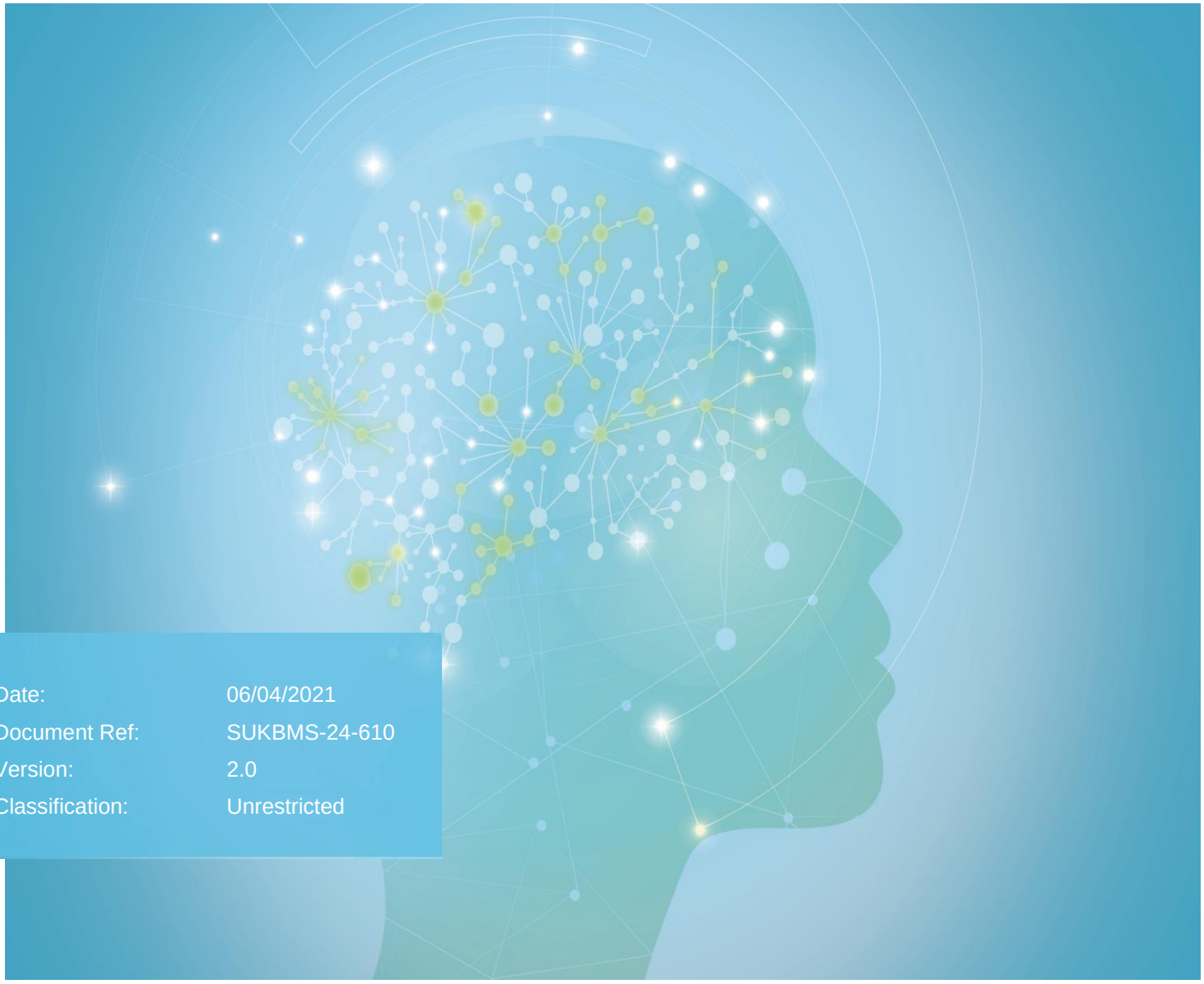
Routine Use Training Workbook

Piccolo Xpress



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Disclaimer

Please note, the information contained in training resources provided by Sysmex should not be used as an alternative to your sites Standard Operating Procedure (SOP)/Contract. If you have any particular questions regarding any site specific use of reagents, consumables and/or equipment please contact your Management Team.

Revision History

Revised Section	Alteration	Name	Date
All sections	New document	E. Jones	April 2021
Contact Us	Title update	K. Elgerton	August 2022

Reference Documents

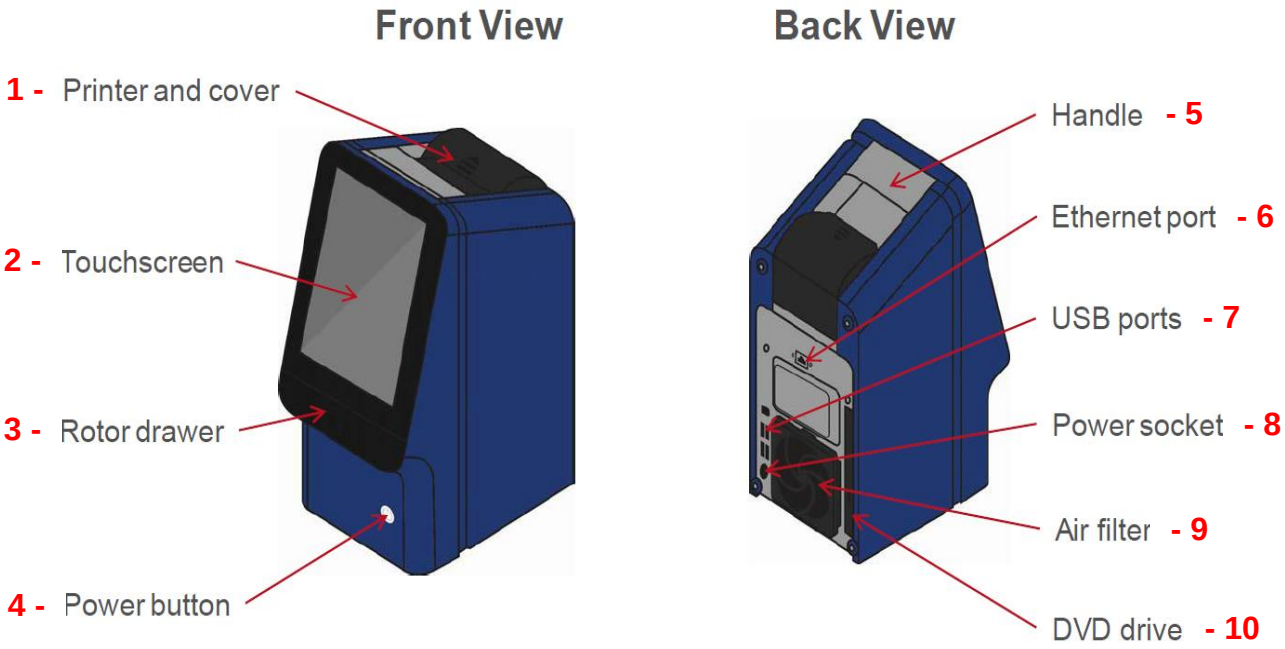
Document title	Version	Date
Piccolo Xpress chemistry analyzer Operator's Manual	09/2018	23.04.21
Piccolo Xpress Quick Reference Guide	1100-7109-1E Rev.D	23.04.21
Sample and Disc Handling	04.02.20	23.04.21
Operating the Piccolo Xpress	100 7178 Rev. B	23.04.21

Explanation of Symbols

Symbol	Explanation
	**Risk of infection –** Always be aware of the dangers of infection, use caution and take appropriate measures.
	**Risk of Injury –** Always be aware of the dangers of injury due to sharp objects, use caution and take appropriate measures.
	**Caution –** Potentially hazardous situation, use caution and take appropriate measures to avoid injury or harm.

Analyer Components

Outside the Piccolo Xpress



1. **Printer and cover -** The printer will provide basic printouts. Option to turn printer off if preferred. Printing is thermal so not suitable for long term storage.
2. **LCD Touchscreen -** The user interface displays the sample ID number, analysis results, instrument status, error messages and various other menus.
3. **Rotor drawer -** The rotor drawer is only accessible via the 'analyser' option on the home screen.
4. **Power button –** Press the button to turn the analyser on/off. The Power button works only when the disc drawer is closed and contains no reagent disc.
5. **Handle –** To carry/move the analyser.
6. **Ethernet Port –** To enable the analyser's connection to a LIS.
7. **USB Port –** To enable data to be sent to an external printer, computer or USB.
8. **Power Socket –** To enable the analyser's connection to UPS/power supply.
9. **Air Filter –** Air filter should be unclipped and cleaned once every 6 months as per maintenance advice.
10. **DVD Drive –** To insert a disc for software updates.

Reagents

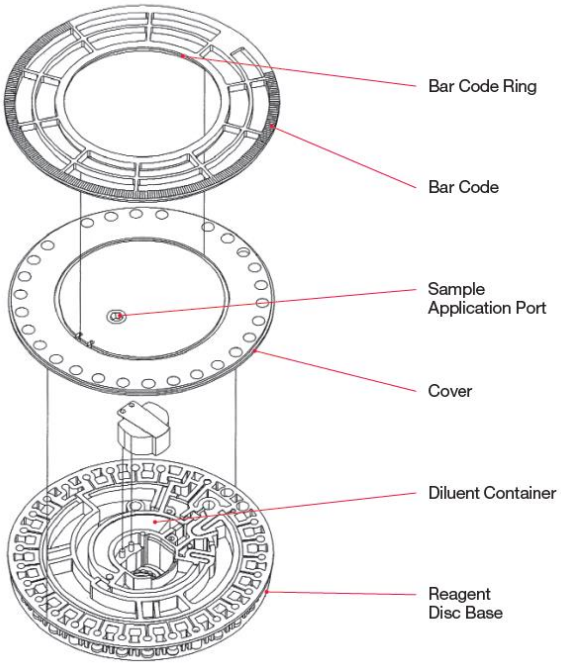
The Piccolo Xpress utilises 17 types of single use reagent disc, providing up to 14 tests per disc. The table below summarises the reagent discs and parameters produced.

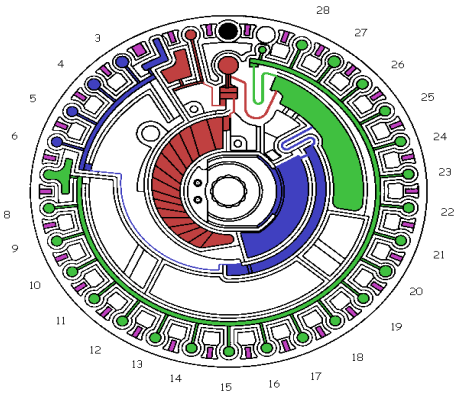
Name of reagent disc	Parameters produced
AmLyte13	ALB, ALT, AMY, AST, BUN, Ca, CK, CRE, CRP, eGFR*, GLU, K+, Na+, TBIL
Comprehensive Metabolic Panel	ALB, ALP, ALT, AST, BUN, Ca, Cl-, CRE, eGFR*, GLU, K+, Na+, TBIL, tCO^2, TP
Basic Metabolic Panel	BUN, Ca, Cl-, CRE, eGFR*, GLU, K+, Na+, tCO^2
Lipid Panel	CHOL, CHOL/HDL*, HDL, LDL*, nHDLc*, TRIG, VLDL*
Lipid Panel Plus	ALT, AST, CHOL, CHOL/HDL*, GLU, HDL, LDL*, nHDLc*, TRIG, VLDL*
Liver Panel Plus	ALB, ALP, ALT, AMY, AST, GGT, TBIL, TP
Electrolyte Panel	Cl-, K+, Na+, tCO^2
General Chemistry 13	ALB, ALP, ALT, AMY, AST, BUN, Ca, CRE, eGFR*, GGT, GLU, TBIL, TP, UA
General Chemistry 6	ALT, AST, BUN, CRE, eGFR*, GGT, GLU
Renal Function Panel	ALB, BUN, Ca, Cl-, CRE, eGFR*, GLU, K+, Na+, Phos, tCO^2
MetLyte 8	BUN, CK, Cl-, CRE, eGFR*, GLU, K+, Na+, tCO^2
Kidney Check	BUN, CRE, eGFR*
Hepatic Function Panel	ALB, ALP, ALT, AST, DBIL, TBIL, TP
Basic Metabolic Panel Plus	BUN, Ca, Cl-, CRE, eGFR*, GLU, K+, LDH, Mg, Na+, tCO^2
MetLyte Plus CRP	BUN, CK, Cl-, CRE, CRP, eGFR*, GLU, K+, Na+, tCO^2
BioChemistry Panel Plus	ALB, ALP, ALT, AMY, AST, BUN, Ca, CRE, CRP, eGFR*, GGT, GLU, TP, UA
MetLac 12	ALB, BUN, Ca, Cl-, CRE, eGFR*, GLU, K+, LAC, Mg, Na+, Phos, tCO^2

*calculated value

A total of 30 cuvettes are located around the periphery of the reagent disc:

- 4 cuvettes contain QC reagent beads for instrument and chemistry quality control
- 1 minimum and 1 maximum absorbance cuvette are used for calibration
- 1 cuvette is specially designed to detect whether the sample volume was sufficient
- 1 cuvette verifies that sufficient diluted sample was delivered to the reaction cuvettes
- 1 empty cuvette captures excess fluids
- 21 cuvettes contain test-specific lyophilized reagent beads





Disposal/handling of the reagent disc

After the reagent disc is removed from the Piccolo Xpress it is considered to be clinical waste and Should be disposed of as per local guidelines for clinical waste removal.

********When changing the reagent disc please wear protective gloves/clothing. The used reagent disc is considered to be clinical waste and should be treated as such. ********

Principles of Analysis and Parameter Production

Spectrophotometry

Chemical reactions occur between reagent beads, the diluent contained in the reagent disc, and the added sample. These reactions produce chromophores that are measured photometrically by the Piccolo Xpress.

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 cuvette contents and the remainder travels through two apertures and is then collimated 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.

Calculation of parameters

Calculation of absorbance

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

$I_{\lambda 10}$ = Intensity of light transmitted through the dark cuvette at wavelength 1

$I_{\lambda 20}$ = 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.

Calculation of rate of reaction

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:

$\Delta A/\Delta T$ = 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

T = Time in minutes

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

Calculation of 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 (Iλ1SC, Iλ2SC) 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

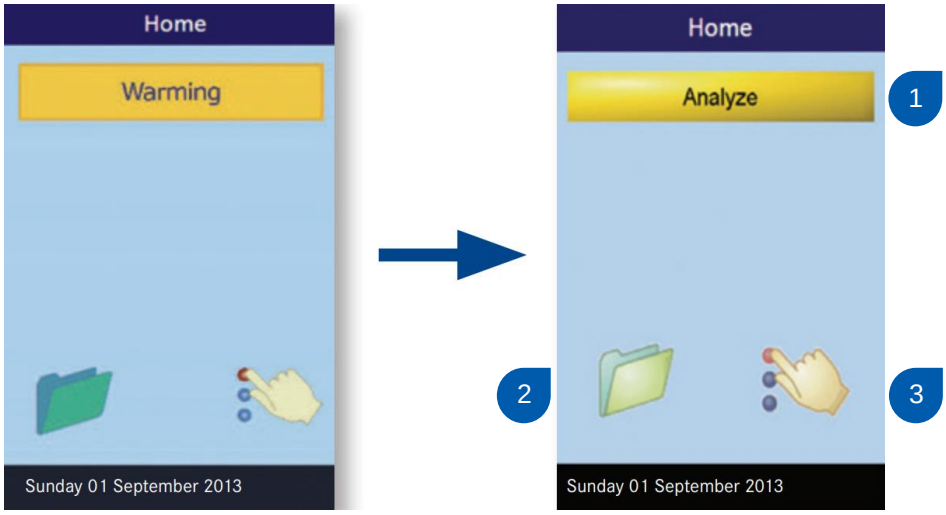
$I_{\lambda XX}$ = Other intensities as described above

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

Quick Guides

Home screen

Upon start up the Piccolo Xpress will default to the main Home Screen. After passing the self-test and reaching operating temperature, the analyser is ready to run the first reagent disc, and displays Analyze.



1 Option to analyse sample

2 Access to recall folder

3 Access to settings

The settings and recall key will allow access to other screens. When the settings key has been selected, the analyser settings screen will appear. From here, you can view basic information about the analyser as well as adjust the:

- date and time
- language
- sound
- display
- printer

Upon selecting the recall folder you will have the option to recall results via ID or date, to then print or transmit these to a connected computer.

Selecting the ‘More Settings’ icon shown above, will open the second Analyser Settings screen. You can use the screen as a starting point to make additional settings, work with reference ranges, and update the analyser’s software.

Select ‘Home’ to return to the analyser’s Home screen at any time. When the screen is touched the instrument will emit a small ‘beep’ to show it has recognised your touch.

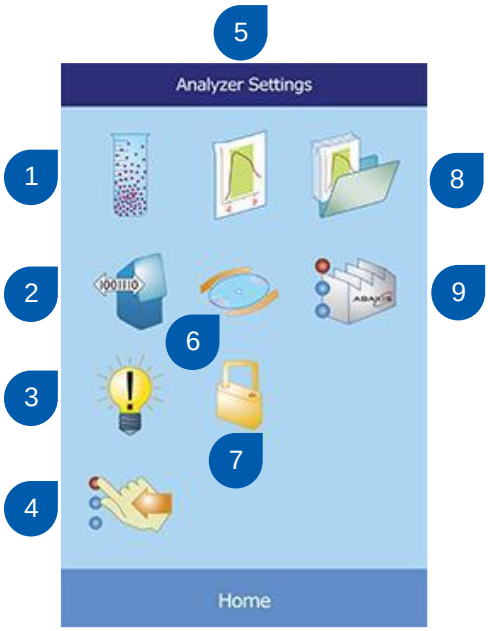
Settings screen

1	Analyser	4	Display	7	More Settings
2	Printer	5	Sound	8	Home
3	Date & Time	6	Language		

Key points of the settings screen

1. The [ANALYSER] key will display the analyser information including serial number and software version.
2. The [PRINTER] key will allow you to configure and set up the default printer, and will also allow you to edit the report and number of copies printed.
3. The [DATE & TIME] key will allow you to use the up and down arrow keys to change the date and time displayed on the analyser.
4. The [DISPLAY] key will allow you to adjust the brightness of the backlight and adjust the delay of the screen saver and power save options.
5. The [SOUND] key will allow you to adjust the volume of the sound produced from screen clicks, alerts and statuses.
6. The [LANGUAGE] key will allow you to select the display language and keyboard type.
7. The [MORE SETTINGS] key will open up a second settings screen, showing further keys for analyser functions.
8. The [HOME] key will return the operator to the HOME screen to process a sample.

More settings screen



1	Units	4	Return to ‘Settings’	7	Security
2	Communication Units	5	Reference Ranges	8	Archive Reference Ranges
3	Advanced	6	Software	9	Factory Settings

Key points of the more settings screen

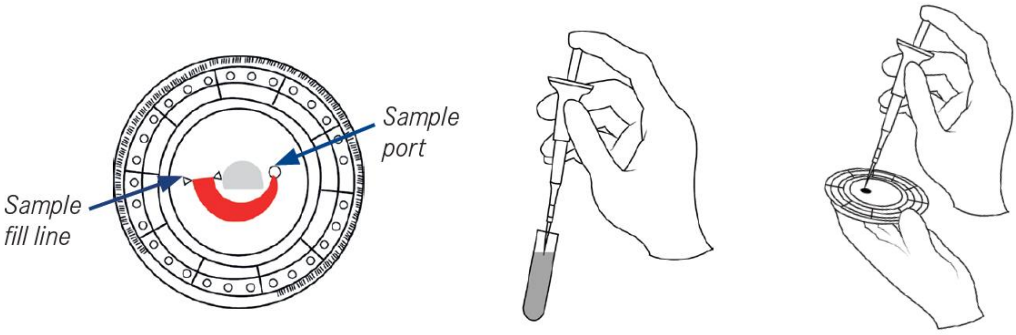
1. The [UNITS] key will allow you change the units used by the analyser when reporting results.
2. The [COMMUNICATION] key will allow you select the communication protocol to be used when transmitting results to an external computer.
3. The [ADVANCED] key will allow you change data entry and analyte options.
4. The [RETURN TO SETTINGS] key will allow you to return to the first settings page.
5. The [REFERENCE RANGES] key will allow you to customer reference ranges for analytes and demographics.
6. The [SOFTWARE] key will allow you to update the analyser’s software upon the provision of a supftware update disc by Zoetis.
7. The [SECURITY] key will allow you to enable various access levels for administrators, operators and controls.
8. The [ARCHIVE REFERENCE RANGES] key will allow you to print, archive and retrieve reference ranges.
9. The [FACTORY SETTINGS] key will allow you to return all settings to their original factory default values.

Sysmem ‘help’ function

When available, the above icon will appear for additional help and information.

Running a patient sample

For sample analysis, 100µl of sample is required for the analyser to function. Whole blood must be anticoagulated with lithium heparin prior to use, with venous samples highly recommended.



1. Take the reagent disc out of its pouch, before attaching a new tip to the end of the 100µl micropipette provided. Once opened, ensure that the disc is used within 10 minutes.
2. Using the micropipette, place the pipette tip at least halfway into the sample, ensuring the plunger is pushed all the way down to the base of micropipette before entering. Slowly release the pipette plunger to draw the sample up into the pipette tip.
3. Tilt the disc to 45° with the sample port above the fill line, so that the entire sample will flow into the sample chamber.
4. Place the pipette tip into the disc’s sample chamber and release the sample. Make sure to keep the pipette plunger pressed down until the pipette tip is removed from the sample port. Should the reagent disc require cleaning, 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.
5. Select ‘Analyze’ on the touchscreen to open the disc drawer and place the disc in the recessed area in the drawer.
6. Select ‘Close’ to close the disc drawer.
7. Enter the patient ID by selecting the ‘Patient’ key and typing in the ID number using the keypad displayed – select ‘Done’ to confirm. The analyser will check the disc type and will then start processing the sample.
8. Once the analyser has finished processing the sample, select ‘Open’ to open the disc drawer and discard the used reagent disc into a biohazard container.
9. To analyze another sample, insert a new reagent disc and repeat the above procedure or when finished, select ‘Close’ to close the disc drawer and to return to the home screen.

Maintenance

Cleaning the analyser

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

Cleaning the case

Clean the analyser with a soft cloth, dampened with a mild, non- abrasive detergent or cleaning solution, a 10% bleach solution, or a 30% isopropyl alcohol solution. Pre- soaked towelettes (isopropyl alcohol) may be used as an alternative. Do not spray or pour any detergents, solutions or other liquids directly onto the analyser. Dampen a soft cloth or disposable paper towel with the detergent, then apply to the analyser.

Cleaning the display

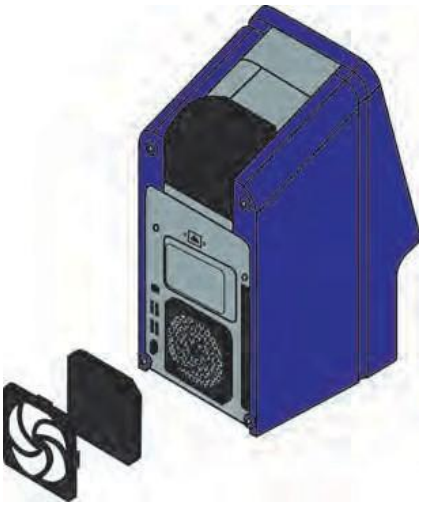
Clean the analyser's screen periodically using a soft, lint-free cloth dampened with a glass-cleaning fluid or window cleaner. The screen can be disinfected using a 10% bleach solution: apply the solution to a lint-free cloth, then wipe the screen.

Cleaning the air filter

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

To clean the air filter:

1. Unplug the analyser and remove the power cord from the back of the analyser.
2. Grasp the black mesh filter in the circular opening and remove it.
3. Wash the filter in warm soapy water and dry completely.
4. Place the clean, dry filter flat in the circular opening and push the sides of the filter behind the edges of the circular opening.
5. Plug the power cord into the back of the analyser.



Running quality control samples

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 indicated
- when test results do not match patient symptoms or clinical findings
- with each new lot (CLIA waived tests in waived status labs)

Handle the control as described in the control package insert.

1. Take the reagent disc out of its pouch, before attaching a new tip to the end of the 100µl micropipette provided.
2. Using the micropipette, place the pipette tip at least halfway into the sample, ensuring the plunger is pushed all the way down to the base of micropipette before entering. Slowly release the pipette plunger to draw the sample up into the pipette tip.
3. Tilt the disc to 45° with the sample port above the fill line, so that the entire sample will flow into the sample chamber.
4. Place the pipette tip into the disc's sample chamber and release the sample. Make sure to keep the pipette plunger pressed down until the pipette tip is removed from the sample port. Should the reagent disc require cleaning, 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.
5. Select 'Analyze' on the touchscreen to open the disc drawer and place the disc in the recessed area in the drawer. Select 'Close' to close the disc drawer.
6. Enter the sample ID by selecting the 'Control' key and typing in the ID number using the keypad displayed – select 'Done' to confirm. The analyser will check the disc type and will then start processing the sample.
7. When processing has finished, the analyser shows that the analysis is complete, and automatically prints the results of the analysis.
8. Select 'Open' to open the disc drawer and discard the used reagent disc into a biohazard container.

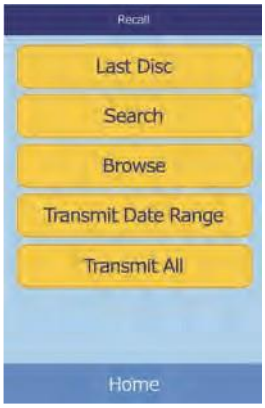
If the results do not print automatically, they can be recalled from the memory and printed.The analyser automatically stores control results in a memory separate from the patient results memory. The 'Recall' function can be used to search for specific control results.

*******Ensure the QC material is prepared and handled as per the package insert.*******

Checking quality control results

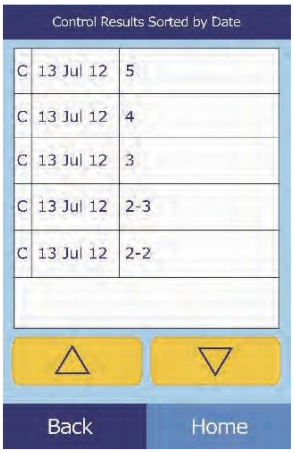
Following sample analysis, the results will be automically printed. To review older results, use the Recall function to search for a particular record according to its control ID number or date, or to view a list of all saved control results sorted by date.

1. In the Home screen, select the Recall icon. 
2. Select ‘Search’.

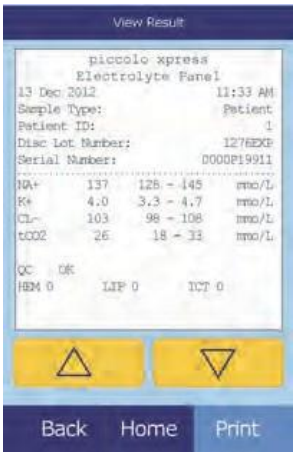


3. In the Search screen, control results can be displayed according to ‘control ID’, or can be searched for by selecting ‘Controls’ and entering the date that the control was performed. Selecting “Date” will display all control and patient samples run on that date.

4. The analyser then displays a list of control results (C) and errors (E), in reverse chronological order from the date entered.



5. Use the up and down arrow keys to scroll through the list.
6. Select the results to display.

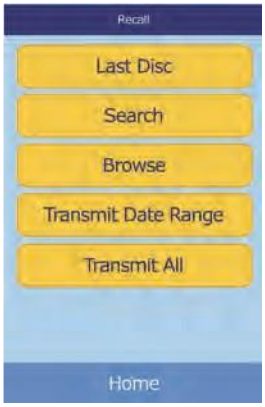


7. Use the up and down arrow keys to scroll through the results.
8. To print these results or transmit them to an external computer, select Print:
   a. Select Print or Transmit.
   b. Select the report: All, Results, iQC, or Error Report.
9. The display then shows ‘Sending Report...’ while the report or results are being printed or transmitted.

Checking sample results

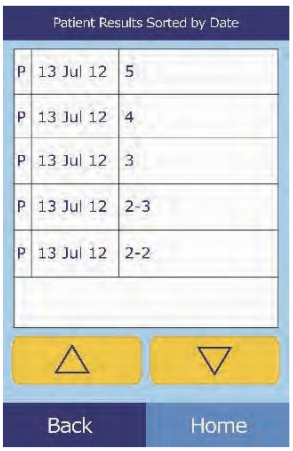
Following sample analysis, the results will be automically printed. To review older results, use the Recall function to search for a particular record according to its patient ID number or date, or to view a list of all saved patient results sorted by date.

1. In the Home screen, select the Recall icon. 
2. Select ‘Search’.

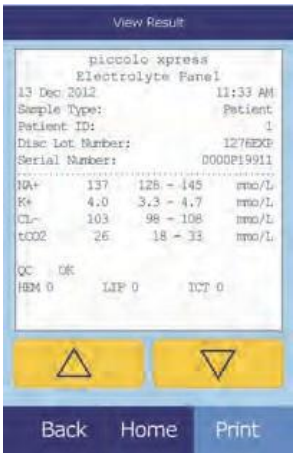


3. In the Search screen, sample results can be displayed according to ‘patient ID’, or can be searched for by selecting ‘Patients’ and entering the date that the sample was ran. Selecting “Date” will display all control and patient samples run on that date.

4. The analyser then displays a list of patient results (P) and errors (E), in reverse chronological order from the date entered.



5. Use the up and down arrow keys to scroll through the list.
6. Select the results to display.

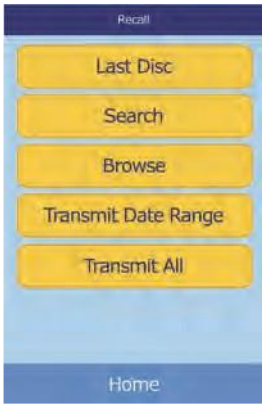


7. Use the up and down arrow keys to scroll through the results.
8. To print these results or transmit them to an external computer, select Print:
   a. Select Print or Transmit.
   b. Select the report: All, Results, iQC, or Error Report.
9. The display then shows ‘Sending Report...’ while the report or results are being printed or transmitted.

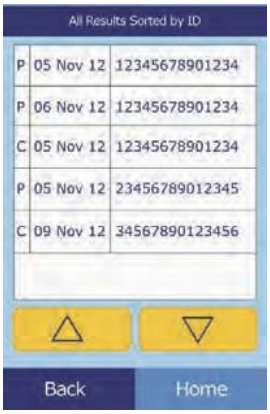
Browsing Results

Use the Recall function to browse through all stored results.

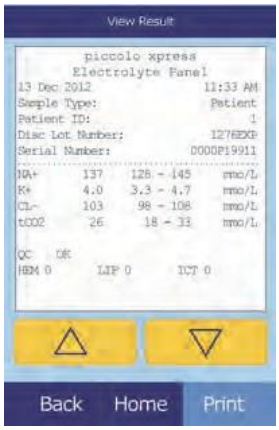
1. In the Home screen, select the Recall  icon.
2. Select Browse.



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



4. Use the up and down arrow keys to scroll through the list.
5. Select the results to display.



6. Use the up and down arrow keys to scroll through the results.
7. 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.
8. The display then shows ‘Sending Report...’ while the report or results are being printed or transmitted.

Understanding flags

The Piccolo Xpress performs a series of internal quality checks to ensure accurate results. When the analyser detects a problem, it either suppresses certain chemistry results (in which case it prints troubleshooting “flags” in place of values), or cancels the run (the disc cancels and no results are printed).

When either of these occurs, you can print or transmit an error report. The following table explains the symbols that may appear on the results printout.

Symbols printed next to the result		
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. 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 “Results” on page 3-11 of the Abaxis Piccolo Xpress Operators Manual.
HEM	Hemolysis interference	
LIP	Lipemia interference	
ICT	Icterus interference	

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