.

Control results can be printed on a result card immediately after the control run is finished, or whenever the control run results are recalled. (See “[Recalling Results from the Last Disc Run](#)” on [page 5-2](#) for details.) Control results are automatically sent to a linked computer.

Handle the control as described in the control package insert. Call Abaxis Technical support for help in interpreting control results.

Note: *Before a control can be run, a control level must be enabled in the reference ranges — see “[To create a new control:](#)” on [page 4-8](#).*

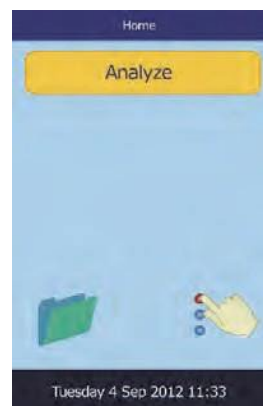
Controls can be run whenever the analyzer displays the Home screen.

Note: *For more details on running controls, see “[Preparing the Reagent Disc](#)” on [page 3-4](#).*

CAUTION: *Discs are fragile — always handle with care. Do not tap discs on the table or work bench to empty the sample port. **Never use a disk that has been dropped.***

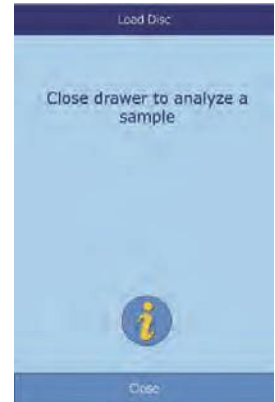
*Inspect every disc for damage before use. **Never use a damaged disc.***

1. In the Home screen, select **Analyze** to open the disc drawer.





2. Place the disc in the drawer, then select **Close** to close the drawer.

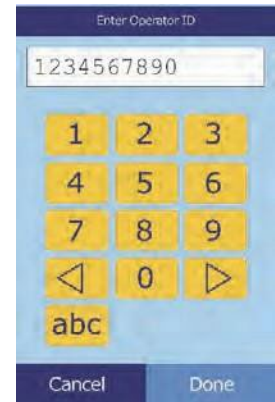
Analysis will begin automatically.





3.  **Optional:** enter the Operator ID, then select **Done**.

The right arrow key () functions as a dash (-), and the left arrow key () functions as a backspace.

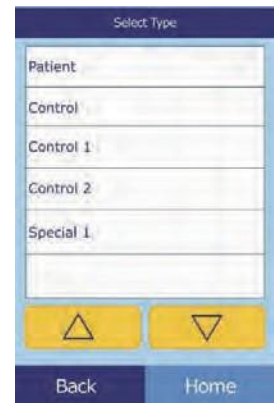
The operator ID is up to 14 characters.



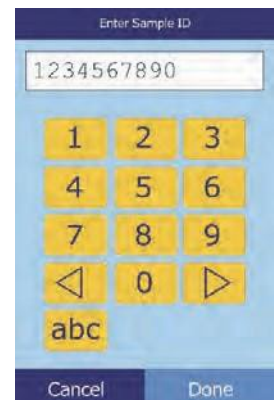
4. Select the control type to use.

Use the up () and down () arrow keys as needed to scroll through the list.

The left screen shows the default: Control.
The screen at right shows custom entries.



5. Enter a sample ID (up to 14 characters), then select **Done**.



- The analyzer will check the disc type, and then begin processing the sample with no further input.



- When the sample is finished processing, the analyzer shows that the analysis is complete and automatically prints the results.

If the results do not print automatically, they can be recalled from memory and printed — see “Searching for Results” on page 5-3.



- Select **Open** to open the disc drawer. Remove the disc from the drawer.

CAUTION: *Dispose of the used reagent disc according to the established biohazard procedures.*

- When finished, select **Close** to close the drawer.

4.16 Security Settings

Use Security Settings to enable various access levels on the analyzer.

- **Administrators** can access all of the analyzer’s settings screens. When this setting is enabled, security features take effect when the first administrator is added, and are disabled if all administrators are deleted. When security is enabled, accessing the second set of settings screens requires a valid Administrator ID and password.

CAUTION: *Record all Administrator IDs in a safe place. If an Administrator ID is lost, the analyzer must be returned to Abaxis for recovery.*

- **Operators** are authorized to operate the analyzer. Once an operator is added, the Operator ID prompt appears whenever analyzing a sample.

Note: *A warning appears if an operator is not authorized or the operator ID needs to be renewed.*

The analyzer can store up to 100 administrators and 100 operators.

- **Controls** sets a date by which a new set of control samples must be run. If new controls are not run by this date, a warning appears whenever a sample is analyzed.

1. In the Home screen, select the **Settings** icon.



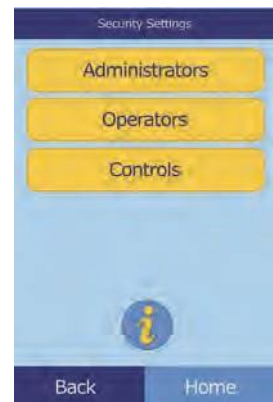
2. Select the **More** Settings icon.



3. Select the **Security Settings** icon.



4. Select the appropriate security option.



Recalling Results

The Piccolo Xpress chemistry analyzer includes a Recall function that provides access to the most recent test results, including patient results, control results, and test errors.

The Recall function is available on the Home screen.

You can search results by patient/control ID number or date, or view patient results or control results by date. You can also view the results in memory one record at a time, and then print the results or transmit them to a computer.

***Note:** The analyzer must be connected to a computer to transmit results. For instructions, see “Adding External Peripheral Devices” on page 10-2.*

This section includes instructions for recalling, viewing, and printing or transmitting results and reports.

<i>5.1 Troubleshooting Flags</i>	<i>5-2</i>
<i>5.2 Recalling Results from the Last Disc Run.....</i>	<i>5-2</i>
<i>5.3 Searching for Results</i>	<i>5-3</i>
<i>5.4 Browsing Results</i>	<i>5-8</i>
<i>5.5 Transmitting All Results.....</i>	<i>5-9</i>

5.1 Troubleshooting Flags

The analyzer performs a series of internal quality checks to ensure accurate results. When the analyzer detects a problem, it either suppresses certain chemistry results (in which case it prints troubleshooting “flags” — such as ~~~, **HEM**, **LIP**, or **ICT** — in place of values) or cancels the run (the disc cancels and no results are printed).

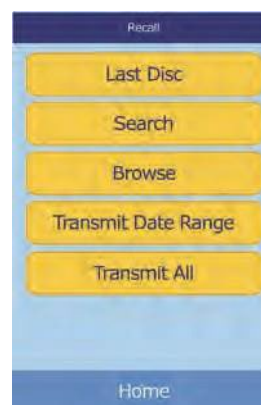
When either of these occurs, an error report can be printed or transmitted as described in the following section.

5.2 Recalling Results from the Last Disc Run

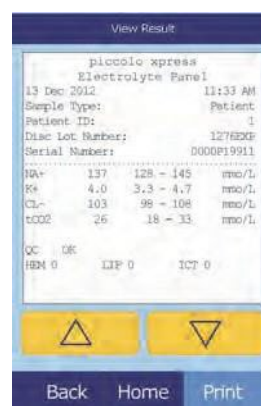
Results of the last disc run can be recalled, printed, or transmitted, as follows.



1. In the Home screen, select the **Recall** icon.

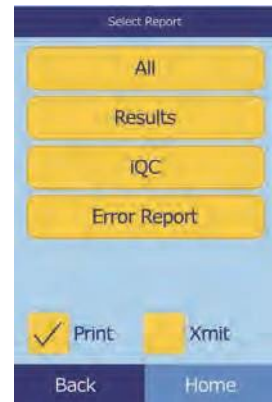


2. Select **Last Disc**.
3. The results from the last disc are displayed. Use the up (Δ) and down (∇) arrow keys to scroll through the results.



4. To print these results or transmit them to an external computer, select **Print**:
 - a. Select **Print** or **Transmit**.
 - b. Select the report: **All**, **Results**, **iQC**, or **Error Report**.

Note: *If the disc produced no results, only **Error Report** will be available.*



The display then shows Sending Report... while the report or results are being printed or transmitted.

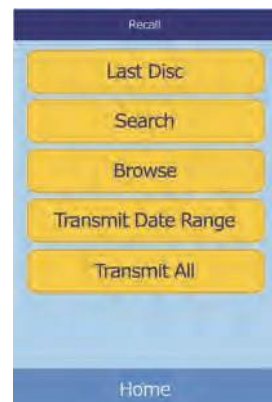
5.3 Searching for Results

Use the Recall function to search for a particular record according to its patient/control ID number or date, or to view a list of all saved patient or control results sorted by date.



1. In the Home screen, select the **Recall** icon.

Note: *If the analyzer contains no saved results, it displays the message No saved results to view.*



2. Select **Search**.
3. Use the Search screen to search for results. See the following:
 - ❑ “Searching for Results by Patient/Control ID” on page 5-4
 - ❑ “Searching for Results by Date” on page 5-5
 - ❑ “Viewing Patient Results or Control Results by Date” on page 5-7



5.3.1 Searching for Results by Patient/Control ID

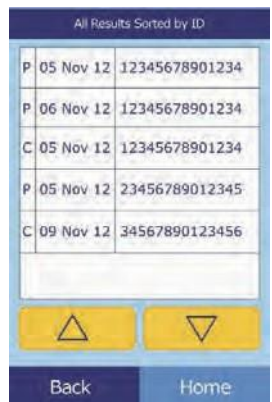
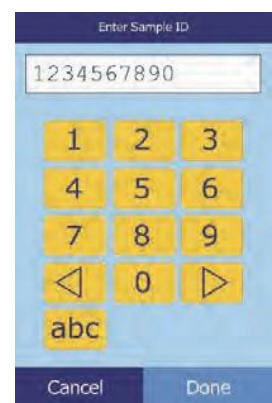
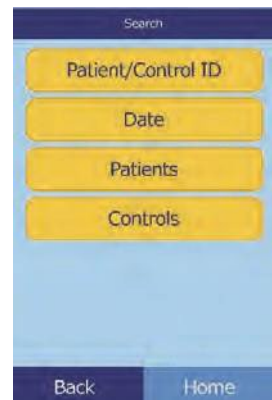
1. In the Search screen, select **Patient/Control ID**.
2. Enter the patient/control ID number.

Use the right arrow key (\triangleright) to enter dashes (-), and the left arrow key (\triangleleft) to backspace.

3. Select **Search**.

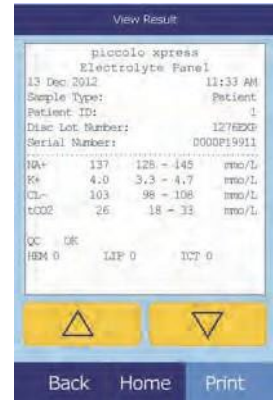
The analyzer then displays a list of results (Patient, Control, and Error) sorted first by patient/control ID, then by date. Any samples with the ID number entered will be at the top, followed by the next closest matches.

Use the up (\triangle) and down (∇) arrow keys to scroll through the list. (The list wraps around when either end is reached.)



4. Select the results to display.

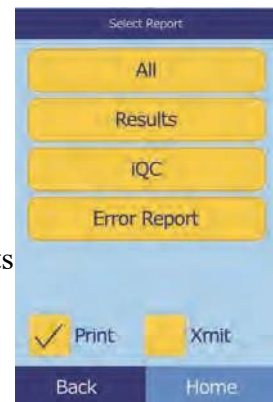
Use the up (\triangle) and down (∇) arrow keys to scroll through the list.



5. To print these results or transmit them to an external computer, select **Print**:

- a. Select **Print** or **Transmit**.
- b. Select the report: **All**, **Results**, **iQC**, or **Error Report**.

The display then shows **Sending Report...** while the report or results are being printed or transmitted.



5.3.2 Searching for Results by Date

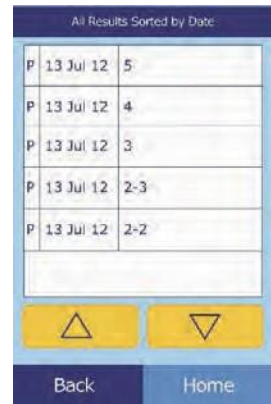
1. In the Search screen, select **Date**.
2. Use the up (\triangle) and down (∇) arrow keys to enter the date of the results.



3. Select **Search**.

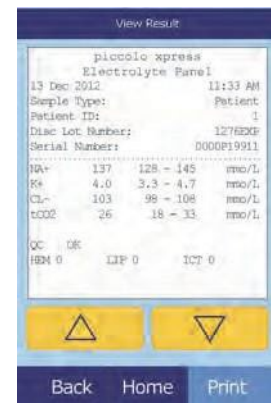
The analyzer then displays a list of results in reverse chronological order, beginning with the date entered.

Use the up (Δ) and down (∇) arrow keys to scroll through the list.



4. Select the results to display.

Use the up (Δ) and down (∇) arrow keys to scroll through the list.

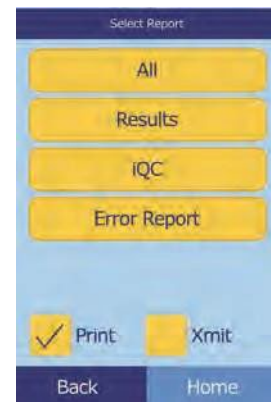


5. To print these results or transmit them to an external computer, select **Print**:

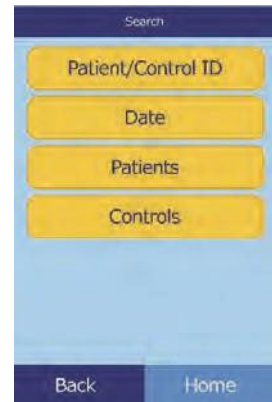
- a. Select **Print** or **Transmit**.
- b. Select the report: **All**, **Results**, **iQC**, or **Error Report**.

The display then shows Sending Report...

while the report or results are being printed or transmitted.

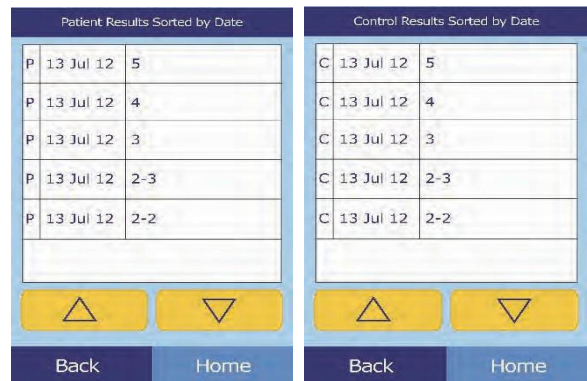


5.3.3 Viewing Patient Results or Control Results by Date



1. In the Search screen, select **Patients** or **Controls**.

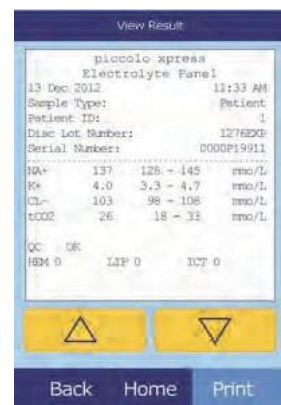
The analyzer then displays a list of patient results (**P**) and errors (**E**), or control results (**C**) and errors (**E**), in reverse chronological order from the date entered.



Use the up (Δ) and down (∇) arrow keys to scroll through the list.

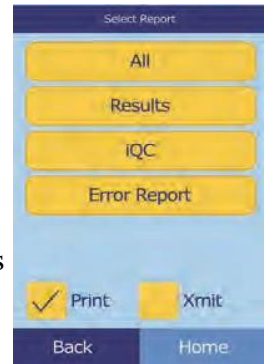
2. Select the results to display.

Use the up (Δ) and down (∇) arrow keys to scroll through the results.



3. To print these results or transmit them to an external computer, select **Print**:
 - a. Select **Print** or **Transmit**.
 - b. Select the report: **All**, **Results**, **iQC**, or **Error Report**.

The display then shows Sending Report... while the report or results are being printed or transmitted.

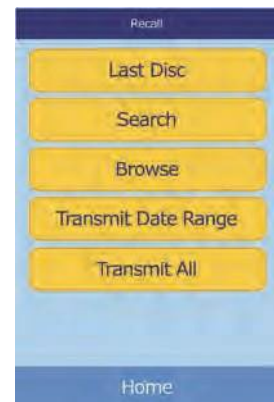


5.4 Browsing Results

Use the Recall function to browse through all stored results.



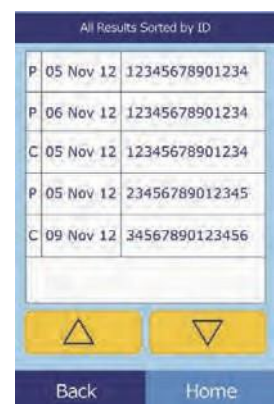
1. In the Home screen, select the **Recall** icon.



2. Select **Browse**.

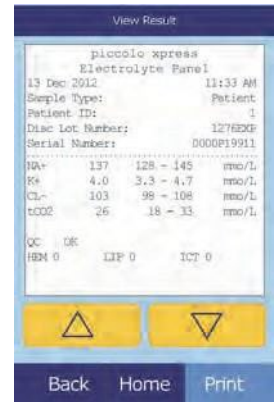
The analyzer then displays a list of all results (**P**atient, **C**ontrol, and **E**rror) in reverse chronological order from the date entered.

Use the up (Δ) and down (∇) arrow keys to scroll through the list.



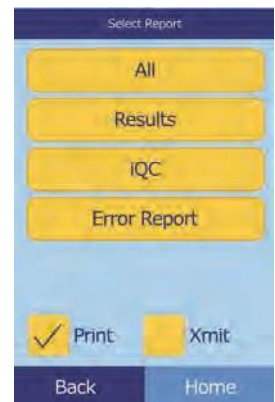
3. Select the results to display.

Use the up (Δ) and down (∇) arrow keys to scroll through the results.



4. To print these results or transmit them to an external computer, select **Print**:
 - a. Select **Print** or **Transmit**.
 - b. Select the report: **All**, **Results**, **iQC**, or **Error Report**.

The display then shows Sending Report... while the report or results are being printed or transmitted.



5.5 Transmitting All Results

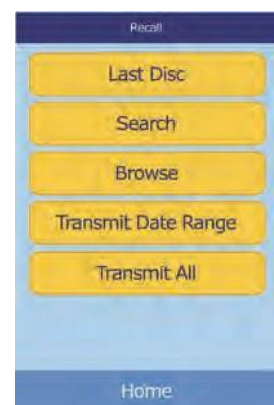
Use this procedure to transmit all stored results to a connected computer.

Note: *The analyzer must be connected to a computer to transmit results. For instructions, see “Adding External Peripheral Devices” on page 10-2.*

1. In the Home screen, select the **Recall** icon
2. Select **Transmit All**.



The analyzer displays Transmitting All... while the records are being sent.



Calibration and Quality Control

6.1 Calibration

The Piccolo Xpress is self-calibrating. The bar code on each reagent disc contains information used to calibrate the analyzer when the disc is run. In addition, each reagent bead in the disc is calibrated to a reference method and/or reference material. The procedures in the previous sections use these features to keep the analyzer calibrated and its results accurate.

6.2 Quality Control Features

The analyzer includes quality control (QC) features such as optical sensing and electronic feedback to ensure accurate results. The analyzer runs a self test on its components and the reagent discs whenever power is turned on or a disc is inserted, and continues testing during analysis. Messages on the display or in the result printout warn of any malfunction or possible error, or explain why no results are reported.

6.2.1 Intelligent Quality Control (iQC)

The analyzer performs an iQC test when power is turned on. iQC ensures that components are functioning properly, and if so, verifies memory functions. Any malfunction will display a message on the screen.

The analyzer software uses statistical methods to ensure accurate results. The lamp flashes up to 13 times for rate chemistries, and typically three times for endpoint chemistries. The distribution of flashes is analyzed, and the standard deviation is compared to a pre-determined limit to make sure the analyzer is functioning properly.

6.2.2 Quality Control During Analysis

During analysis, the analyzer checks its components and the reagent disc to ensure accurate results.

Piccolo Xpress Analyzer

Before analysis begins, the analyzer's photometer takes readings with the light path both blocked and unblocked to determine the correct light intensity range, then makes sure the range is within specification. It also continually checks the performance of the motor, flash, and optics during analysis.

Reagent Disc

The analyzer checks the disc during analysis to confirm the following:

- calibration factors
- expiration date
- presence of all reagent beads
- timing of fluid movement through the disc
- diluent and sample mixing
- sufficient sample in the disc
- proper dissolution of the reagent beads when mixed with sample

Each disc also contains reagents to detect exposure to extreme conditions such as temperature and humidity. The message QC OK appears in the printout when results are within expected ranges. Otherwise, no results are printed, and run canceled appears on the display.

The analyzer also monitors reaction performance. For rate chemistries, the analyzer confirms that the reactions are linear with time and slope is within range, and monitors substrate depletion. In endpoint chemistries, the analyzer verifies the flatness (completeness) of the endpoints.

Sample

Samples are checked for physical interference. The analyzer estimates the sample indices for hemolysis (HEM), lipemia (LIP), and icterus (ICT) using absorbance readings for the sample at 340 nm, 405 nm, and 467 nm, respectively. It then compares them to pre-established limits for each method. A result card is printed when all three are below the method limits. If even one index exceeds the limit, the result is suppressed and the error condition is displayed as **HEM**, **LIP**, or **ICT**.

6.3 Running External Controls

The Run Controls menu function automatically stores control results in a memory separate from the patient results memory (see [“Running Controls” on page 4-31](#)). The Recall function may be used to search for specific control results without searching through all patient results stored in memory.

7.1 Error Messages

The Piccolo Xpress can display warning and error messages when problems occur. These messages include an internal error code that will assist Abaxis Technical Support in diagnosing the problem. Record the error message and/or print an error report before calling Abaxis Technical Support.

7.2 Electrostatic Discharge/Electrical Transients

If the analyzer experiences an electrostatic discharge, electrical fast transient/burst or surge, the analyzer's iQC system is designed to trigger an abort of the active run. If this happens, cancel the analysis (see “Canceling Analysis” on page 3-11), then power the analyzer off and back on again to restore the analyzer to operating condition. NOTE: Depending on the installation, this event may alternatively manifest as either a “freeze up”, or a shutdown.

7.3 Technical Support

If the troubleshooting recommendations contained in this section do not correct the problem with the analyzer or the reagent discs, please contact Abaxis Technical Support:

Abaxis Inc.

- call +1 800-822-2947
- email AB-PiccoloTechSupport@zoetis.com
- send a fax to +1 877-349-2087

Abaxis Europe GmbH

- call +49 (6155) 780 21 - 300
- email int.piccolosupport@zoetis.com
- send a fax to +49 (6155) 780 21 - 111

7.4 Disc Cancellations

If the disc cancels, record the following information or print an error report and contact Abaxis Technical Support:

- lot number
- product name
- 4-digit error code
- specimen type and sample

7.5 Instrument and Result Messages

The analyzer performs a series of internal quality checks to ensure accurate results. When a problem is detected, the analyzer will either suppress certain chemistry results (~~~, **HEM**, **LIP**, or **ICT** printed in place of values) or cancel the run (disc cancels and no patient results printed). When either of these situations occur, the operator should proceed as described below.

7.5.1 Chemistry Suppression

In this situation, patient results print, but some results do not have numerical values. Instead, the results include troubleshooting flags (~~~, **HEM**, **LIP**, or **ICT**) printed in place of values.

If this happens, record the error code, print an error report using the Recall function (see [“Recalling Results” on page 5-1](#)), and contact Abaxis Technical Support to review the error report.

7.5.2 Disc Cancellation

In this situation, the display shows Run Canceled and does not print patient results. The display also shows an error code and a brief description of the error.

If this happens, record the error code, print an error report using the Recall function (see [“Recalling Results” on page 5-1](#)), and contact Abaxis Technical Support to review the error report.

7.5.3 Symbols on the Results Printout

The following table explains the symbols that may appear on the results printout.

Symbols printed next to the result (see “Running a Patient Sample” on page 3-6)		
Symbol	Meaning	Notes
*	The result is outside the reference range.	An asterisk (*) is printed next to the analyte concentration if the results are outside the range. An asterisk is also printed if the result is at the upper or lower limit of the range, but because results are rounded, these are considered out-of-range as well. For example: Na+ 145* (128–145) Cl- 98* (98–108)
<	The result is lower than the dynamic range.	For more information on results with < or > printed before the value, print an error report (see “Recalling Results” on page 5-1). This report includes patient results, but the values approximate the analyte concentration.
>	The result is higher than the dynamic range.	
H	After an LD value, indicates that hemolysis might affect the results.	
< and H	If < appears before and H after an LD result, hemolysis is more extensive (100–150 mg/dL) and the true LD value is less than reported.	
C	The result was calculated.	
!	Confirm Low Recoveries. This indicates at least one analyte has a lower concentration than normally expected.	Re-run the sample. If the message recurs, results may fit patient profile clinically, or the sample may be problematic.
N/C	Not Calculated.	
Symbols (flags) printed instead of results		
Symbol	Meaning	Notes
~~~	Chemistry interference	See <a href="#">“Results” on page 3-11</a> .
HEM	Hemolysis interference	
LIP	Lipemia interference	
ICT	Icterus interference	

Call Abaxis Technical Support if the entire numerical line is displayed on the error report, including the line HEM (H), LIP (L), and ICT (I).



## 7.6 Reinitializing the Analyzer

If required, use the reinitialization function to return all settings to their original factory default values (including the clock). This will also clear all patient results, control results, and custom reference ranges from memory. Perform the following steps to reinitialize the analyzer.



1. In the Home screen, select the **Settings** icon.



2. Select the **More Settings** icon.

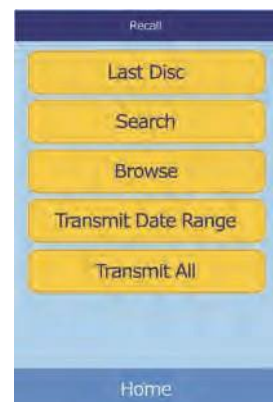


3. Select the **Factory Settings** icon.

4. Archive the analyzer's reference ranges — including custom reference ranges — so they can be restored after the analyzer is reinitialized. For instructions, see [“Printing and Archiving Reference Ranges”](#) on page 4-11.

**CAUTION:** *The next step is irreversible. All settings — including custom reference ranges — are returned to their factory values, and the memory is cleared. Results previously stored, however, are not affected.*

5. Select **YES** to restore all factory settings and to clear all memory from the analyzer.



6. Refer to the following sections to reset any custom reference ranges, the date and time, or the units of measurement:
  - [“Customizing Reference Ranges”](#) on page 4-2
  - [“Changing Date and Time”](#) on page 4-15
  - [“Selecting Units”](#) on page 4-17

## 8.1 Principles of Procedure

The operator introduces a heparinized whole blood sample (or heparinized plasma, serum, or control) into the reagent disc, which contains a diluent and test-specific reagent beads. The operator then places the disc in the Piccolo Xpress chemistry analyzer and enters the appropriate identification numbers. The analyzer automatically performs the remainder of the testing protocol.

The disc spins and whole blood is separated into plasma and blood cells. During this time, the disc is heated to 37°C (98.6°F). Precisely measured quantities of plasma and diluent enter the mixing chamber and are mixed together. Through centrifugal and capillary forces, the diluted plasma is distributed to cuvettes on the perimeter of the disc. Reagent beads in the cuvettes are dissolved by the diluted plasma. This solution is thoroughly mixed and the resulting chemical reactions are monitored photometrically by the analyzer. Optical signals generated by the chemical reactions are used to calculate analyte concentrations. Calibration data specific for the chemistries in each disc are provided to the analyzer by the bar code printed on the bar code ring.

Results print automatically when the analysis is completed. Analyte concentrations and reference ranges for each test in the panel and sample indices are included on a printout, providing a paper copy of the results. Results are also stored in the analyzer's memory and can be transmitted to external computers. The used disc is removed and discarded.

The Piccolo Xpress is then ready to analyze another sample.

## 8.2 Principles of Operation

Chemical reactions occur between reagent beads, the diluent contained in the reagent disc, and the added sample. These reactions produce chromophores (atoms that give a substance its color) that are measured photometrically (using light). The microprocessor then calculates the concentrations of the analytes.

The measurement optics include a stroboscopic xenon lamp, a wavelength selection system, and a multiple-wavelength detector. Light from the lamp is directed by a mirror to pass through each cuvette. Some light is absorbed by the contents, and the remainder travels through two apertures and is then collimated (lined up in a beam) by a lens. Collimated light is split by beam splitters and interference filters at pre-determined wavelengths (340, 405, 467, 500, 515, 550, 600, 630, and 850 nm), and captured at each wavelength by photodiodes (a semiconductor that measures electrical resistance).

The chemical reactions are designed to produce chromophores that absorb light at known wavelengths. The photometer measures light that is transmitted through a chromophore-containing cuvette (the reaction cuvette). The transmitted light, when corrected for flash-to-flash variability and electronic offset, is indirectly related to the analyte concentration of the sample. Transmittance measurements are converted to absorbance using the relationship:  $\text{absorbance} = -\log(\text{transmittance})$ .

System errors and factors that may interfere with sample result calculations are eliminated by measuring light intensity at four locations of the reagent disc: 1) the method-specific cuvette containing test reagent, sample, and diluent; 2) the sample blank cuvette containing sample blank reagent, sample, and diluent (used in endpoint reactions, see below); 3) the open cuvette, which allows all the light to pass through; and 4) the dark cuvette, which blocks the passage of light.

Light passing through a reaction cuvette is measured both at the wavelength that is absorbed by the chromophore ( $I_{\lambda 1RC}$ ) and at a wavelength not absorbed by the chromophore ( $I_{\lambda 2RC}$ ). The ratio of these two measurements corrects for cuvette optical quality and flash-to-flash variability in the light source. The intensity of light transmitted through the open cuvette ( $I_{\lambda 1OC}$ ,  $I_{\lambda 2OC}$ ) is measured at the same two wavelengths as the light transmitted through the reaction cuvette. A correction for electronic offset is made at the same two wavelengths by measuring the residual signal when the dark cuvette is in the optical path ( $I_{\lambda 10}$ ,  $I_{\lambda 20}$ ).

The equation for calculating absorbance is:

$$A = -\log \left[ \frac{(I_{\lambda 1RC} - I_{\lambda 1_0}) / (I_{\lambda 2RC} - I_{\lambda 2_0})}{(I_{\lambda 1OC} - I_{\lambda 1_0}) / (I_{\lambda 2OC} - I_{\lambda 2_0})} \right]$$

where:

- A = Absorbance at wavelength 1, referenced to wavelength 2
- $I_{\lambda 1RC}$  = Intensity of light transmitted through the reaction cuvette at wavelength 1
- $I_{\lambda 2RC}$  = Intensity of light transmitted through the reaction cuvette at wavelength 2
- $I_{\lambda 1_0}$  = Intensity of light transmitted through the dark cuvette at wavelength 1
- $I_{\lambda 2_0}$  = Intensity of light transmitted through the dark cuvette at wavelength 2
- $I_{\lambda 1OC}$  = Intensity of light transmitted through the open cuvette at wavelength 1
- $I_{\lambda 2OC}$  = Intensity of light transmitted through the open cuvette at wavelength 2

This is the basic equation to measure analyte concentrations in the rate methods and endpoint reactions used in chemistries.

## 8.2.1 Rate Methods

The rate of the reaction is calculated from the difference between absorbances measured at certain defined intervals on the linear portion of the reaction curve. Absorbances are taken throughout the read time to confirm the linearity of the reaction curve. The absorbance rates are converted to analyte concentrations by using the disc-specific calibration factors that are encoded on the bar code ring.

The equation for rate methods is:

$$\frac{\left\{ -\log \left[ \frac{(I_{\lambda 1RC} - I_{\lambda 1_0}) / (I_{\lambda 2RC} - I_{\lambda 2_0})}{(I_{\lambda 1OC} - I_{\lambda 1_0}) / (I_{\lambda 2OC} - I_{\lambda 2_0})} \right]_F \right\} - \left\{ -\log \left[ \frac{(I_{\lambda 1RC} - I_{\lambda 1_0}) / (I_{\lambda 2RC} - I_{\lambda 2_0})}{(I_{\lambda 1OC} - I_{\lambda 1_0}) / (I_{\lambda 2OC} - I_{\lambda 2_0})} \right]_B \right\}}{\text{Time Period}}$$

where:

- $\Delta A / \Delta \tau$  = Rate of change of absorbance
- F = Measurements taken at time F on linear portion of reaction curve
- B = Measurements taken at time B on linear portion of reaction curve
- $\tau$  = Time in minutes
- $I_{\lambda XX}$  = Other intensities as described above

## 8.2.2 Endpoint Reactions

Reagents, samples, and chromophores all absorb light in endpoint reactions. Light absorption by the samples must be subtracted so that the analyte concentration can be isolated. The absorbance of the sample is measured in a sample blank cuvette. Some chemistries employ a generic sample blank and others (such as total bilirubin) use a dedicated sample blank. The intensity of the light passing through the sample blank cuvette ( $I_{\lambda 1SC}$ ,  $I_{\lambda 2SC}$ ) is measured at the same wavelengths as is the light passing through the reaction cuvette.

The equation for endpoint reactions is:

$$A = -\log \left[ \frac{(I_{\lambda 1RC} - I_{\lambda 1_0}) / (I_{\lambda 2RC} - I_{\lambda 2_0})}{(I_{\lambda 1OC} - I_{\lambda 1_0}) / (I_{\lambda 2OC} - I_{\lambda 2_0})} \right]$$

where:

$I_{\lambda 1SC}$  = Intensity of light transmitted through the sample blank cuvette at wavelength 1

$I_{\lambda 2SC}$  = Intensity of light transmitted through the sample blank cuvette at wavelength 2

$I_{\lambda XX}$  = Other intensities as described above

The net absorbance is converted to analyte concentration using data encoded in the bar code printed on the bar code ring.

# Maintenance and Service

The Piccolo Xpress chemistry analyzer requires minimal maintenance. Clean the exterior of the analyzer weekly with mild detergent and a soft, damp cloth. The air filter requires cleaning twice per year. Regular maintenance will help ensure reliable operation, and frequency will depend on environmental conditions.

**CAUTION:** *Abaxis recommends only the cleaning methods described in this section. If for some reason another method is needed, contact Abaxis Technical Support beforehand to verify that the proposed method will not damage the analyzer. Abaxis is not responsible for damage caused by non-recommended cleaning methods.*

## 9.1 Cleaning the Analyzer

Clean the external case and display at least weekly. Inspect the instrument casing during cleaning to ensure it is free of damage or cracks.

### 9.1.1 Cleaning the Case

Clean the analyzer with a soft cloth, dampened with a mild, non-abrasive detergent or cleaning solution, such as Simple Green[®], a 10% bleach solution, or a 30% isopropyl alcohol solution. Pre-soaked isopropyl towelettes may also be used and can be purchased from computer retailers.

Do not spray or pour any detergents, solutions, or other liquids directly onto the analyzer. Dampen a lint-free soft cloth or disposable paper towel with the detergent, then apply to the analyzer.

## 9.1.2 Cleaning the Display

Clean the analyzer's screen periodically using a soft, lint-free cloth dampened with a glass-cleaning fluid or window cleaner. Disinfect the screen using a 10% bleach solution applied to a lint-free cloth.

**CAUTION:** Do not use any cleaner containing alcohol. Do not spray cleaner directly onto the display — dampen the cloth instead.

## 9.2 Cleaning Spills

Observe universal precautions¹ when cleaning spills on the analyzer. Use a 10% bleach solution (1 part bleach to 9 parts water) to clean spills, following the standard cleaning guidelines in “Cleaning the Analyzer” on page 9-1.

**Note:** For further guidelines on handling and disposing of hazardous laboratory wastes, refer to “Clinical Laboratory Waste Management; Approved Guideline—Second Edition” (GP5-A2), from the Clinical and Laboratory Standards Institute (formerly NCCLS). See <http://www.clsi.org>.

## 9.3 Cleaning the Air Filter

The air filter in the back of the analyzer should be cleaned at least twice per year. Check the air filter more often if it is located in an environment with excessive dust or dirt.

To clean the air filter:

1. Unplug the analyzer and remove the power cord from the back.
2. Remove the air filter cover by pulling gently.
3. Wash the filter in warm soapy water, rinse, and dry completely before reassembling.
4. Replace clean and dry air filter into its cover and push the clips back into position.
5. Plug the power cord back into the analyzer.



1. Clinical and Laboratory Standards Institute (formerly NCCLS). 2005. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—3rd Edition (M29-A3). Wayne, PA: CLSI; pp 29–31. Clinical and Laboratory Standards Institute (formerly NCCLS). 2002. Clinical Laboratory Waste Management; Approved Guideline—2nd Edition (GP5-A2). Wayne, PA: CLSI.

6. Plug the power cord into the power source, and press the Power button on the front of the analyzer. The analyzer will perform a diagnostic self test. It may take up to another four minutes for the heaters to bring the analyzer disc chamber to operating temperature.

Refer to “[Troubleshooting](#)” on page 7-1 if the analyzer does not successfully pass the self test. See “[Running a Patient Sample](#)” on page 3-6 to run samples.

## 9.4 Updating the Analyzer Software

Abaxis provides software updates on a CD-ROM to registered owners. Replacement software is mailed immediately whenever a new software version is released. See “[Viewing Analyzer Information](#)” on page 4-15 to determine the software version installed in the analyzer. Contact Abaxis Technical Support immediately if the software version is not the most recent release.

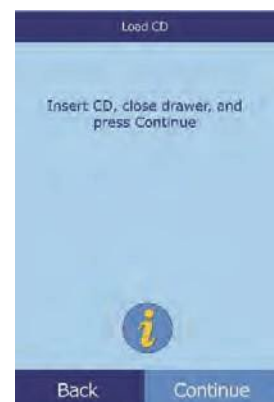
*Note:* Be sure to update the software every time an update CD is received from Abaxis.

Update the analyzer software as follows:

1. In the Home screen, select the **Settings** icon.
2. Select the **More Settings** icon.



3. Select the **Software Update** icon.
4. Place the CD in the drawer, press the drawer closed.
5. Select **Continue** to begin update.





The analyzer automatically restarts when the update is complete.



**CAUTION:** *To avoid damaging the analyzer, do not remove the CD or remove power until after the analyzer shuts down and restarts completely.*

## 9.5 Returning the Analyzer to Abaxis for Service

The analyzer must be shipped in an authorized shipping container. Authorization for shipping and servicing must be obtained in advance from Abaxis Technical Support.

**Note:** *All patient data are erased when an analyzer is serviced – be sure to back up all patient records before shipping. For instructions, see “Transmitting All Results” on page 5-9.*

# Adding External Peripheral Devices

This section describes how to connect a printer or computer to the Piccolo Xpress, how to install the driver software, and how to capture test results from the analyzer on a Windows PC using HyperTerminal.

- 10.1 Connecting an External Printer..... 10-2*
- 10.2 Adding External Peripheral Devices..... 10-2*
- 10.3 Transmission Specifications..... 10-2*
- 10.4 Installing the Abaxis Driver..... 10-3*
- 10.5 Capturing Results with HyperTerminal ..... 10-9*

## 10.1 Connecting an External Printer

Results can be printed using any USB-compatible external printer approved by Abaxis. For a list of approved printers, call Abaxis Technical Support at 800-822-2947 (for Europe, contact [int.piccolosupport@zoetis.com](mailto:int.piccolosupport@zoetis.com)).

Connect the printer as described in the printer's instructions. See “Printer Settings” on page 4-24 for configuration instructions.

## 10.2 Adding External Peripheral Devices

The analyzer can transmit patient and control results to a computer in multiple formats through the USB serial port. The computer requires terminal emulation software (such as HyperTerminal, included with Windows 95 through Windows XP) and driver software to communicate with the analyzer.

Abaxis can also provide data files for interfacing with an LIS/EMR system. Contact Abaxis Technical Support for details.

Test results can be saved to a text file for viewing with word processing, spreadsheet, and database applications. This section describes the transmission specifications and hardware connections, and using HyperTerminal to capture results to a text file.

*Note: Data management systems can be interfaced with the analyzer to collect analysis results. Because the installation for each type of data management system differs, please contact your data management system supplier for more information.*

## 10.3 Transmission Specifications

<b>Cable</b>	USB cable
<b>Baud rate</b>	9600
<b>Data type</b>	ASCII
<b>Parity</b>	None
<b>Word length</b>	8 bits
<b>Stop bit</b>	1
<b>Start of transmission and new page sentinel</b>	Form Feed (decimal 12 or hexadecimal 0C)
<b>End of line sentinel</b>	Carriage Return (decimal 13 or hexadecimal 0D) and Line Feed (decimal 10 or hexadecimal 0A)
<b>End of transmission sentinel</b>	End-of-File (decimal 26 or hexadecimal 1A)
<b>Max number characters/line</b>	30 (including Carriage Return and Line Feed)
<b>Max number lines</b>	26

*Note: The exact contents of the printout are transmitted. In some cases a backslash (\) should be*

interpreted as a foreslash (/). For example, “mmo\L” is equivalent to “mmol/L”, and “mmo\L” is “mmol/L” in the transmitted results.

## 10.4 Installing the Abaxis Driver

This section describes how to install a software driver to communicate with a Windows, Linux, or Macintosh computer. The analyzer installs on the computer as a virtual communication port in the operating system.

### 10.4.1 Installing on a Windows PC

Installing the driver on a Windows PC requires the following:

10.4.1.1 Piccolo Xpress analyzer

10.4.1.2 PC with Windows operating system and a free USB port

10.4.1.3 Type A/Type B USB cable

10.4.1.4 Abaxis Driver CD (P/N 1100-7019)

**Note:** *Driver installation in Windows may require a user account with administrative privileges.*

*The screenshots in these instructions are from a typical Windows XP Professional installation. Some of these screens may vary in other versions of Windows.*

Install the driver as follows.

**Note:** *Do not connect the analyzer to the PC or turn the analyzer on until specifically directed to do so by the set-up wizard on the PC.*

1. Turn on the PC, and insert the Abaxis Driver CD into the CD drive.
2. Connect the USB cable to a Type A connector on the PC and to the uppermost USB connector (Type B) on the back of the analyzer.
3. Turn on the analyzer. Wait for the PC to recognize the analyzer and start the Found New Hardware Wizard — this may take a few minutes.

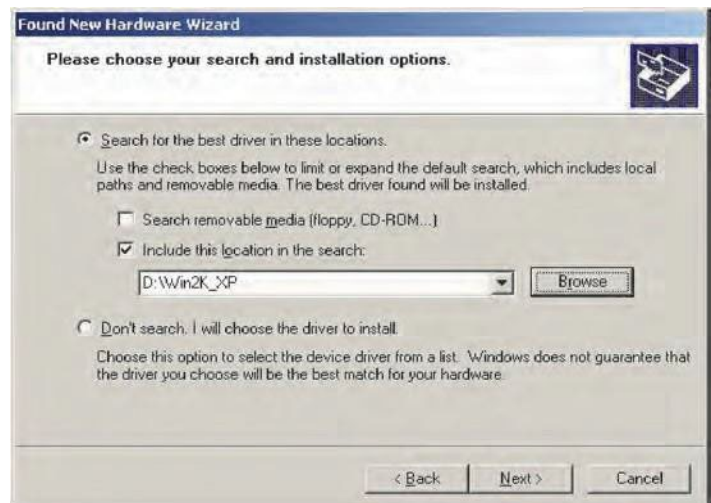
- If the wizard asks to connect to Windows Update, select **No, not this time**, then click **Next**.



- Select **Install from a list or specific location**, then click **Next**.



- Select **Search for the best driver in these locations**, then check **Include this location in the search**.



- Click **Browse**, then navigate to the CD drive containing the Abaxis Driver CD.

- On the drive, select the correct folder for the PC's version of Windows:

- For Windows 2000, XP, Vista, or 7: select the **Win2K_XP** folder.
- For Windows 98 or ME: select the **Win98_ME** folder.

- Click **Next**.

- If a warning states that the software has not passed the Windows Logo testing, click **Continue Anyway**.

The wizard then copies files from the CD to the PC.

11. When this dialog opens, click **Finish**.



12. After a moment, the Found New Hardware Wizard starts again. If the wizard asks to connect to Windows Update, select **No, not this time**, then click **Next**.



13. Select **Install from a list or specific location**, then click **Next**.



14. Select **Search for the best driver in these locations**, then check **Include this location in the search**.

15. Click **Browse**, then navigate to the CD drive.

16. On the drive, select the correct folder for the PC's version of Windows:

**For Windows 2000, XP, or 7:** select the **Win2K_XP** folder.

**For Windows 98 or ME:** select the **Win98_ME** folder.

17. Click **Next**.

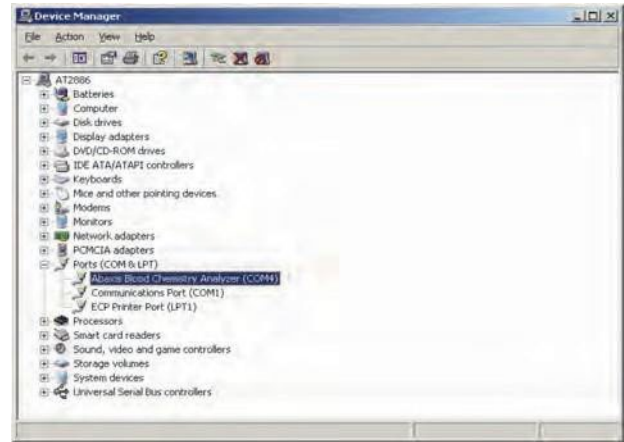
18. If a warning states that the software has not passed the Windows Logo testing, click **Continue Anyway**.

The wizard then copies files from the CD to the PC.

19. When this dialog opens, click **Finish**.



20. Open the Windows Device Manager:
  - ❑ For Windows 2000, XP, Vista, or 7: click **Start > Control Panel > Hardware and Sound > Device Manager**.
  - ❑ For Windows 98 or ME: click **Start > Control Panel > Performance and Maintenance > System**. Click the **Hardware** tab, then click **Device Manager**.
21. In Device Manager, click the **+** before **Ports (COM & LPT)**.
22. Record the port to which the analyzer was assigned (COM4 in the figure at right). You will need this later to capture test results.



## 10.4.2 Installing on a Linux PC

Connecting the Piccolo Xpress to a PC running the Linux operating system requires the following:

- 10.4.2.1 Piccolo Xpress analyzer
- 10.4.2.2 PC with Linux (kernel version 2.4 and above) and a free USB port
- 10.4.2.3 Type A/Type B USB cable

**Note:** *The driver is included in Linux kernel version 2.4 and above, but must be enabled to use.*

Enable the driver as follows.

**Note:** *Do not connect the analyzer to the PC or turn the analyzer on until specifically directed to do so.*

1. Turn on the PC, and log in as **root**.
2. Connect the USB cable to a Type A connector on the PC and to the uppermost USB connector (Type B) on the back of the analyzer.
3. Turn on the analyzer.
4. Open a terminal window on the PC, and enter the command **modprobe ftdi_sio** to enable the driver.
5. Configure any PC applications (such as minicom) to communicate with the analyzer over the virtual communication port (such as /dev/ttyS0).



### 10.4.3 Installing on a Macintosh Computer (OS X only)

Installing the driver on a Macintosh computer running system OS X requires the following:

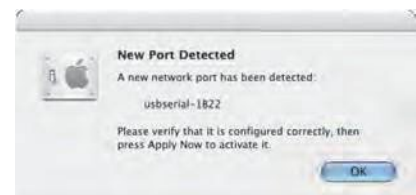
- 10.4.3.1 Piccolo Xpress analyzer
- 10.4.3.2 Macintosh computer with Mac OS X and a free USB port
- 10.4.3.3 Type A/Type B USB cable
- 10.4.3.4 Abaxis Driver CD (P/N 1100-7019)

**Note:** *The screenshots in these instructions are from a typical Mac OS X installation. Some of these screens may vary in other versions of Mac OS X.*

Install the driver as follows.

**Note:** *Do not connect the analyzer to the computer or turn the analyzer on until specifically directed to do so.*

1. Turn on the computer, and insert the Abaxis Driver CD into the computer's CD drive.
2. In the Finder, go to the CD drive and run the driver installer:
  - For an Intel-based Macintosh:** open the **Mac\Intel** folder and run the file **FTDIUSBSerialDriver_vX_X_X.dmg**.
  - For a PowerPC-based Macintosh:** open the **Mac\PPC** folder and run the file **FTDIUSBSerialDriver_vX_X_X.dmg**.
3. Follow the instructions that appear on the screen, and restart the computer when prompted.
4. Connect the USB cable to a Type A connector on the computer and to the uppermost USB connector (Type B) on the back of the analyzer.
5. Turn on the analyzer.
6. Go to **Applications > System Preferences > Network** to enable the virtual communications port. Click **OK**.



7. Select **Network Port Configurations** from the **Show** list.
8. Check the **On** box for the new port, then click **Apply Now**.



9. As needed, configure the computer's applications to communicate with the analyzer using the new virtual communication port.

## 10.5 Capturing Results with HyperTerminal

### 10.5.1 Setting Up HyperTerminal

This section describes how to set up and use Windows HyperTerminal to capture and transmit analyzer test results.

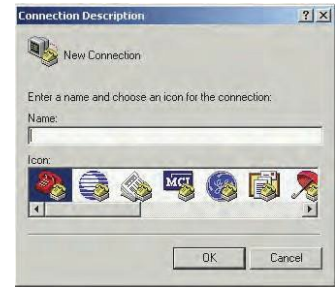
*Note:* The screen captures and menu configurations shown here may vary depending on your version of Windows.

1. From the Windows desktop, click **Start > Programs > Accessories > Communications > HyperTerminal > HyperTrm.exe** to start the HyperTerminal setup wizard.



*Note:* If HyperTerminal is not present, install it by going to **Start > Settings > Control Panel > Add/Remove Programs (Add/Remove Windows Components > Communications tab)**. Consult Windows help for details.

2. Type a descriptive name (such as Abaxis) for the connection, then click **OK**.



3. Use the **Connect using** menu to select the port that the analyzer is connected to, which was recorded previously (see page 10-7), then click **OK**. The other settings are not required.

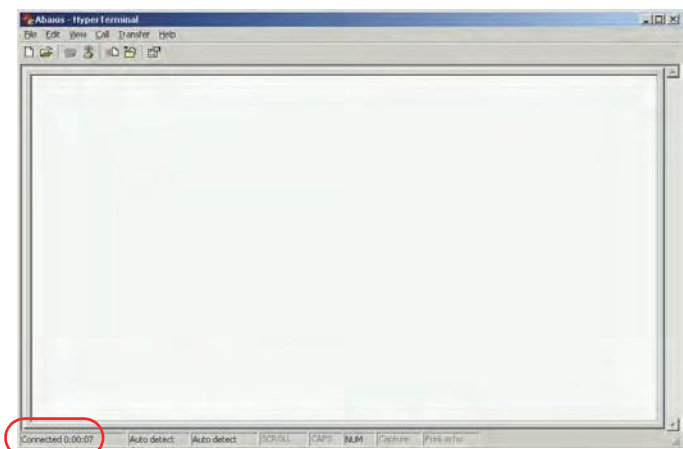


**Note:** *If the port is unknown, select any port. If needed, run the wizard again to try other ports.*

4. In the port's Properties dialog, change **Bits per second** to **9600**, then click **OK**.



5. If a valid port was selected, a new HyperTerminal session will start. The status pane on the lower left corner of the window should display **Connected** as shown.

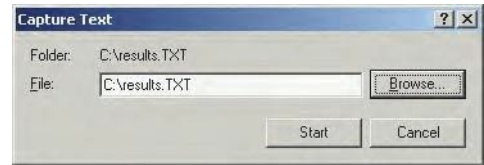


**Note:** *If an error message appears, close HyperTerminal **without** saving changes. Run the HyperTerminal setup wizard again, and choose a different port.*

6. Click **File > Save As** on the menu to save the HyperTerminal session. Note where the session file is saved so that it can be loaded in the future (create a shortcut on the desktop if necessary). Proceed to the next section for instructions on capturing results.

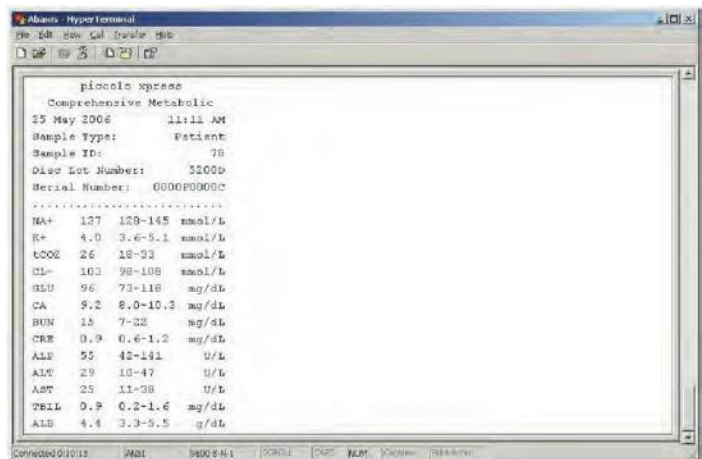
## 10.5.2 Running HyperTerminal

1. Prepare HyperTerminal to capture results by loading a saved session file or by creating a new session file as described in “Capturing Results with HyperTerminal” on page 10-9.
2. Click **Transfer > Capture Text** on the menu. Select or type in a path and file name, then click **Start**.



Any results transmitted to the computer from this point forward will be captured in the designated text file.

3. Transmit results to the computer following the instructions in “Transmitting All Results” on page 5-9. The results will appear in the HyperTerminal window, as shown in this example. In addition, the results can be manually copied and pasted into other applications by highlighting the results and using the **Edit** menu.



**Note:** *If the results do not appear in the HyperTerminal window, an incorrect port may have been selected in setup. Repeat the setup and select a different port as described in “Capturing Results with HyperTerminal” on page 10-9.*

4. After the results are transmitted, select **Transfer > Capture Text > Stop** in the menu. The captured text file can be used by most word processing, spreadsheet, and database applications.
5. Close HyperTerminal by selecting **File > Exit** in the menu.