piccolo xpress chemistry analyzer

Piccolo Xpress™ Operator training

YOUR CLINICAL TRIAL PARTNER FOR SMARTER EQUIPMENT SOLUTIONS

Woodley Trial Solutions is a Division of Woodley Equipment Company

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Training Objectives

The training will consist of the following items:

- **System Set-up and overview**
- **Reagent Storage and Handling**
- **Quality Control**
- **Participant Testing**
- **Maintenance**
- **Re-Supply**
- **Technical Support**

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Setting Up the Analyzer

Make sure that the Analyser is:

- **On a sturdy, level surface, free of vibration and sudden jolts.**
- **In an ambient operating temperature of 15–32 ºC (59–90 ºF).**
- **In an environment free of animal hair, dust, and other contaminants.**
- **Not placed near a sunny window or another heat source.**
- **At least six inches from the wall for access to the power connection and USB ports.**

Note: If the analyzer is subjected to an electrostatic discharge event, you may need to restart the unit. 2.

Plug the power jack into the analyzer, and 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 surge protector or battery backup for the analyzer. WARNING: USE ONLY THE PICCOLO POWER SUPPLY. ANY OTHER POWER SUPPLY WILL DAMAGE THE INSTRUMENT.

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The Karisma Clinical Trial will be using 2 Biochemistry Panels:

Hepatic Function Panel

Metlac 12 Panel

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Both types of Panel are used in exactly the same way and it does not matter which panel is tested first.

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All Piccolo Reagent Discs are individually packaged and sealed in foil pouches.

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They are shipped and stored refrigerated and can be used directly from the refrigerator.

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Upon shipment arrival you will be required to check the temperature of the Discs which should be cold or at room temperature.

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Disc storage and handling

• Store all reagent discs as described on their respective labels. When stored as described on their respective labels, all reagents in the disc are stable until the expiration date printed on the foil pouch and encoded on the bar code ring. The analyzer will reject an expired disc.

• A disc can be used directly from the refrigerator without warming.

• A disc can remain in its sealed pouch at room temperature for a cumulative period of 48 hours. Longer time at room temperature can cause suppression of chemistries and disc aborts.

• Do not expose discs, in or out of the foil pouches, to direct sunlight or to temperatures above 32° C (90° F). • Inspect the unopened foil pouch for tears and punctures. A torn or damaged pouch may allow moisture to reach the disc and adversely affect reagent performance.

• Open the disc pouch at the notch on the top right edge of the package. A disc must be used within 20 minutes of opening the pouch. Once the pouch is opened, do not place the disc back in the refrigerator for use at a later time.

• Discs are fragile. Handle with care. Do not tap the disc on the table or work bench to empty the sample port. Do not use a disc that has been dropped.

• Keep discs clean. Handle them only at the edges to avoid smudges on the optical surfaces. Use a lint-free tissue to remove blood from the disc surface.

• Write the patient identification number on the disc surface in the space indicated in the figure to the right (optional). Do not write anywhere else on the disc or on the bar code ring.

• Hold reagent discs flat after introducing the sample or control to avoid spillage.

• The used disc can be replaced in the pouch for disposal.

• BIOHAZARD: Used reagent discs contain body fluids. Follow good laboratory working practices. Handle all used discs as if they are contaminated with hepatitis or other infectious diseases.

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The Piccolo technology was originally developed for use in the Space Shuttle.

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Each self-contained reagent disc is single use. One patient, one disc.

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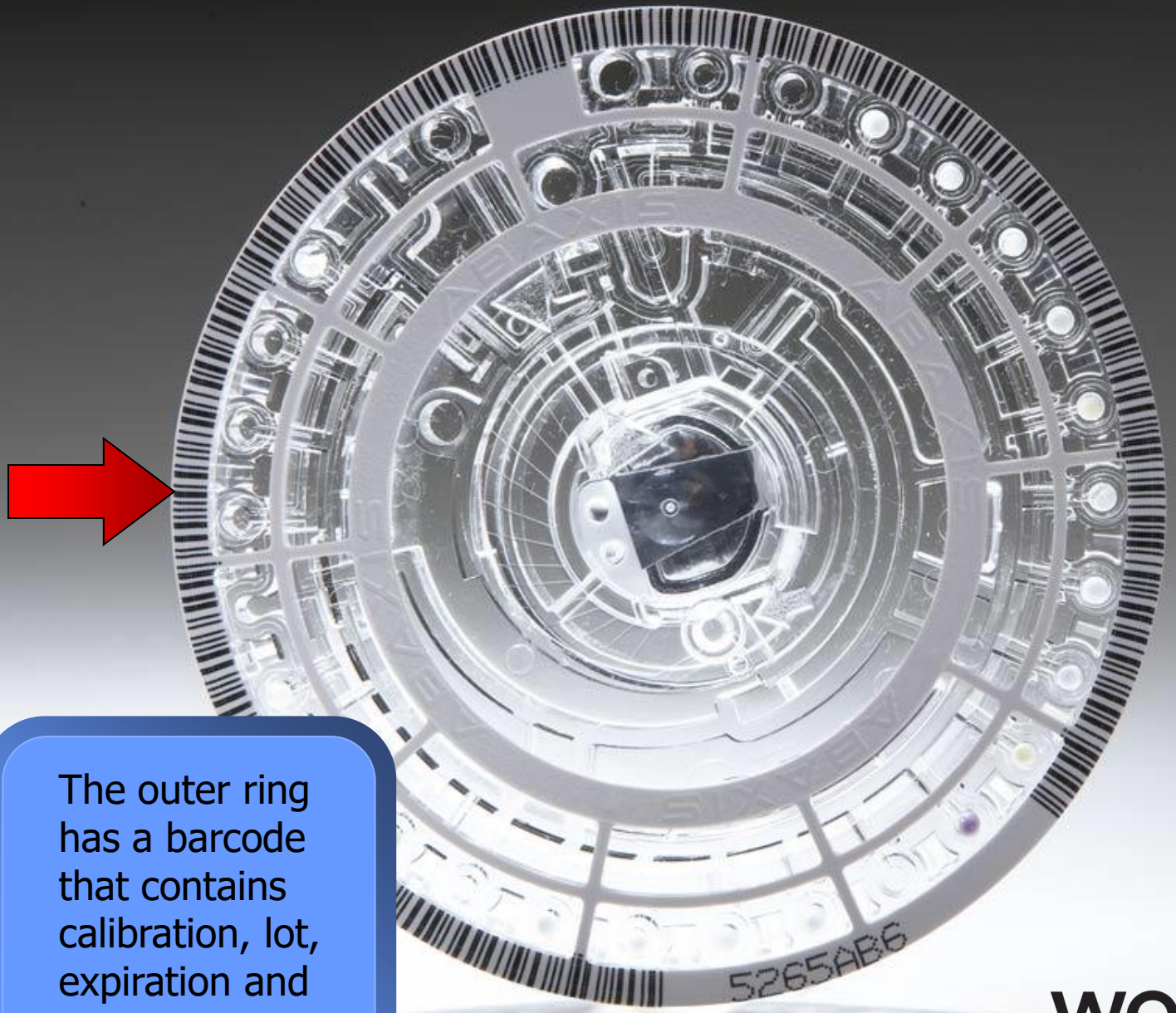

The outer ring has a barcode that contains calibration, lot, expiration and disc type.

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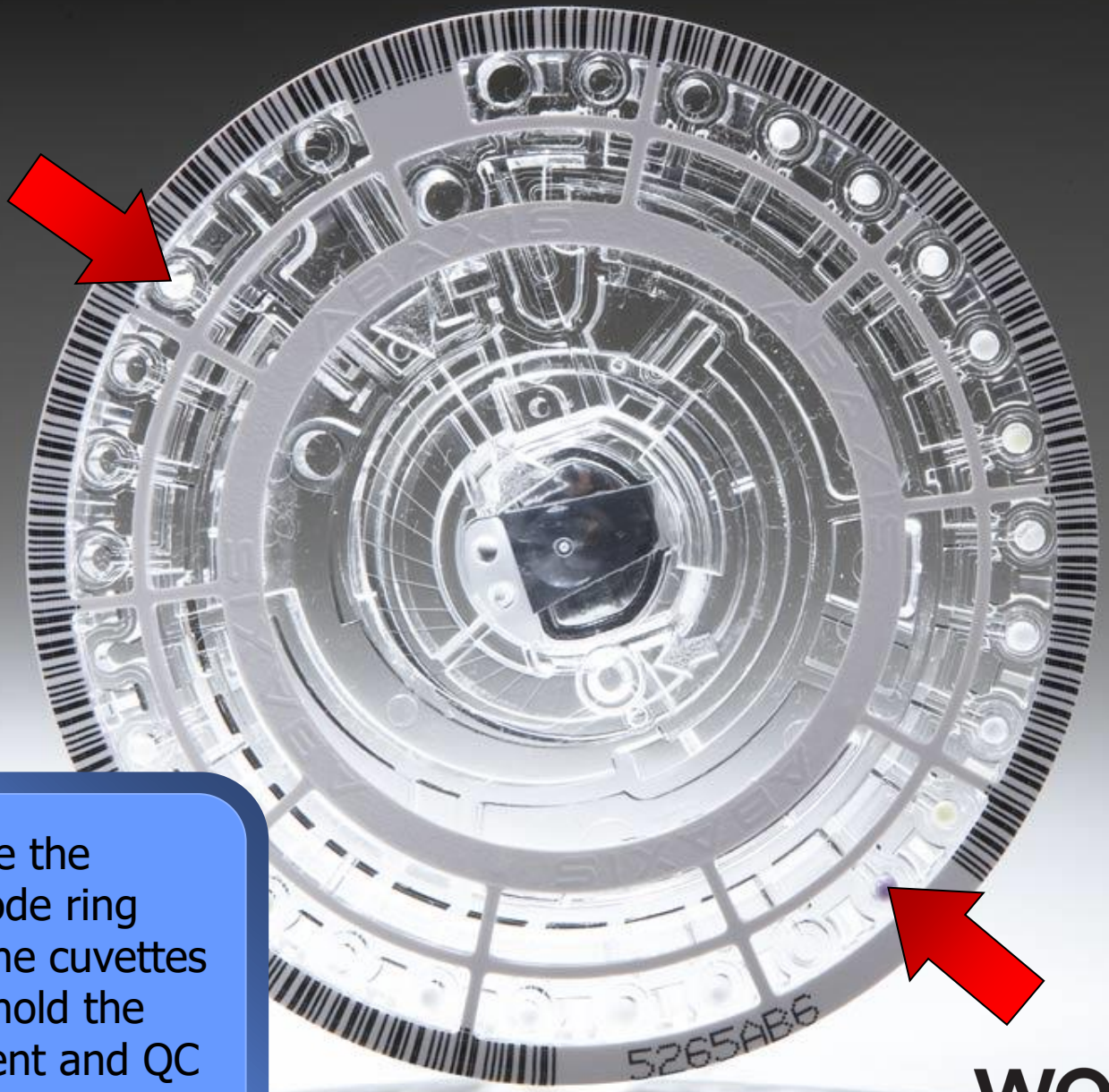

Inside the barcode ring are the cuvettes that hold the reagent and QC beads.

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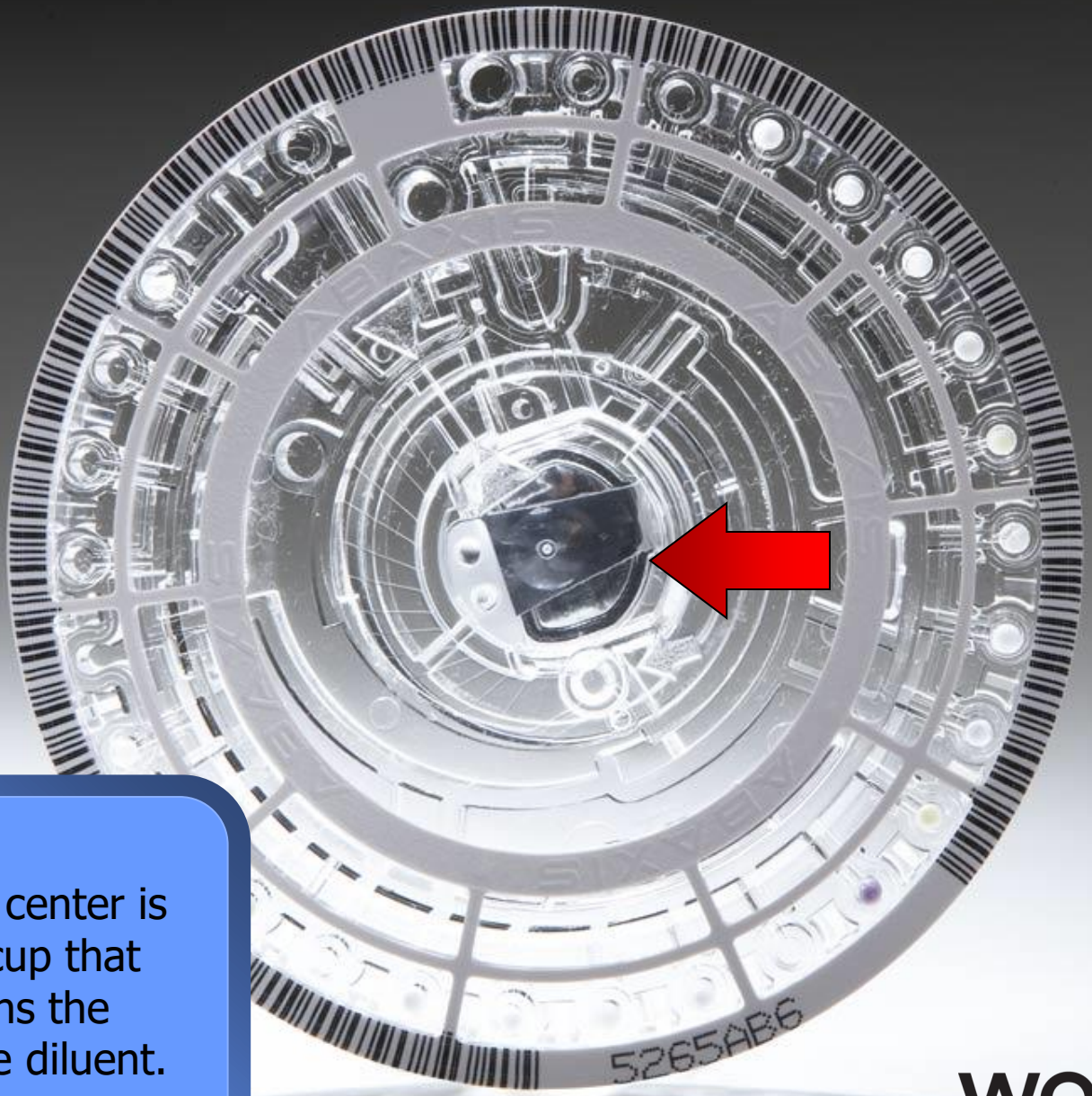

In the center is a foil cup that contains the sample diluent.

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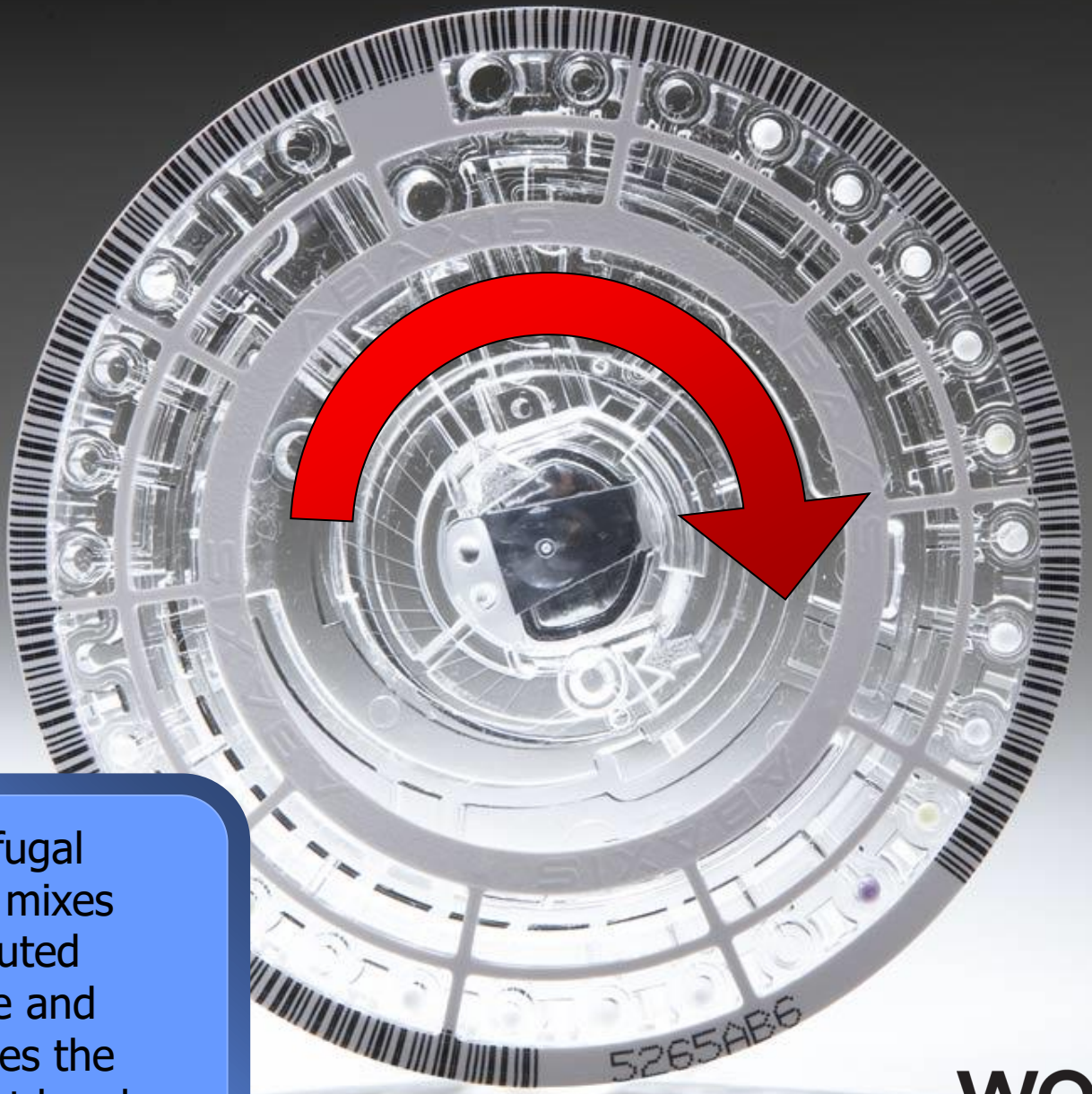

Centrifugal action mixes the diluted sample and hydrates the reagent beads.

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What is Quality Control ?

- Quality control is used to verify the analyser is performing correctly
- This process involves testing a sample with known values.
- You will be expected to compare these results to the expected target values.
- If the results are not within the expected limits, this could indicate a problem with the system.

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What is Quality Control ?

For the purposes of the KARISMA Trail it is essential that you perform Quality Control tests as follows:

- 1. Once per week - this will ensure the Piccolo is in working order and ready to be used whenever needed.
- 2. Running a Quality Control test can be used instead of a patient sample for purposes of training new users/operators/staff.
- 3. Whenever Unexpected results are discovered, performing an acceptable Quality Control test will confirm that the analyser is performing correctly.
- 4. If a new LOT of Reagent Disks is going to be used, this will confirm that the new Reagent Disks are performing correctly.

The Piccolo has been supplied with the latest QC LOT and target values pre-installed.

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Performing a Quality Control Test

UNOPENED:
Store refrigerated (+2ºC to +8ºC).
Stable to expiration date printed on individual vials.

OPENED
Store refrigerated (+2ºC to +8ºC). Reconstituted serum is stable for 8 hours at +15ºC to +25ºC or 7 days at +2ºC to +8ºC and 1 month when frozen once at –20ºC (see Limitations). Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

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Performing a Quality Control Test

PREPARATION

The Piccolo Quality Control is supplied in powdered form along with the specific control diluent.

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Performing a Quality Control Test

PREPARATION

Grip the pipette in the palm of your hand so that you can use your thumb to depress and release the pipette plunger, as shown in this image.

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Performing a Quality Control Test

PREPARATION

While holding the diluent vial steady on the bench, aspirate 1000ul of diluent into the pipette, be careful not to pipette too quickly as this may introduce bubbles and will affect results.

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Performing a Quality Control Test

PREPARATION

Carefully dispense the 1000 µL of diluent into the vial containing the QC powder.

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Performing a Quality Control Test

PREPARATION

- **Close the serum vial and invert gently several times.**
- **Allow to stand for 30 minutes before use.**
- **Ensure contents are completely dissolved by swirling gently. Avoid formation of foam.**
- **Do not shake.**

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Performing a Quality Control Test

PREPARATION

Any unused material can be refrigerated and will remain stable for 7 days at 2-8 C. Prior to reuse, mix contents thoroughly.

Performing a Quality Control Test

Samples and controls are run identically by the analyzer. However, using the Run Controls option in the Menu function stores control results separately from patient results in the analyzer memory

Performing a Quality Control Test

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Performing a Quality Control Test

Transferring the Quality Control sample to the disk

Using the Piccolo 100 µl volume pipette, firmly attach a new tip to the end of the pipette.

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Performing a Quality Control Test

Transferring the Quality Control sample to the disk

Grip the pipette in the palm of your hand so that you can use your thumb to depress and release the pipette plunger, push the pipette button to the stop position and hold it down for sample pickup.
Immerse the tip 2–3 mm below the surface of the sample, as shown at right. Slowly release the button to pick up the sample. Pause, then remove the pipette from the sample tube.
Make sure there are no air bubbles or air gaps in the pipette tip.

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Performing a Quality Control Test

Transferring the Quality Control sample to the disk

Place the pipette tip into the disc's 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.
Push the plunger down with a slow, continuous motion. Take care not to overfill the sample chamber. The sample will fill the sample chamber and form a line between the two arrows molded on the disc.
Keep the pipette plunger pressed down until the pipette tip is removed from the sample port. Discard the pipette tip into a biohazard container.

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Performing a Quality Control Test

Transferring the Quality Control sample to the disk

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Performing a Quality Control Test

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Performing a Quality Control Test

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

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Performing a Quality Control Test

Place the disc in the drawer, then select Close to close the drawer.
Analysis then begins automatically.
As the run begins, the Piccolo will ask you what type of sample you're running

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For a Patient Sample, Select Patient, and then enter a patient ID number.

For a Control, Select the Control option.

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Performing a Quality Control Test

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Performing a Quality Control Test

Select the control type to use. Use the up and down arrow keys as needed to scroll through the list.

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Performing a Quality Control Test

Enter the control Lot No then select Done

The analyzer then checks the disc type, and then begins processing the sample with no further input.

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Performing a Quality Control Test

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

When finished, select Close to close the drawer

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Performing a Quality Control Test

When the QC analysis has completed, the system will store the QC results and print them out on the built-in thermal printer (store print out in a file as per Karisma protocol).

Check that the QC values are within range according to the Piccolo QC result printout.

You should now upload QC results to https://www.woodleyequipment.com/clinical-trials/KARISMA

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Performing a Quality Control Test

When to perform a Quality Control Test

1. At least every 30 days or with each new lot number of disc panels (whichever comes first). this will ensure the Piccolo is in working order and ready to be used whenever needed.

2. For purposes of training new users/operators/staff

3. When test results do not match patient symptoms or clinical findings.

4.If a new LOT of test reagent discs are going to be used.

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Operator to run a quality control now

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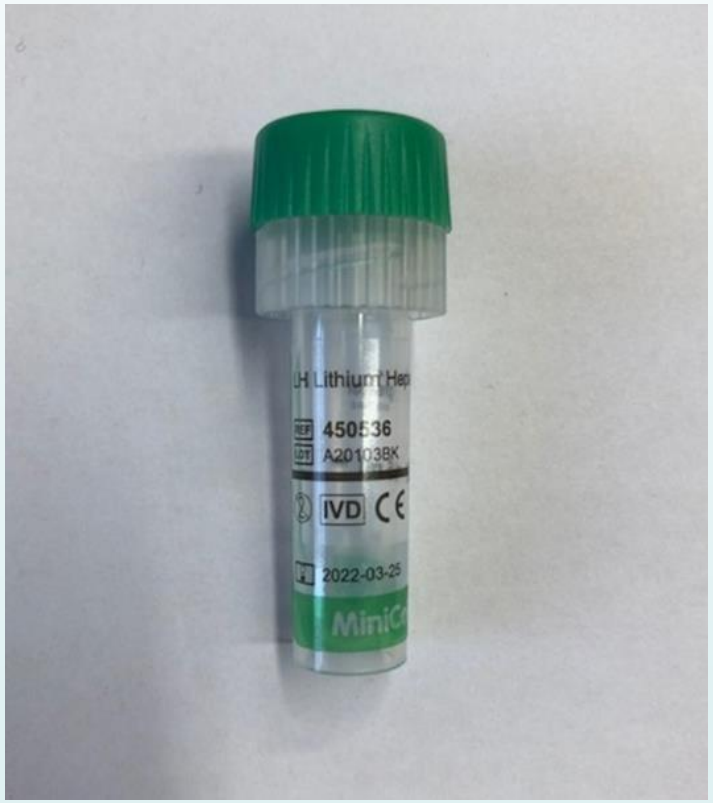
Performing a Patient Sample

Sample Types

- **Samples for the KARISAMA trial must be collected in to the Lithium Heparin tubes provided.**
- **Either Venous or Capillary blood can be used.**
- **As soon as the blood is in the tube invert several times to mix with the anticoagulant to prevent clotting. Do not shake as this will cause haemolysis leading to erroneous results.**



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Performing a Patient Sample

Using the Piccolo 100 µl volume pipette, firmly attach a new tip to the end of the pipette.

Analyze Whole Blood within 60 minutes of draw. Plasma & Serum may sit at room temperature up to 5 hours

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Performing a Patient Sample

Grip the pipette in the palm of your hand so that you can use your thumb to depress and release the pipette plunger, push the pipette button to the stop position and hold it down for sample pickup.
Then immerse the tip 2–3 mm below the surface of the sample, as shown at right. Slowly release the button to pick up the sample. Pause, then remove the pipette from the sample tube. Make sure there are no air bubbles or air gaps in the pipette tip.

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Performing a Patient Sample

Place the pipette tip into the disc's 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.

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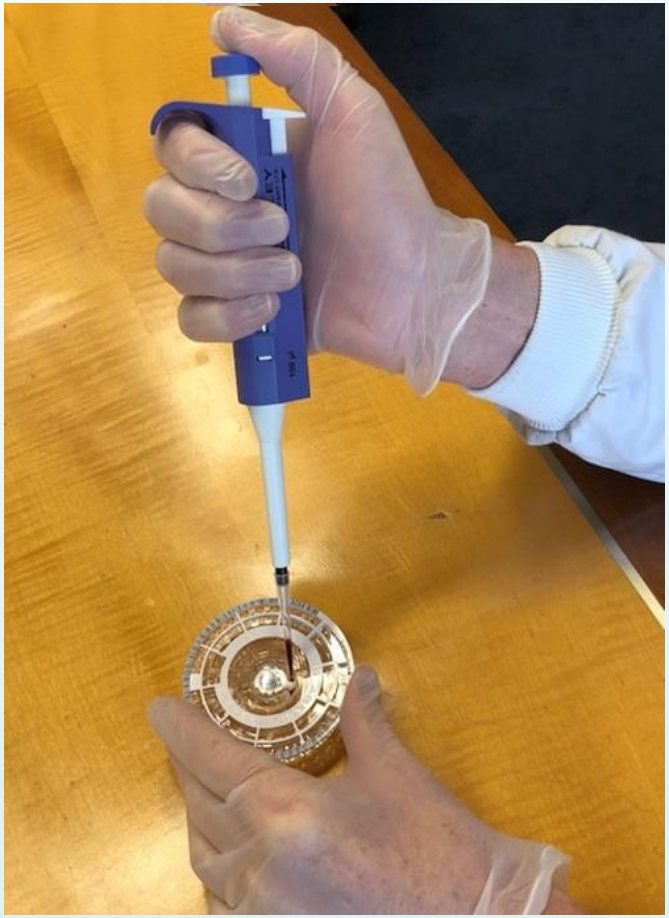
Performing a Patient Sample

Push the plunger down with a slow, continuous motion. Take care not to overfill the sample chamber. The sample will fill the sample chamber and form a line between the two arrows moulded on the disc.
Keep the pipette plunger pressed down until the pipette tip is removed from the sample port. Discard the pipette tip into a biohazard container.



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Performing a Patient Sample

Keep the pipette plunger pressed down until the pipette tip is removed from the sample port.

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Performing a Patient Sample

Start the test within 10 minutes of transferring sample to Disc.

Analyze Whole Blood within 60 minutes of draw. Plasma & Serum may sit at room temperature up to 5 hours

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Performing a Patient Sample

Start the test within 10 minutes of transferring sample to Disc.

Analyze Whole Blood within 60 minutes of draw. Plasma & Serum may sit at room temperature up to 5 hours

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Performing a Patient Sample

Select **Analyze** on the touchscreen to open the disc drawer.
The messages shown are then displayed.

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The Piccolo Xpress is as easy to use as a CD Player. Just load it and go.

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Press the Close button to close the drawer and begin the run.

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As the run begins, the Piccolo will ask you what type of sample you're running.

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For a Patient Sample, Select Patient, and then enter a patient ID number.

For a Control, Select the Control option.

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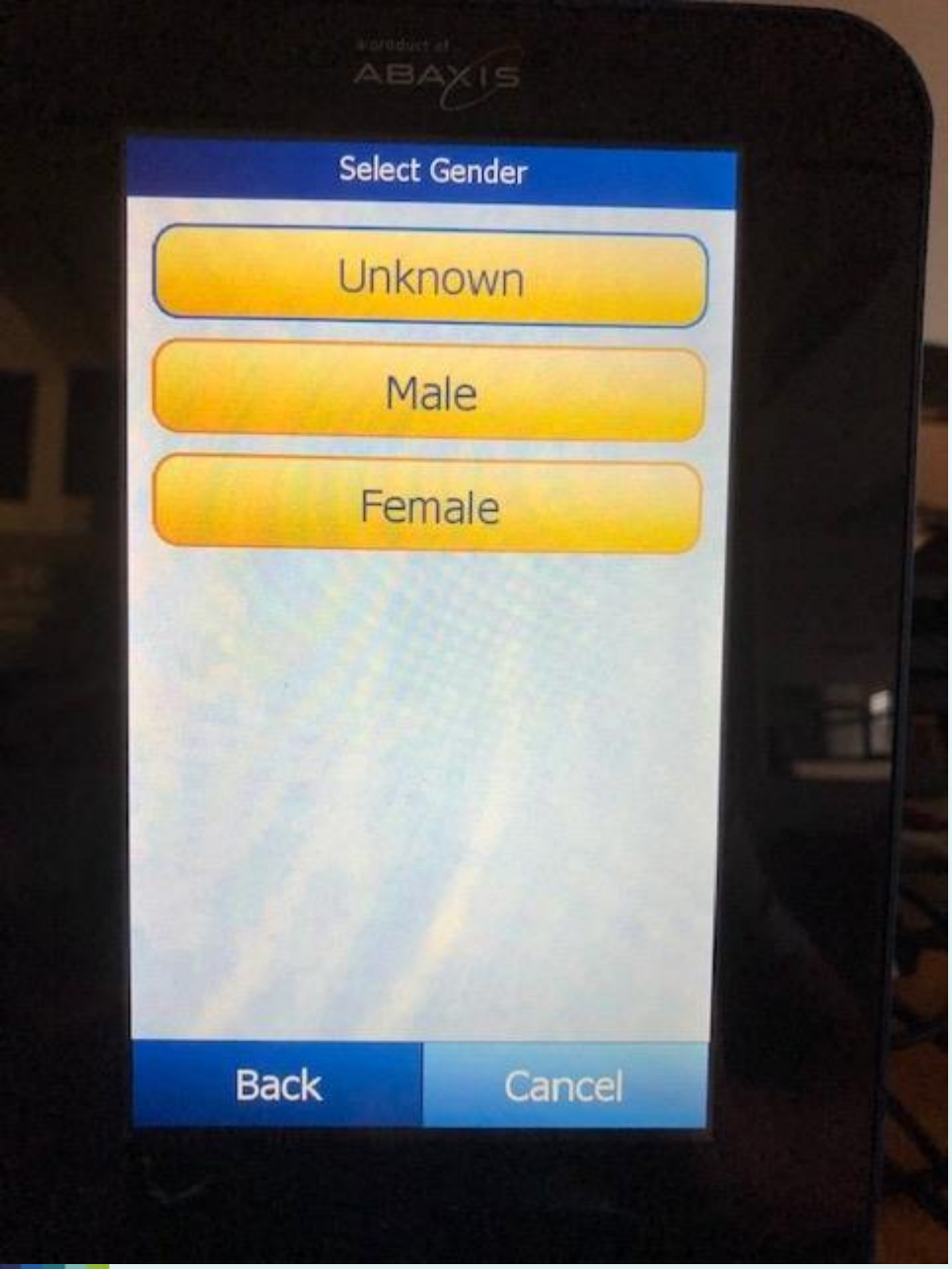

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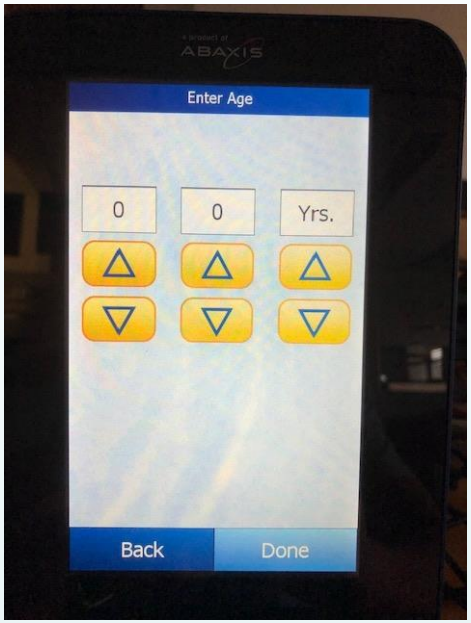

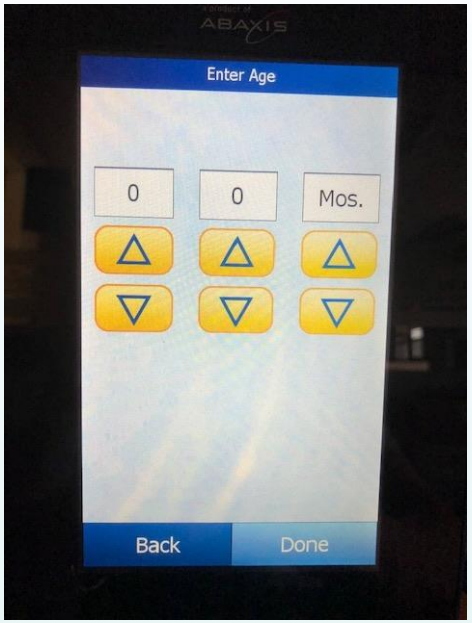

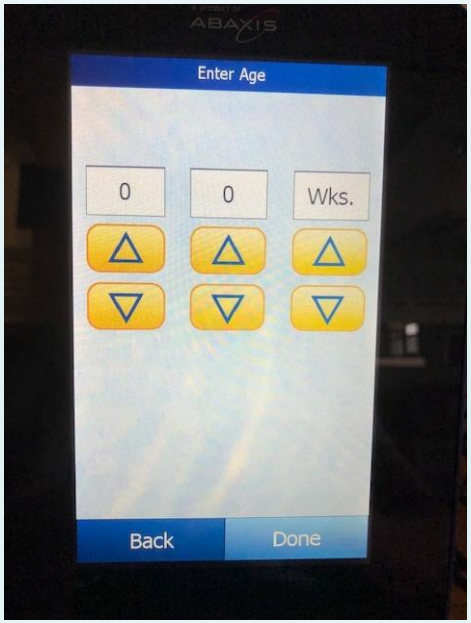

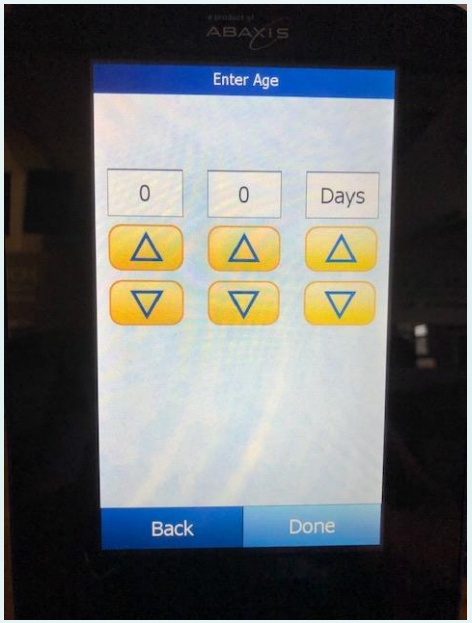

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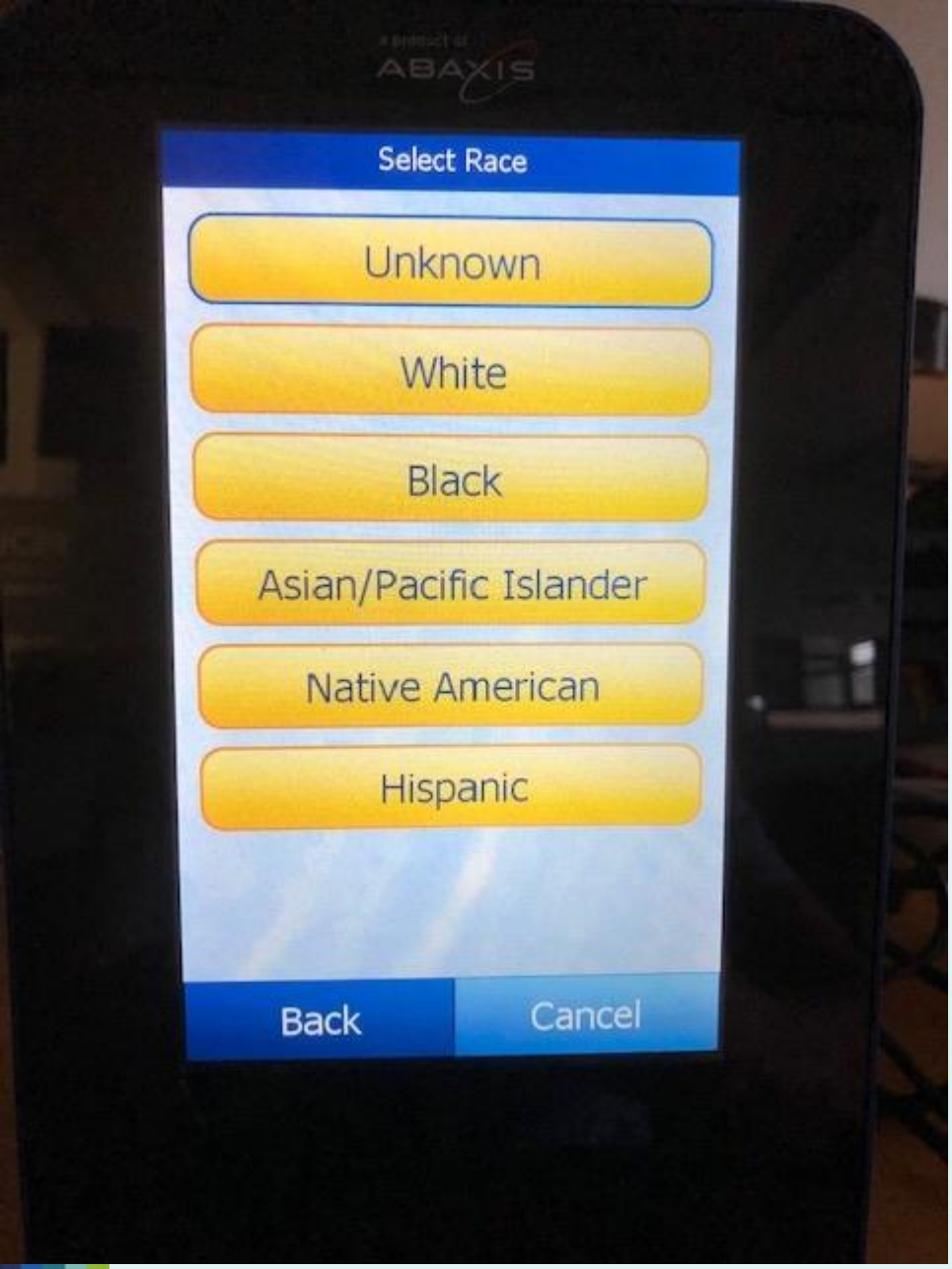

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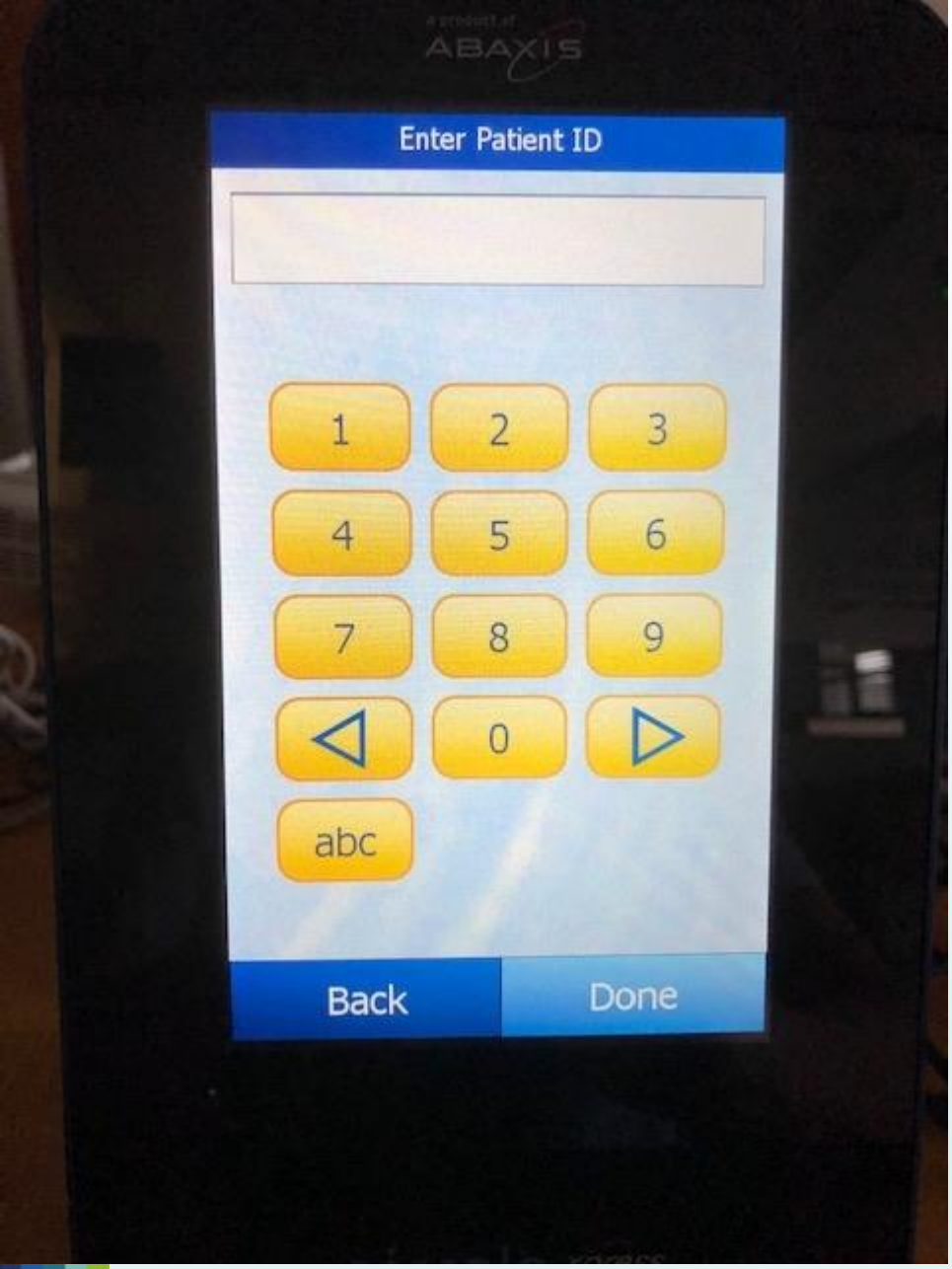

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Enter the subject Identification Number

sssspppDxx**H**yyy

- **first 4 digits (ssss) are the site number as assigned by the Sponsor**

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Enter the subject Identification Number

- **sssspppDxxHyyy**
- **following 3 digits (ppp) are the patient number…001, 002, 003 etc**

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Enter the subject Identification Number

- **sssspppDxxHyyy**
- **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 screening visit 'Dsc' and unscheduled visit 'Dun')

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Enter the subject Identification Number

- **sssspppDxxHyyy**
- **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 screening visit 'Hscr' and unscheduled visit 'Huns')

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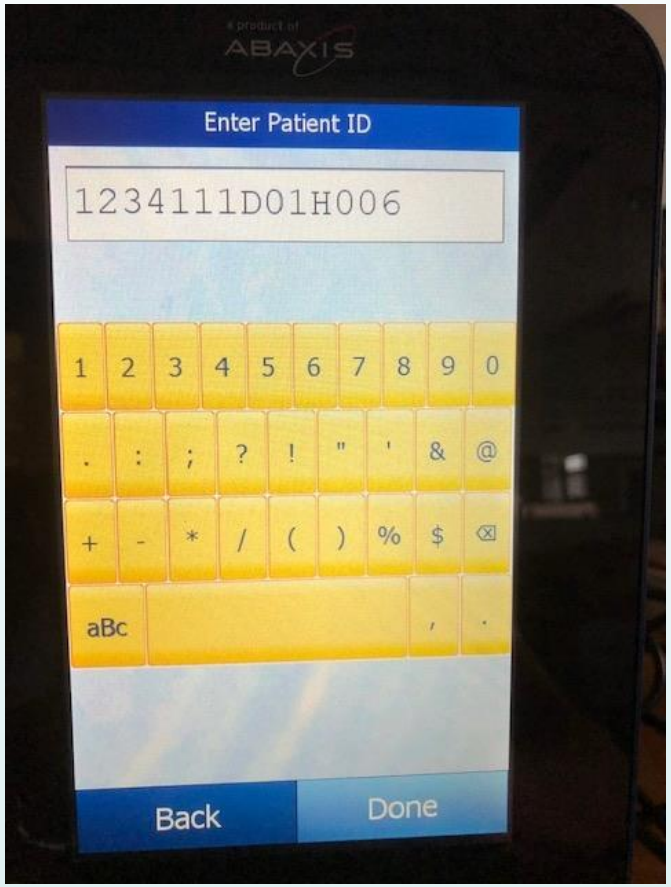
Example



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Enter the subject Identification Number

This information is available in the Quick User Guides for each analyser and also on a laminate attached to the side of each analyser.

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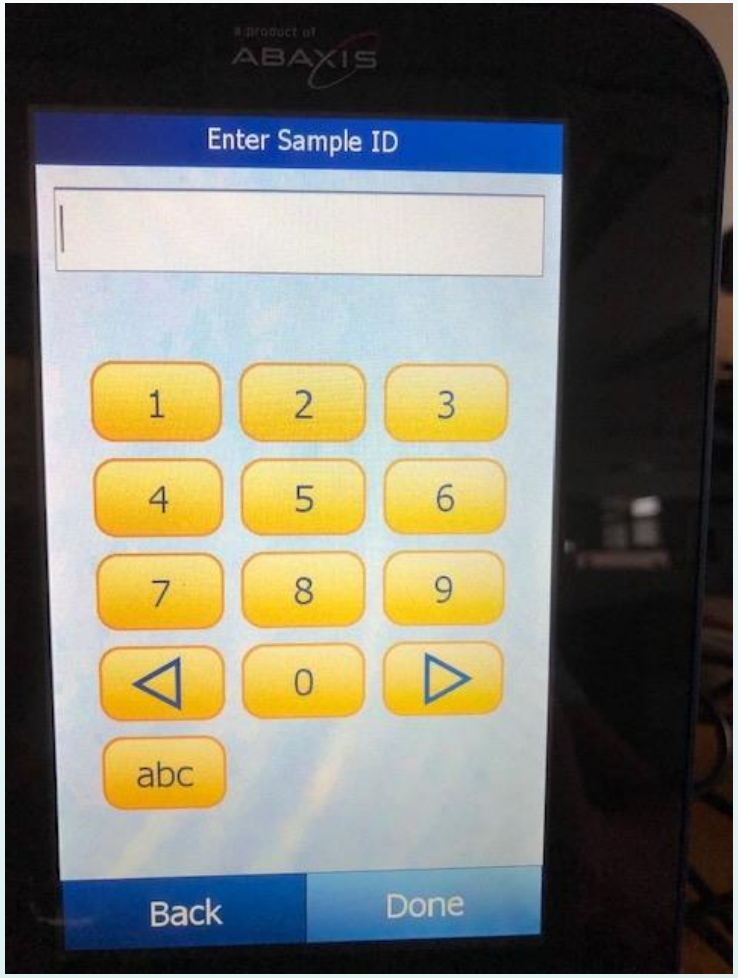
Next the system will prompt for Sample ID, this can be left blank, just press Done



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After about 12 minutes, the run will be complete, and a printout will appear in the top of the analyzer.

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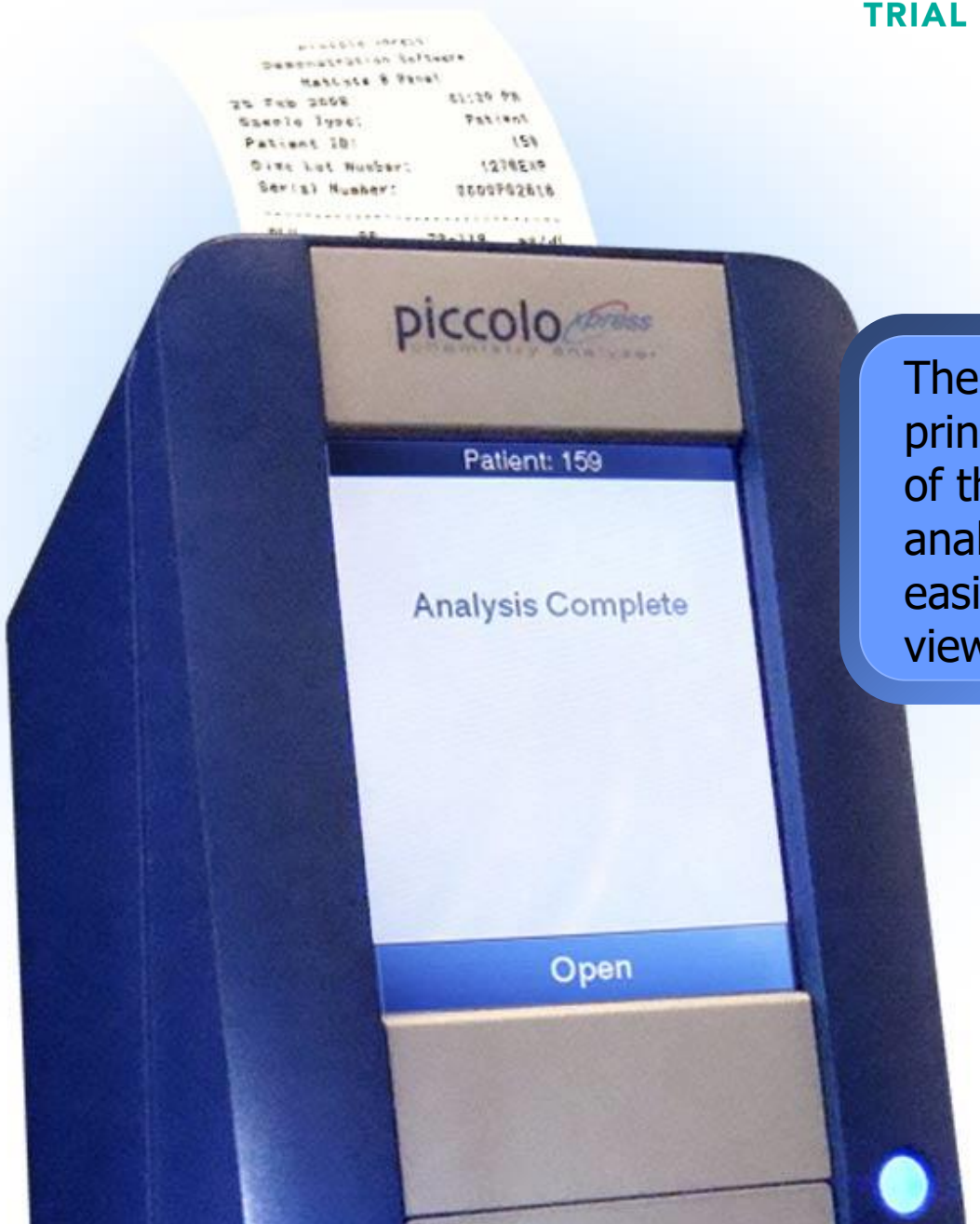
The results will be printed and should be retained in the patient results file. The results will also be automatically transmitted to the Novartis server



The roll-tape printout comes out of the top of the analyzer and is easily torn out for viewing and use.

piccolo xpress

Demonstration Software

MetLyte 8 Panel

25 Feb 2008 01:29 PM

Sample Type: Patient

Patient ID: 159

Disc Lot Number: 1276EXP

Serial Number: 0000P02616

GLU	96	73-118	mg/dL
BUN	15	7-22	mg/dL
CRE	0.9	0.6-1.2	mg/dL
CK	115	30-380	U/L
NA+	137	128-145	mmol/L
K+	4.4	3.6-5.1	mmol/L
CL-	103	98-108	mmol/L
tCO2	26	18-33	mmol/L

QC OK

HEM 0 LIP 0 ICT 0

The output contains all the patient and run info. Results are shown along with reference ranges. Abnormal results are shown with an asterisk. At the bottom, QC and interferent info is displayed.

Press the Open button on the analyzer to open the drawer and discard the Disc.

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Discard the used Disc in a biohazard container.

Close the drawer, Using the Close button and you're ready for the next run.

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The Piccolo analyser requires minimal maintenance

Clean the exterior of the analyser weekly with a mild detergent and soft damp cloth

Clean the air filter at the rear of the analyser twice per year. Full details can be found in the manufacturers user manual

- Error Messages • The analyser can display warning and error messages when problems occur. These messages include an internal error code that will assist Woodley Technical Support in diagnosing the problem. Record the error message and/or print an error report before calling Woodley Technical Support at 44 1204 669033
- Electrostatic Discharge • If the analyser experiences an electrostatic discharge while running a sample, it may “freeze up.” If this happens, cancel the analysis, then power the analyser off and back on again. This should restore the analyser to operating condition.
- Disc Cancellations • If the disc cancels, record the following information or print an error report and contact Woodley Technical Support at 44 1204 669033: • ■ Lot number • ■ Reagent Disk Type • ■ 4-digit error code • ■ Specimen type and sample ID

Your clinic will have been supplied with an adequate amount of reagent discs and supplies for the number of subjects in the trial.

In the event additional supplies are required, order from the KARISMA PRTAL via the link below. This can be found in the quick user guide.

https://www.woodleyequipment.com/clinical-trials/KARISMA

For advice or technical support contact karisma tech support

Call: +44 1204 669033 Alternatively,
email: karismatechsupport@woodleyequipment.com