Document Name	**Piccolo Quick User Guide**
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Document Release Date	V4 of 25-Nov-2021

Version No	Version date	Brief description of changes included in new version
1	01-July-2021	NA – initial version
2	20-August-2021	• Use of 1ml blood collection bottles removed • Indication of how much blood to collect into 0.5ml bottles • Inclusion of 0.5ml bottle image • Instruction to run second panel immediately after first panel • Inclusion of Karisma Trial number in the header • Addition of coding for patient ID information
3	05-October-2021	• All instances of the term **rotor** replaced by the term **reagent disk**
4	25-November-2021	• Update to web address

Piccolo Quick Reference Guide

V4 of 25.11.2021

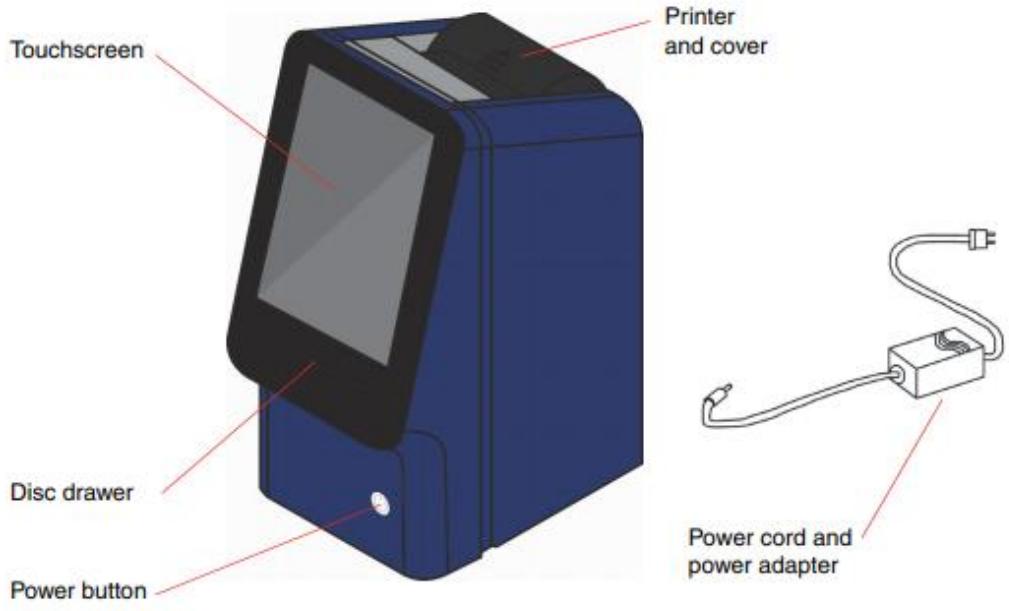
This document is a quick reference guide. For more comprehensive information please refer to the Piccolo Operator's Manual on https://fs10.formsite.com/LMMdv0/karisma/index.html

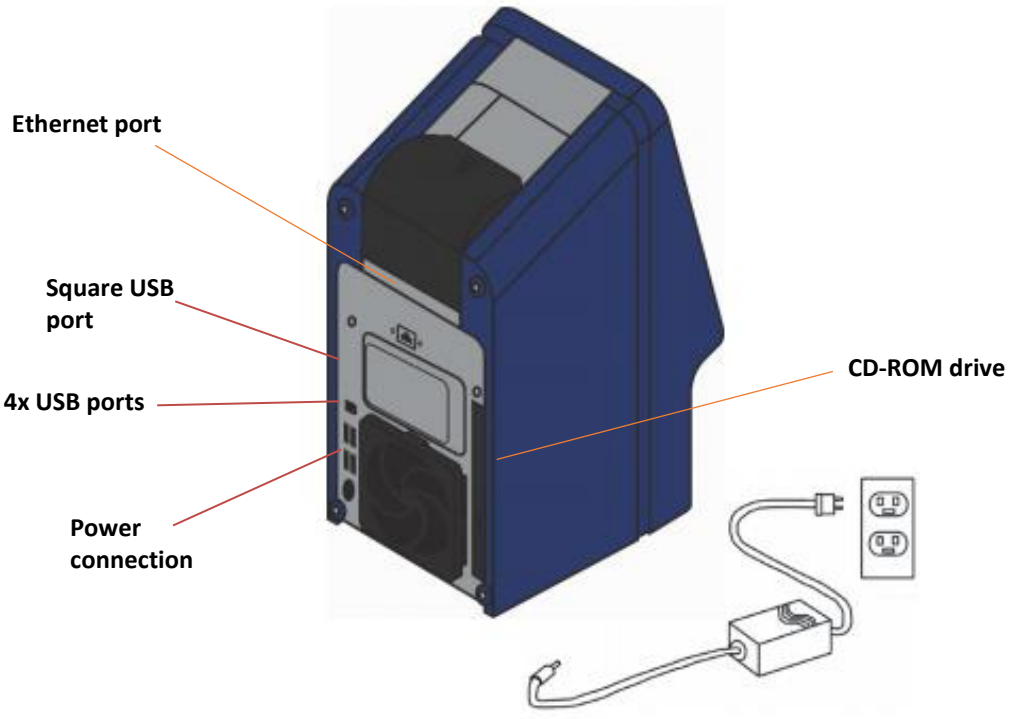
Quick Reference Guide Contents

Please read through the Quick User guide before using the Piccolo

This document is a quick reference guide. For more comprehensive information please refer to the Piccolo Operator's Manual on https://fs10.formsite.com/LMMdv0/karisma/index.html

External features of the Piccolo



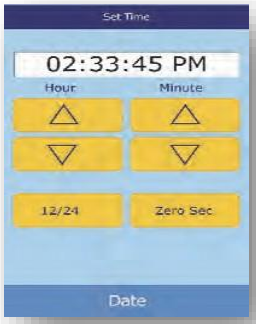


Setting up the Piccolo

1. Place the Piccolo on a level surface that is free from hair,dust and other contaminants. Do not place the analyser near a sunny window or other heat source. Make sure the analyser is 20cm from any wall to provide adequate ventilation.
2. Connect the Piccolo power adaptor to the mains power and the power connection on the back of the analyser.
3. Refer to the 'Connecting Analysers to POCcelerator' document to connect Piccolo via ethernet.
4. Turn on the Piccolo by pushing the button on the front of the analyser.
5. Perform a QC test (refer to page 5-7 on how to run a QC) before testing patient samples.

Please Note: The Piccolo will be set up with the correct settings for the study before shipping. The below points should only be adjusted if the settings have been changed at the clinic.

1. Unwrap the paper roll and place in the printer so that the paper unrolls from the bottom towards the front of the analyser. Make sure a few centimeters of the paper extends out of the printer slot. Close the printer cover.
2. Push the power button on the front of the analyser to switch on. The analyser will warm up and perform an iQC.
3. Once the analyser has passed the self test and is ready to run a test, the date and time can be adjusted.
4. In the Home screen, select the Settings icon 
5. Select the Date and Time icon 
6. Use the up and down arrow keys to adjust the hour and minutes.
7. Select 12/24 to switch between 12- and 24-hour time formats.
8. Select Zero Sec to set the seconds to zero.
9. Select Date to save.
10. In the Set Date screen, use the up and down arrow keys to adjust the day, month, and year.
11. Select Done to save.
12. Select-  ensure the communication setting is set to ASTM 1394-97



Warning – To avoid scratching the screen do not use sharp or hard objects to touch the screen

How to Reconstitute a Biochemistry Control Vial

Why Run a Quality Control (QC)?

-To assess the quality and performance of the practice laboratory.
-To ensure that results generated by the Piccolo are correct.
-QC monitors staff, equipment, reagents and result reporting.

QC Storage:

Store at 2-8ºC before and after reconstitution. QC should be stored in a fridge with continuous temperature monitoring conditions with data recording for access later

QC testing frequency:

QC should be tested once a month (Level 1).

Preparing the QC reagent

1. Remove serum and diluent vials from the refrigerator and allow to warm at room temperature for 5 minutes

2. Carefully open and remove the bung from a vial of serum and a vial of serum diluent.
3. Attach a new pipette tip to the 1mL pipette, push down the plunger and insert the pipette tip into the diluent vial. Carefully release the plunger to draw up the diluent and remove pipette from vial.

4. Put the diluent filled pipette tip into the serum vial. Push down plunger to pipette 1mL of diluent into the serum vial.
5. Close the serum vial, gently invert 10 times -Do NOT shake. Let the vial stand on bench for 30 minutes at room temperature.

6. Ensure the contents are completely dissolved by swirling gently. Do NOT shake.

7. The control is now reconstituted and ready to be analysed

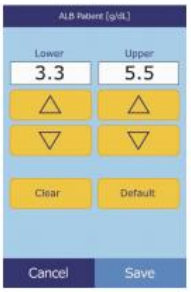
QC Stability:

Reconstituted QC is stable for 8hours at room temperature. Open vial reconstituted stability is up to 7 days if stored at 2-8ºC.

Running a Quality Control

Setting up the Control Values in the Piccolo- NB: the QC ranges will be installed before shipping. Please amend them if QC lot number changes during the study**.**

1. Select the settings icon  then next page.
2. Select Reference range icon  - All- Demographic- Control
3. Select the parameter, then lower or upper. Use the up and down arrows to modify the ranges according to the RANDOX QC data sheet supplied with the QC.
4. Press Save to store changes
5. Repeat steps 2-4 for the other parameters.
6. Go back to the home page once completed.



Testing the QC

1. Gently invert the QC 10times before testing. Do NOT shake the sample.
2. Attach a new pipette tip to the end of the 100µl pipette provided. Do not touch the end of the tip.
3. Using your thumb push down the plunger on the top of the pipette to the stop position.
4. Immerse the pipette tip below the surface of the QC.
5. Slowly release the plunger to draw up the QC, avoid drawing in any air, as this will cause the reagent disk to fail.
6. Remove the pipette from the QC sample.
7. Insert the pipette tip into the sample port indicated by an arrow on the reagent disk. The pipette tip should make contact with the bottom of the sample chamber.
8. Keep the reagent disk level and the pipette tip perpendicular to the surface of the reagent disk.
9. Gently push down the plunger at the top of the pipette to the stop position. All of the QC should have been expelled into the sample chamber. Keeping the plunger held down, gently remove the pipette tip from the sample port. The plunger may now be released, remove the disposable tip from the pipette and discard the tip.
10. Analysis should begin immediately (not more than 10minutes) after dispensing the QC into the reagent disk.
11. Press Analyse on the main screen and place the reagent disk in the drawer
12. Press Close
13. Select Control and enter the lot number of the QC in use.
14. When the QC analysis has completed, the system will store the QC results, print out on the built-in thermal printer (store print out in a file) and automatically transfer via the POCcelerator system.
15. Upload QC results to https://fs10.formsite.com/LMMdv0/karisma/index.html Check that the QC values are within range according to the Piccolo QC data sheet for the lot number in use.
16. Select OPEN to open the drawer and remove the used reagent disk, the reagent disk can be disposed in a clinical waste bin.

Please refer to page 14 for instructions on what to do if the QC is out of range

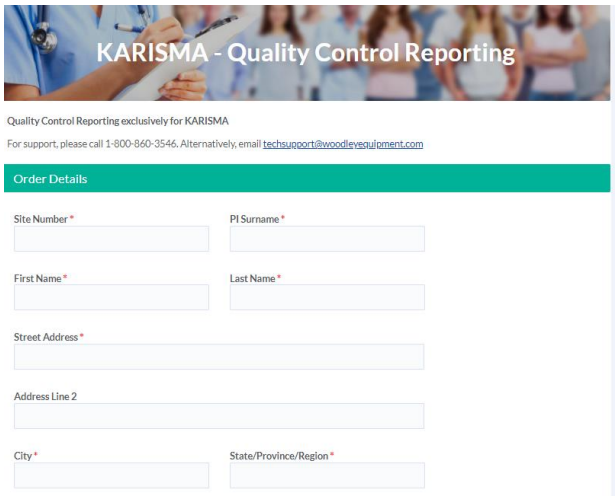
Uploading QC results to KAE609B12201 (KARISMA) website

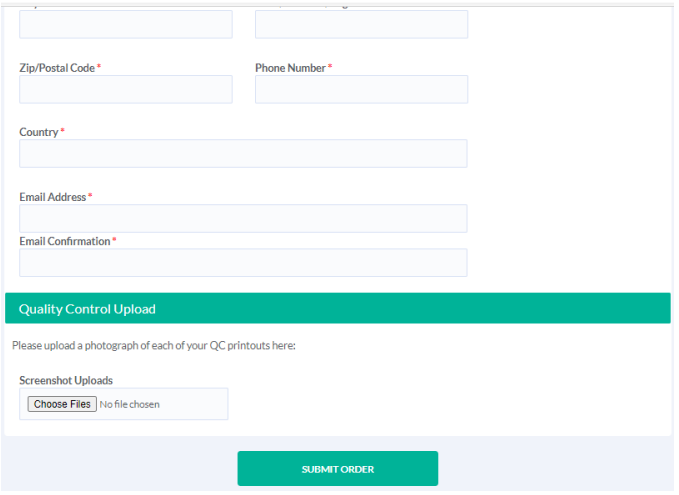
1. Follow the link to: https://fs10.formsite.com/LMMdv0/karisma/index.html

2. Input all information into all fields.

3. Using a mobile phone, take a photo of the QC print out

4. Upload photo using the 'Choose File' option. Once the photo is selected and all fields have been filled with the correct information. Press 'Submit QC'





If QC is within the Piccolo QC reference range, patient testing can continue.

If QC is out of range, refer to the Troubleshooting on page 14, if unsure upload results to KAE609B12201 (KARISMA) website https://fs10.formsite.com/LMMdv0/karisma/index.html and wait for further assistance from Technical Support. Do NOT run any further patient tests if QC is out of range.

Testing a Patient Sample

Sample Preparation

Required sample type:

- MiniCollect® Tube 0.5 ml LH Lithium Heparin green cap- Can be used for either **finger prick** blood collection or **venous** blood collection

- Refer to below documents on how to take a patient sample (these documents can also be found on https://fs10.formsite.com/LMMdv0/karisma/index.html

Blood Collection Manual.pdf

Blood collection Preanalytics Manual.p

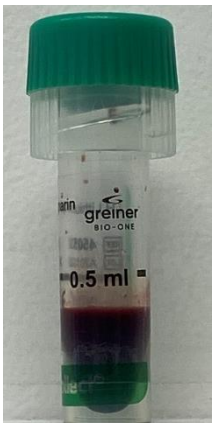
Volume Required:

- The system uses 100µl of whole blood per test panel – for the KARISMA trial there are 2 different Panel Reagent disks, Metlac 12 and Hepatic panel. The following procedure will describe how to run either of the reagent disks. The reagent disks can be processed in any order but please run the second reagent disk as soon as possible after the results of the first reagent disk are printed.

- **Testing must be conducted within 60 minutes of collecting the sample into the Minicollect 0.5ml LH Lithium Heparin tube at room temperature**

- To prevent haemolysis of the sample, do not refrigerate, freeze, or shake whole-blood sample.

- The MiniCollect® Tube 0.5 ml LH Lithium Heparin can hold 0.5ml blood but please only fill approximately half-way i.e between 0.20ml to 0.25ml to ensure that we stay within the maximum blood collected from patients per protocol (see image below).



Preparing the Reagent Disk

Reagent disks should be stored at 2-8ºC (store in a fridge with continuous temperature monitoring conditions with data recording for access later) and can be used straight from the refrigerator without the need for warming - Avoid placing unopened reagent disks in temperatures greater than 25ºC (77ºF) for more than 48 hours. Opened reagent disks must be used within 20minutes.

1. Before using a reagent disk, carefully check the foil pouch for any damage. Tear open the package from the upper right side of the pouch.

2. Remove the reagent disk gently with finger and thumb from the foil pouch.
3. After removal use your other hand to hold the reagent disk by the edge. **Avoid contact with reagent disk surface where optical measurement takes place.**
4. Check the reagent disk for any damage – do not use reagent disks that have been dropped or damaged.
5. After opening the pouch, the reagent disk **must be used within 20 minutes**. **Do not place the reagent disk back in the refrigerator for later use**.

Adding the sample to the reagent disk

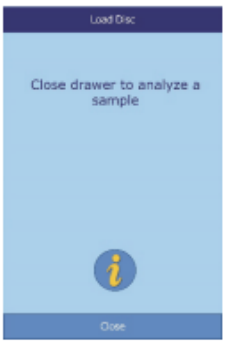
1. Gently invert the Lithium Heparinised whole blood sample 10 times. Do NOT shake the whole blood sample.
2. Attach a new pipette tip to the end of the 100µl pipette provided. Do not touch the end of the tip.
3. Using your thumb push down the plunger on the top of the pipette to the stop position.
4. Immerse the pipette tip below the surface of the sample.
5. Slowly release the plunger to draw up the sample, avoid drawing in any air, as this will cause the reagent disk to fail.
6. Remove the pipette from the sample tube.

7. Insert the pipette tip into the sample port indicated by an arrow on the reagent disk. The pipette tip should make contact with the bottom of the sample chamber.
8. Keep the reagent disk level and the pipette tip perpendicular to the surface of the reagent disk.
9. Gently push down the plunger at the top of the pipette to the stop position. All of the sample should have been expelled into the sample chamber. Keeping the plunger held down, gently remove the pipette tip from the sample port. The plunger may now be released, remove the disposable tip from the pipette and discard the tip.
10. Analysis should begin immediately (not more than 10minutes) after dispensing the sample into the reagent disk.

Starting Analysis with first panel –

Use either Metlac 12 or Hepatic panel, it is not important which panel is used first.

11. Press the **Analyse** icon on the touch screen to open the drawer at the front of the Piccolo.



12. Hold a reagent disc that contains a sample by its edge, with the barcode side facing up and the disc kept level. Avoid touching the surface of the reagent disc. Gently place the disc into the recessed area in the drawer and press **CLOSE** to close the disc drawer.

13. Use the touch screen to select Patient, enter the patient's gender, age, DOB, race and enter the Patient ID, see below and also on the label found on the side of the analyser.

Coding for Patient ID

When testing patient bloods on the Piccolo, each patient should be identified using a designated code. Please use the designated codes below when entering Participant information:

Naming format for the 14-digit subject ID that will be manually entered in the device at site:

sssspppDxxHyyy

- first 4 digits (ssss) are the site number as assigned by the Sponsor
- following 3 digits (ppp) are the patient number…001, 002, 003 etc
  (numerical exception applies to dummy visits where the patient number will be 'dum')
- following 3 digits (Dxx) are the visit day as per protocol. Always a 'D' followed by 2 numerical digits...01, 02, 03, 04, 06, 08, 15, 22 and 29
  (numerical exception applies to the dummy visit 'Ddu', screening visit 'Dsc' and unscheduled visit 'Dun')
- following 4 digits (Hyyy) are the visit time post-dose as per protocol. Always a 'H' followed by 3 numerical digits...006, 012, 018, 024, 030, 036, 042, 048, 072, 120, 168, 336, 504 and 672
  (numerical exception applies to the dummy visit 'Hdum', screening visit 'Hscr' and unscheduled visit 'Huns')

Below is a summary and examples.

Dummy Visit	Screening Visit	FV as per protocol	LV as per protocol	Unscheduled visits
1002dumDduHdum	1002001DscHscr	1002001D01H006	1002001D29H672	1002001DunHuns
- Site Number = 1002	- Site Number = 1002	- Site Number = 1002	- Site Number = 1002	- Site Number = 1002
- Patient Number = dum	- Patient Number = 001	- Patient Number = 001	- Patient Number = 001	- Patient Number = 001
- Visit Name = Ddu	- Visit Name = Dsc	- Visit Name = D01	- Visit Name = D29	- Visit Name = Dun
- Time Point Name = Hdum	- Time Point Name = Hscr	- Time Point Name = H006	- Time Point Name = H672	- Time Point Name = Huns

14. The fully automated analysis will now commence. The analysis time is 12minutes for whole blood.

15. When the analysis is completed, the system will store the test results, print out on the built-in thermal printer (store print out in a file) and automatically transfer via the POCcelerator system.

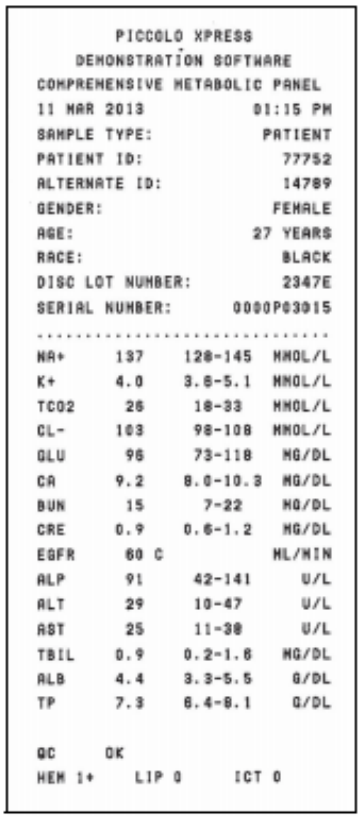
16. Select OPEN to open the drawer and remove the used reagent disk, the reagent disk can be disposed in a clinical waste bin.

Starting Analysis with the Second Panel Type-

17. Now initiate the testing of the second panel type **as soon as possible** after results of the first panel have printed, follow the same procedure starting from point 1 above. Ensuring that the sample is fully mixed again.

To cancel a test in progress, press the CANCEL icon on the screen, the system will prompt for confirmation. **A reagent reagent disk cannot be re used if a test has been cancelled.**

Interpreting Results



```
        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:       0000P03915
.............................
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    8.6-10.3  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
HEM 1+    LIP 0     ICT 0
```

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.

Extensive testing of the Piccolo Xpress chemistry analyzer has shown that in very rare instances, sample dispensed into the reagent reagent disk may not flow smoothly into the sample chamber, so that an inadequate amount of sample is analyzed. This can cause several results to unexpectedly fall outside the reference ranges: if this happens, repeat the test using a new reagent disk.

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

The symbols ~~~ are printed in place of numbers when a result cannot be determined — that is, when the result is suppressed. A result may be suppressed 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 prompts you 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 the message persists, the sample may be problematic.

HEM, LIP, or ICT is printed in place of the analyte concentration if haemolysis, lipemia, or icterus, respectively, has adversely affected the results. Examine the sample indices to determine if more than one interferent is affecting a particular result.

KAE609B12201- KARISMA Biochemistry Reference Ranges

Adult patients (18 years or older): reference ranges from Piccolo Analyser
Non-adult (less than 18 years): reference ranges from Nelson Textbook of Pediatrics, 21 Edition

Analyte Name	Units (SI)	Reference Interval		
		Age	Male	Female
ALP	U/L	1-9Yr	145 - 420	145-420
		10-11Yr	140 - 560	140 - 560
		12-13Yr	200 - 495	105 - 420
		14-15Yr	130 - 525	70 - 230
		16-17Yr	65 - 260	50 - 130
		Adult	53 - 128	42 - 141
ALT	U/L	1-11Month	12 - 45	12 - 45
		1 – 17Yr	5 - 45	5 - 45
		Adult	10 - 47	10 - 47
AST	U/L	1 – 11Month	22 - 63	22 - 63
		1 – 2Yr	20 - 60	20 - 60
		3 – 9Yr	15 - 50	15 - 50
		10 – 15Yr	10 - 40	10 - 40
		16 – 17Yr	15 - 45	5 - 30
		Adult	11 - 38	11 - 38
BILDIR***	umol/L	1month – 17Yr	0 – 5.1	0 – 5.1
		Adult	0 – 5.1	0 – 5.1
BILI	umol/L	1 month – 17Yr	<17	<17
		Adult	3.4 – 27.4	3.4 – 27.4
ALB	g/L	8 days – 11months	19 - 49	19 - 49
		1 – 3Yr	34 - 42	34 - 42
		4 – 17Yr	35 - 56	35 - 56
		Adult	33 - 55	33 - 55

Analyte Name	Units (SI)	Reference Interval		
		Age	Male	Female
CA	mmol/L	<18Yr	2.2 – 2.7	2.2 – 2.7
		Adult	2.0 – 2.58	2.0 – 2.58
CREAT	umol/L	0 – 3Yr	2.65 – 44.2	2.65 – 44.2
		4 – 6Yr	2.65 – 52.2	2.65 – 52.2
		7 – 9Yr	19.4 – 52.2	19.4 – 52.2
		10 – 13Yr	27.4 – 77.8	27.4 – 77.8
		14 – 17Yr	44.2 – 93.7	44.2 – 93.7
		Adult	53 - 106	53 - 106
GLUC	mmol/L	6months – 17Yr	3.3 – 5.5	3.3 – 5.5
		Adult	4.1 – 6.6	4.1 – 6.6
Lactate	mmol/L	1 – 11months	1.1 – 2.3	1.1 – 2.3
		1 – 6Yr	0.8 – 1.5	0.8 – 1.5
		7 – 15Yr	0.6 – 0.9	0.6 – 0.9
		16 – 17Yr	0.53 – 2.10	0.53 – 2.10
		Adult	0.53 – 2.10	0.53 – 2.10
K#	mmol/L	6 – 11 months	3.5 – 6.1	3.5 – 6.1
		1Yr – 17Yr	3.6 – 5.1	3.6 - 5.1
		Adult	3.6 – 5.1	3.6 – 5.1
SODIUM#	mmol/L	6month – 11Yrs	134 - 143	134 – 143
		12 – 17Yr	135 - 145	135 - 145
		Adult	128 - 145	128 – 145
BICARB	mmol/L	6month – 17Yr	22 - 29	22 – 29
		Adult	18 - 33	18 - 33
BUN**	mmol/L	6month – 11Yr	1.8 – 6.4	1.8 – 6.4
		12 – 17Yr	2.5 – 6.4	2.5 – 6.4
		Adult	2.5 – 7.9	2.5 – 7.9
eGFR	mL/min	Adult	>60	>60

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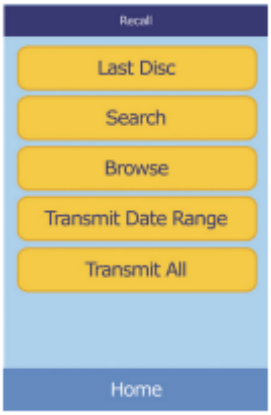
https://fs10.formsite.com/LMMdv0/karisma/index.html

Accessing Previous Results

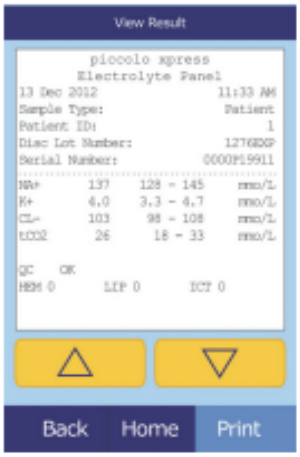
The Piccolo stores 5000 patient and control results in the memory. To access these stored results:

1. Press the recall icon  on the main menu
2. Results can be searched by the last reagent disk tested, filter by patient/control ID or date, browse all results stored or Transmit results from a specific date or transmit all results to POCcelerator.



3. Select the result to be displayed and use the up and down arrows to scroll through the list of parameters.

4. Press Print to reprint the selected patient/control result, iQC report, error report or all of these reports.



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Troubleshooting/FAQ

Reagent disk Errors

If the reagent disk cancels, record the following information or print an error report and contact Woodley Equipment Technical Support:

- Lot number
- Product name
- 4-digit error code
- Specimen type and sample

Instrument and Result Messages

The Piccolo Xpress chemistry analyser performs a series of internal quality checks to ensure accurate results. When the analyser detects a problem, the analyser 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.

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 and contact Woodley Equipment Technical Support to review the error report.

Disc Cancellation

In this situation, the display shows Run Cancelled 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 and contact Woodley Equipment Technical Support to review the error report.

Symbols on the result printout

Symbol	Meaning	Notes
*	The result is outside the reference range	An asterisk (*) is printed next to the analyte concentration if the results are outside of the range. * is also printed if the result is at the upper or lower limit of the range because results are rounded, these are considered out of range as well. For example, Na- 145* (128 – 145)
<	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 haemolysis might affect the results	
< and H	If < appears before and H after an LD result, haemolysis 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 reoccurs, results may fit patient profile clinically, or the sample may be problematic
N/C	Not calculated	

Symbols printed instead of results

Symbol	Meaning
~~	Chemistry interference
HEM	Haemolysis interference
LIP	Lipaemia interference
ICT	Icterus interference

Frequently Asked Questions

Q/ The reagent disk has been left out of the fridge, is this reagent disk ok to use?
A/ If the reagent disk has been stored in its foil pouch for no more than 48hours, it is ok to use. If the reagent disk has been out of temperature for longer than this period, do not use this reagent disk.
After the pouch has been opened, the reagent disk should be used within 20minutes.

Q/ Do I need to warm up the reagent disk before testing?
A/ No you do not need to warm up the reagent disk before testing, the reagent disks can be used straight from the fridge.

Q/ What are the power requirements to operate the analyser?
A/ The analyser requires 100-240 volts AC, 50-60 Hz

Q/ What do I do if one or more of the QC values are out of range?
A/ Check that the reagent disks and QC being used is in date and has been stored correctly, check that the lot number on the QC data sheet matches the lot number on the QC vial. Repeat the QC. If still out, make up a fresh vial of the QC and retest. Upload QC results to https://fs10.formsite.com/LMMdv0/karisma/index.html and wait for further assistance from Technical Support. Do NOT run any further patient tests.

Q/What do I do if some of the patient results look unexpectedly abnormal?
A/ Please repeat the test using a new reagent disk and double check the correct pipetting techniques are followed.

Q/What do I do if there is a power cut?
A/ If the Piccolo is in standby during the power cut, just switch the analyser back on and continue testing. If the Piccolo was running a test when the power cut out, start up the analyser again and use another reagent disk to run a test, when the drawer opens remove the previous reagent disk.

Q/ How do I order more consumables for the Piccolo?
A/. You can order consumables through the attached link
https://fs10.formsite.com/LMMdv0/karisma/index.html

Q/ What if I need technical support?
A/ Please contact Woodley Equipment Technical Support team at
karismatechsupport@woodleyequipment.com