## Blood Gases Ionized Calcium Lactic Acid Amperometric electrode ABL90 Flex Plus TEST CODES: C2ABG VBG UABG UVBG POCICA LA

#### I. PRINCIPLE:

The ABL90 FLEX PLUS analyzer is an in vitro diagnostic, portable, automated analyzer that quantitatively measures, pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinized whole blood, capillary, venous and arterial whole blood.

There are four different measuring principles employed in the sensors in the ABL90 FLEX PLUS analyzer.

A. Potentiometry:

The potential of an electrode chain is measured by a voltmeter, and related to the concentration of the sample (the Nernst equation). The potentiometric measuring principle is applied in the pH, pCO2, K+, Na+, Ca2+, and Cl sensors.

B. Amperometry:

The magnitude of an electrical current that flows through an electrode chain is proportional to the concentration of the substance that is oxidized or reduced at a electrode in the chain. The amperometric measuring principle is applied in the *c*Glu and *c*Lac sensors. A constant polarization voltage is applied between the anode and the reference electrode. The current runs through the anode and cathode chain. This chain is measured by an ammeter.

- - The oxygen for this reaction is supplied by the membrane system as well as by the oxidation of H2O2 at the platinum anode.
  - b. The H2O2 produced by the enzyme reaction is transported across the inner membrane to the platinum anode.
- 2. When a potential is applied to the electrode chain, the oxidation of H2O2 produces an electrical current proportional to the

amount of H2O2, which in turn is directly related to the amount of lactate. H2O2  $\circledast$  2H+ + O2 + 2e-

- 3. At the counter electrode a reduction process that consumes electrons will occur:
  - a. H2O2 + 2e- ® 2OH- (This process consumes excess H2O2 not consumed in the reaction above)
  - b. ½O2 + H2O + 2e- ® 2OH- (This process consumes excess O2 not consumed in the reaction above)
  - c. 2H2O + 2e- BH2 + 2OH- (This process occurs only at the cathode)
- 4. Any of these three reactions at the cathode will serve to neutralize the protons generated in the second reaction, so the total change in acidity is caused by the gluconic acid/pyruvate only.
- C. Optical pO2:

The optical system for pO2 is based on the ability of O2 to reduce the intensity and time constant of the phosphorescence from a phosphorescent dye that is in contact with the sample. This measuring principle is applied in the pO2 sensor.

D. Spectrophotometry:

Light passes through a cuvette that contains a hemolyzed blood sample. The absorption spectrum is used to calculate oximetry parameters. This measuring principle is used for *c*tHb (total hemoglobin concentration), *s*O2 (oxygen saturation)*F*O2Hb (fraction of oxyhemoglobin in total hemoglobin), *F*COHb (fraction of carboxyhemoglobin in total hemoglobin), *F*MetHb (fraction of methemoglobin in total hemoglobin).

## II. CLINICAL SIGNIFICANCE:

A. Lactic Acid:

Elevated levels of lactate are mainly found in conditions of hypoxia such as shock, hypovolemia, and left ventricular failure. Elevated Lactic acid found in conditions associated with diseases such as diabetes mellitus, neoplasia, liver disease and in conditions associated with drugs or toxins such as ethanol, methanol or salicylates.

B. Ionized Calcium:

lonized calcium represents the true "bioavailable" calcium in the circulation. In situations where the total calcium is normal but does not fit the clinical picture, e.g. hyperparathyroidism, a determination of the ionized calcium will, many times, show an elevation in the "bioavailable" calcium component. This may be due to alterations in protein concentrations, especially albumin that binds most of the calcium in the circulation.

C. Carboxyhemoglobin:

The analyzer can measure concentrations of certain hemoglobin derivatives. The hemoglobin derivatives carboxyhemoglobin, sulfhemoglobin, and methemoglobin cannot carry oxygen. Carboxyhemoglobin forms when carbon monoxide binds to hemoglobin. Carboxyhemoglobin levels may be used to monitor oxygen therapy. Sulfhemoglobin and methemoglobin may result from the ingestion of certain medicines or exposure to chemicals.

D. Blood Gases:

Blood gases give the measurement of pH, pO2, pCO2, HCO3, base excess/deficit and Oxygen saturation. The evaluation is important in assessing metabolic and respiratory acid/base balance, oxygen saturation and lung function (ventilation).

- E. Measurement process
  - 1. The measurement process is similar for all types of measurement, patient sample analysis, built-in QC measurements, ampoulebased QC measurements, calibration-verification measurements and calibration measurements.
  - 2. The sample (patient sample, QC solution or calibration solution) is aspirated or drawn into the sensor measurement chamber and the oximetry measurement chamber.
    - a. Measurements are done as soon as the sample is in the chambers. Liquid sensors control the process and can detect sample inhomogeneity and air bubbles in the sample. If any problems are found or the sample volume is too low, the measurement is aborted and the problem reported in a message attached to the result.
    - b. A rinse is done.
    - c. A status calibration is done for all parameters.
- F. Rinse process
  - A rinse is done after a measurement is completed.
    - 1. The sample is removed.
    - 2. The system is rinsed with a mixture of solution and air/gas.
    - 3. The system is filled with CAL1 to prepare for next sample.
    - 4. During the rinse procedure, a check of the fluid transport system is done.

## III. SPECIMEN:

A. Venous Blood Gas, Carbon Monoxide, Ionized Calcium and Lactic Acid: Fresh blood from a full draw tube containing sodium or lithium heparin anticoagulant (green top, non-gel tube) is acceptable. Whole blood should be analyzed immediately, or within 30 minutes from collection time for optimum results. Do not remove the top or centrifuge the sample before testing. Mix the tube by gentle inversion ten times prior to testing. The Section: Chemistry CH-0602 sample volume for analysis is 65 ul.

- B. Arterial Blood gas samples require heparinized syringes. Samples that cannot be analyzed within 30 minutes may be placed in an ice water bath. Blood gas samples at 0-4° C are best analyzed within 30 minutes but are valid up to one hour.
- C. Cord Blood samples are placed on ice. At temperatures of 0-4 °C, the cord pH and base excess results obtained from the samples are valid up to 30 minutes. Cord Blood specimens received from 30 minutes up to 1 hour, can be tested and a disclaimer added with the results:

"Specimen received and tested at \_\_\_\_\_ minutes after collection. Optimum results  $\leq$  30 minutes. Suggest clinical correlation."

- D. Capillary tube samples will remain in a <u>horizontal</u> position at 0-4°C and must be analyzed within 30 minutes.
- E. Carbon Monoxide (CO) samples are stable for 3 days when at 2 8°C.
- F. Unacceptable Specimens:
  - 1. Clotted specimens
  - 2. Insufficient quantity
  - 3. Wrong anticoagulant or contaminated
  - 4. ABG, not on ice and more than 15 minutes from collection time
  - 5. Air contamination
- G. Specimen Retention:
  - 1. Patient blood gas samples are held for 2 days plus the present day.
  - 2. Specimens are stored in the specimen refrigerator.

#### IV. REAGENTS :

- A. Solution Pack SP90, REF 944-157
  - 1. Pack is stable until the expiration date on the label when stored at 2-25°C within 20-80% humidity.
  - 2. Pack must be at room temperature prior to use.
  - 3. On board stability is 30 days or when the number of activities is zero.
- B. Sensor Cassette SC90, REF 946-008 (600 tests)
  - 1. Stable until the expiration date on the label when stored at 2-8°C within 20-80% humidity.
  - 2. On board stability is 30 days.
  - 3. Sensor Cassette must come to room temperature prior to replacement. Minimally 4 hours but not to exceed 48 hours.
- C. Inlet Gasket Holder, REF 903-585
- D. Inlet Connector Gasket, REF 834-662
- E. Syringe Clot Catcher, REF
- F. Flush Device REF, 905-918
- G. QUALICHECK Opener/Adapter REF 925-214
- H. Qualicheck 5+ external QC

- All three levels are stable until the expiration date on the label when stored at 2-25°C. If stored at 25 -32°C, stability is for 15 days. Ampoules must be at a constant temperature (between 18-32°C) for 5 hours prior to use. Use the solution immediately after the ampoule is opened. Ampoules are light sensitive.
- 2. Qualicheck 5+ external QC Level 1, REF 944-017 (red color code)
- 3. Qualicheck 5+ external QC Level 2,REF 944-018 (yellow color code). Only used for troubleshooting issues.
- 4. Qualicheck 5+ external QC Level 3, REF 944-019 (blue color code)
- Qualicheck Calibration Verification Kit, REF-VK-R5 Kit is stable until the expiration date on the label when stored at 2-8°C. Ampoules must be at a constant temperature (between 18-32°C) for 5 hours prior to use. Use the solution immediately after the ampoule is opened. Ampoules are light sensitive.
- J. ctHb Calibration Solution S7770, REF-944-021. Store at 2-25°C. Ampoules must be at a constant temperature (between 18-32°C) for 5 hours prior to use. Use the solution immediately after the ampoule is opened. Ampoules are light sensitive.
- K. Thermal printer paper REF-984-070

## V. INSTRUMENTATION/EQUIPMENT : ABL90 FLEX

VI. CALIBRATION: The analyzer performs a one point or two point calibration.

- A. Automatic calibrations:
  - 1. The analyzer automatically performs a 2-point calibration based on the internal analyzer schedule.
  - 2. A 1-point calibration is automatically performed with each patient sample or at 2-hour intervals if a patient sample has not been run within that time frame.
  - 3. To find the status of calibrations:
    - a. Tap MENU>Analyzer status
    - b. Tap the Calibration button
- B. An unscheduled calibration can be requested from the Analyzer status screen.
  - 1. Make sure that the analyzer is Ready status.
  - 2. Tap Menu>Start programs>Calibration programs>Calibration.
- C. Calibration of tHB

The optical system is calibrated in 2 points to determine the cuvette path length and zero point "blank calibration" for tHb. The Total Hemoglobin (tHB) calibration is performed every 3 months on the external S7770 ctHb Calibration Solution and the transparent Cal3 solution from the solution pack. The cuvette path length is determined using Lambert-Beer's law by measuring the absorbance of the colored dye in the ctHb Calibration

Solution. The zero point is the current measured by the photodiode array on the transparent solution in the cuvette.

- 1. Before performing a Total Hemoglobin (tHB) calibration:
  - a. Ampoules must be at a constant temperature (between 18-32°C) for 5 hours prior to use. Use the solution immediately after the ampoule is opened. Ampoules are light sensitive.
  - b. The analyzer must be in Ready status.
  - c. Check to see that are no calibration errors on the tHB parameter.
- 2. Hold the ampoule between your thumb and first finger and shake it vigorously for a minimum of 15 seconds.
- 3. Hold the ampoule neck-side up between your fingers and tap the top until all solution collects in the lower part of the ampoule.
- 4. Put the top of the ampoule in the Qualicheck Opener/Adapter and apply pressure to break off the neck of the ampoule.
- 5. Tap Menu>Start programs>Calibration programs>tHB CAL.
- 6. Scan the barcode on the insert for the S7770 ctHB Calibration Solution.
- 7. The analyzer opens the inlet.
- 8. Place the Qualicheck Opener/Adapter with the ampoule over the inlet gasket and press it upwards. The probe extends into the ampoule to aspirate the sample.
- 9. When prompted by the analyzer, remove the adapter.
- 10. The analyzer will close the inlet when sampling is finished.
- 11. Calibration Results:
  - a. Sensitivity results between 80 120 % without errors are acceptable.
  - b. Calibration results: To find a calibration result
    - 1) Tap Menu>Data logs>Calibration log.
    - 2) Select the calibration.
  - c. Understanding calibration results:
    - 1) Bold black –a result from the current calibration
    - 2) Dark grey—a result from a previous calibration. The result is still valid.
    - 3) Red and Bold red—an error occurred. A message attached to the result describes the error.
  - d. To see messages on a calibration result:
    - 1) Tap Menu>Data logs>Calibration log.
    - 2) Select the calibration.
    - 3) Tap the Result button.
    - 4) Tap the Messages button.
  - e. To troubleshoot messages on results:
    - 1) Select the message.
    - 2) Tap the Troubleshoot button.

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- 3) Follow instructions on the screen.
- f. To see trends in calibration results:
  - 1) Tap the Trend button.
  - 2) Select the parameters.
  - 3) Tap the View Trend button.
- 12. Calibration Verification: Performed every 6 months using ABL90 FLEX Qualicheck Calibration Verification Kit.
  - a. Administrative Log in is needed.
  - b. Tap menu>Utilities > Setup Analysis setup > Syringe modes.
  - c. Tap the Cal Verification button in the secondary modes field.
  - d. Perform the Verification as instructed.
  - e. Tap the Close button.

#### VII. QUALITY CONTROL:

Automatic quality control management (AQM) is the name given to quality control procedures that the analyzer is programmed to do automatically. Automatic test sequences are done with each measurement to ensure that all parts of the analyzer operate within specifications. A System Check is performed once a day, at startup or when new consumables are installed. An Analysis check is performed with every patient sample or a minimum of every hour if no samples are run according to pre-scheduled calibration and QC activities.

- A. Internal QC Three QC solutions in the Solution Pack are scheduled to be done every 8 hours according to a preset internal schedule. Each parameter is measured with at least 3 levels of quality control material during a 24 hour period. The assigned values and acceptable ranges for each parameter and level are entered automatically into the ABL 90 FLEX each time a new solution pack is installed.
  - The ABL 90 automatically assesses all automatic QC results and flags any result that is outside the acceptance ranges. If a result falls outside the acceptance range for a parameter, that particular parameter will be inactivated until a subsequent QC analysis is successful for the out of range parameter. Measurements are scheduled by default to be done in connection with: replacement of the Solution Pack, replacement of the Sensor Cassette or at Startup.
  - 2. The analyzer automatically takes action to correct a problem. If the action fails, a message is shown and the analyzer goes into these modes giving instructions about what to do: Operator Action Needed, Troubleshooting Needed or Intervention Required.
  - 3. To find the latest QC result:
    - a. Tap Menu>Analyzer status>Quality Control
    - b. In the Built-in QC field, select the measurement
    - c. Tap the Result button.

- B. External QC The ABL90 FLEX Qualicheck Controls Level 1 and 3 are run every 30 days, with each new lot number of Solution Pack and Sensor Cassette or with each shipment of a given lot number.
  - 1. Run controls in the ampule QC mode and record the testing on the maintenance logsheet.
  - 2. Results must be within the acceptable limits to continue patient testing.
- C. Performing Manual Liquid Quality Control
  - 1. Check that there are no calibration errors prior to running QC.
  - 2. The QC is at room temperature (13-32 C) for at least 5 hours prior.
  - 3. Hold the ampoule between the thumb and first finger when you shake it.
  - 4. Shake the ampoule vigorously for 15 seconds before it is opened.
  - 5. Hold the ampoule neck-side up and tap the top until all the solution collects in the lower part of the ampoule.
  - 6. Put the ampoule in the QUALICHECK Opener/Adapter.
  - 7. Apply pressure to break off the neck of the ampoule.
  - 8. Put the ampoule in the Qualicheck Opener/Adapter to hold the ampoule during the QC measurement. Turn the Qualicheck Opener/Adapter with the ampoule so the Radiometer logo faces upwards.
  - 9. Measure the QC material immediately after the ampoule is opened.
  - 10. Tap Menu>Analyzer status>Quality Control.
  - 11. Select the correct lot of QC solution in the Ampoule-based QC field. QC solutions are identified by a Solution name and lot number.
  - 12. Tap the Start Ampoule QC button.
  - 13. Put the Qualicheck Opener/Adapter with the ampoule over the inlet gasket.
  - 14. Push the Qualicheck Opener/Adapter with the ampoule into the analyzer as far it will go and hold it there.
  - 15. Hold the adapter until the analyzer tells you to remove it. The analyzer closes the inlet.
- D. Entering a new QC Lot into the analyzer software:
  - 1. Menu> Utilities > Setup >QC setup
  - 2. QC solutions: verify that the desired QC slot is highlighted. Do not override/delete previous QC materials.
  - 3. Using the manufacturer's package insert from the new lot of QC, identify the correct barcode for the ABL90 FLEX.
  - 4. Scan the barcode.

#### VIII. PROCEDURE:

- A. Prior to a sample measurement, check the Analyzer status is Ready.
- B. Check the color of the analyzer status traffic light located on the main screen.
- C. Once the inlet is opened, you only have a short time to complete the actions necessary.
  - 1. Mix the sample. Uniform distribution of red cells is important for reliable results.
    - a. Mix a vacutainer sample by inverting the tube 10 times to ensure the sample is homogeneous.
    - b. It is recommended that syringe specimens be mixed for a minimum of two minutes. Using a motion that rotates the syringe through two dimensions, roll the syringe between your hands horizontally and vertically. Then mix end to end.
    - c. Remix capillary tubes by applying an external magnet to the metal flea from end to end for 5 seconds.
  - 2. Hold the sample and tap the Syringe picture on the screen.
  - 3. The analyzer opens the inlet.
  - 4. Select the mode for the test ordered.
  - 5. Uncap the test tube or remove the syringe cap.
  - 6. Add a syringe clot catcher to Cord Blood syringe before testing.
  - 7. Follow the instructions on the screen.
  - 8. Place and hold the lip of the syringe or test tube against the collar of the Inlet Gasket.
  - 9. Push the syringe or test tube into the analyzer as far as it will go and hold it there. Make sure that the probe extends into the sample and stays there during sample aspiration.
  - 10. Do not bend the probe.
  - 11. Hold sample in position until the analyzer tells you to remove the sample.
  - 12. The analyzer closes the inlet.
  - 13. Enter the necessary data in the Patient identification screen by scanning the patient's barcode. The relevant patient identification input fields will be filled in automatically.
  - 14. The Patient result screen will be displayed automatically when the measurement has been completed.
  - 15. Check the results and the parameter status. If there is no marking next to the parameter, the parameter was measured without any problem.

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- 16. If the Patient result screen opens before you have entered the necessary data, tap the ID button. Edit the necessary data.
- 17. To find a patient result:
  - a. Tap Patient results log button in the top right hand corner
  - b. Arrow to the patient
  - c. Tap the Result button.
  - d. OR Tap Menu> Latest Result
- D. Proficiency test modes

Proficiency test mode is a process that lets you verify the performance of your analyzer with accredited test solutions. The CAP survey samples MUST be run in the Proficiency Test Mode.

- 1. Proficiency test mode
  - a. Select Syringe mode on main screen.
  - b. Select other modes button from the right side of the screen.
  - c. Select Prof Test button.
     Note: Make sure a small black mark is shown in the top right-hand corner of the button.
  - d. Using the Qualicheck opener/adapter remove the top of the ampoule and place it back in the adapter to sample the CAP specimen.
  - e. Put the Qualicheck Opener/Adapter with the ampoule over the inlet gasket.
  - f. Push the Qualicheck Opener/Adapter with the ampoule into the analyzer as far it will go and hold it there until the analyzer tells you to remove it.
  - g. The analyzer closes the inlet.
  - h. Enter identification information on the screen.
  - i. Remove the printout results and attach them to the proficiency paperwork.

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| IX. REPORT | REPORTING RESULTS<br>Reportable Range<br>AMR/CRR |             |        | Critical Value |        | Reference Range   |  |
|------------|--|-------------|--------|----------------|--------|---|--|
|            | рH   | 6.818-7.797 |        | <7.2 & >7.6    |        | 7.35 - 7.45 Arterial<br>7.31 - 7.41 Venous                          |  |
|            | pCO2   | 15.4-98.3   |        | <20 & > 70 r   | nmHg   | <ul><li>35 - 45 mmHg Arterial</li><li>41 - 51 mmHg Venous</li></ul> |  |
|            | pO2  | 30.1-488    |        | <40 mmHg       |        | 80-100 mmHg<br>35-40 mmHg   |  |
|            | HCO3   | Calculated  |        |                |        | 22-26 mmol/L  |  |
|            | TCO2   | Calculated  |        | <10 & >50 m    | nmol/L | 24-32 mmol/L  |  |
|            | ctHb   | 0.1-24.0    |        | < 7.0 g/dL     | See L  | IS for age related range  |  |
|            | sO2  | .3-100.0    |        |                |        | 95-100%   |  |
|            | COHgb  | 1.00-92.2   |        | >15%           |        | 0- 1.5% smoker 1.5-5.0%   |  |
|            | MetHgb   | 1.00-30.0   |        |                |        | 0.4-1.5 %   |  |
|            | iCa++  | 2.00-9.92   |        | <2.8 & >6.4    | mg/dL  | 4.8-5.2 mg/dL   |  |
|            | Lac  | 0.4-24      | Call a | ll > 2.0       | 0.4-1. | 9 mmol/L  |  |

#### X. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. Troubleshooting

Troubleshooting is necessary when the analyzer goes into an Operator Action Needed, Troubleshooting needed or Intervention Required mode. It may also be necessary to troubleshoot messages in the **Analyzer status** screen.

 Operator Action Needed and Troubleshooting needed modes show text and video instructions to guide you through each troubleshooting procedure and show you what to do to get out of the troubleshooting mode. After each troubleshooting procedure, the analyzer makes checks to find out if the issue has been resolved. If not, a new

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the analyzer will go into the Intervention Required mode.

- 2. Intervention Required mode
  - a. Do the first action shown in the Suggested actions frame.
  - b. Tap the Test again button.
  - c. If the analyzer does not go out of Intervention Required mode, do the next action.
  - d. Tap the Test again button.
  - e. If the analyzer does not go out of Intervention Required mode, do steps c and d again.
  - f. If none of the actions cause the analyzer to go out of Intervention Required mode, contact your local Radiometer representative.
- B. Troubleshooting modes causes

| Troubleshooting mode   | Possible causes  |
|------------------------|--|
| Operator Action Needed | A consumable must be replaced  |
| Troubleshooting needed | Fluid transport errors were found  |
| Intervention Required  | <ul> <li>If the troubleshooting procedures in<br/>the <b>Troubleshooting needed</b> mode did<br/>not resolve the issue</li> <li>All other possible errors</li> </ul> |

# C. Messages in the Analyzer status screen: The traffic light in the **Analyzer** status button is yellow or red

- 1. Tap Menu > Analyzer status.
- 2. Tap the button adjacent to a yellow or red traffic light.
- 3. Choose an option and follow the steps for it.

| Option            | Steps                                     |  |  |
|-------------------|---|--|--|
| To troubleshoot a | Follow the instructions on the screen.    |  |  |
| Recommended       |   |  |  |
| action            |   |  |  |
| To troubleshoot   | To troubleshoot errors in the Built-in QC |  |  |
| Quality control   | and Ampoule-based QC fields:              |  |  |
| messages          | a) Select the quality control measurement |  |  |
|                   | marked by a red ? clock symbol.           |  |  |
|                   | <b>b)</b> Tap the <b>Result</b> button.   |  |  |

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|-----------------|--|--|--|--|
|                 | c) Tap the Messages button.                      |  |  |  |
|                 | d) Select the message.                           |  |  |  |
|                 | e) Tap the <b>Troubleshoot</b> button.           |  |  |  |
|                 | f) Follow the instructions on the screen.        |  |  |  |
|                 | To troubleshoot messages in the QC               |  |  |  |
|                 | Messages field:                                  |  |  |  |
|                 | a) Select the message.                           |  |  |  |
|                 | b) Tap the Troubleshoot button.                  |  |  |  |
|                 | c) Follow the instructions on the screen.        |  |  |  |
| To troubleshoot | To troubleshoot calibrations marked by a         |  |  |  |
| Calibrations    | red ? or clock symbol.                           |  |  |  |
| messages        | a) Select the marked calibration.                |  |  |  |
|                 | <b>b)</b> Tap the <b>Result</b> button.          |  |  |  |
|                 | c) Tap the Messages button.                      |  |  |  |
|                 | d) Select the message.                           |  |  |  |
|                 | e) Tap the Troubleshoot button.                  |  |  |  |
|                 | f) Follow the instructions on the screen.        |  |  |  |
|                 | To troubleshoot messages in the                  |  |  |  |
|                 | Message field:                                   |  |  |  |
|                 | a) Select the message.                           |  |  |  |
|                 | <b>b)</b> Tap the <b>Troubleshoot</b> button.    |  |  |  |
|                 | c) Follow the instructions on the screen.        |  |  |  |
| To troubleshoot | a) Select the message.                           |  |  |  |
| Consumables or  | <b>b)</b> Tap the <b>Troubleshoot</b> button.    |  |  |  |
| System          | <b>c)</b> Follow the instructions on the screen. |  |  |  |
| messages        |  |  |  |  |

D. Flushing the fluid transport system:

- 1. Draw tap water into the Flush Device up to the 2.5 mL mark.
- 2. Pull the plunger of the Flush Device up to the 5 mL mark to draw air into it.
- 3. Tap the **Press to start video guidance** button.
- 4. Pull off the inlet cover.
- 5. Tap the **Action completed** button. The analyzer opens the inlet.
- 6. Wait until the Solution Pack is ejected.
- 7. Remove the Solution Pack.
- 8. Tap the **Action completed** button.
- 9. Pull out the Inlet Gasket Holder.
- 10. Tap the **Action completed** button. The analyzer closes the inlet.
- 11. Put a tissue or a cloth under the inlet.
- 12. Tap the **Action completed** button.

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- 13. Connect the tip of the Flush Device to the waste connector in the Solution Pack compartment.
- 14. Tap the Action completed button.
- 15. Hold the Flush Device as shown.
- 16. Inject a very small quantity of air to fill approximately 1 cm of the tube.
- 17. Hold the Flush Device as shown.
- 18. Inject a very small quantity of water to fill approximately 1 cm of the tube.
- 19. Do steps 15 to 18 again repeatedly to clean the fluid transport system.
- 20. Tap the **Action completed** button.
- 21. Inject water until an unbroken stream of water comes out of the Inlet Probe.

**Note:** The fluid path is flushed, when this is possible. **Note:** If it is not possible, do steps 15 to 18 and step 21 again.

- 22. Tap the Action completed button.
- 23. Disconnect the Flush Device.
- 24. Remove the tissue or the cloth.
- 25. Tap the **Action completed** button. The analyzer opens the inlet.
- 26. Put the new Inlet Gasket holder over the slide and insert it. Make sure that the Inlet Probe is in the center of the gasket and that the Inlet Gasket Holder clicks in place.
- 27. Tap the **Action completed** button.
- 28. Put your thumbs on the white part of the Solution Pack and push the Solution Pack into its compartment until it clicks in place. The analyzer closes the inlet.
- 29. Put on the inlet cover.
- 30. Tap the Action completed button.
- E. Operator actions requested in analyzer messages
  - 1. To request a tubing refill

Tap Menu > Start programs > Auxiliary programs > Tubing refill.

- 2. To request a liquid sensor adjustment
  - Tap Menu > Start programs > Auxiliary programs > Liquid sensor adjust.
- To request a pump calibration
   Tap Menu > Start programs > Auxiliary programs > Pump calibration.
- 4. To request a rinse

Tap Menu > Start programs > Auxiliary programs > Rinse.

#### F. Troubleshooting Analyzer messages

This procedure can be used to find out what operator actions are necessary to troubleshoot messages.

- 1. Note the message number (on the left of the message).
- 2. Find the message and operator actions in the *Analyzer messages* table.
- 3. The messages in the table are sorted by number.
- 4. If more operator actions are available, start with the first action listed and see if this resolves the issue. If not, continue with the next action listed.
- 5. Message 751 is only found in the Activity Log to inform the user about activities that have taken place. The message is blank (empty) in the database, and when an activity occurs the actual status information is appended to it resulting in the logged 751-message. If the setting "Log All Measuring Activities" is enabled in Miscellaneous Setup, all wet section activities will be logged in the Activity Log as 751-messages.

 G. Shutting down, moving and restarting the analyzer: Shutdown is a safe procedure for you to close down the analyzer. There are 2 procedures a Temporary shutdown and a Long term shutdown.

Note: Do not use the power switch to shut down the analyzer.

1. Temporary shutdown of the analyzer

- a. Usually, the analyzer is kept switched on so that it is ready to use at any time. However, in some situations, it is necessary to do a temporary shutdown:
- b. A temporary shutdown of one analyzer will be performed each month after the Solution Pack has expired.
- c. When an analyzer without a battery must be moved to a new location
- d. When an analyzer with a low-charge level battery must be moved to a new location
- e. When the analyzer tells you to do a shutdown (for example, during a troubleshooting procedure)
- f. After a non-USB keyboard or mouse is connected to an analyzer that is switched on.
- g. If the analyzer is shut down for more than 2 hours, the Sensor Cassette must be replaced.
- 2. Temporary shutdown
  - a. Tap Menu > Utilities > Temporary shutdown.
  - b. Tap the **Confirm shutdown** button.

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- c. Wait until the Windows program tells you that it is shutting down.
- d. When Windows program has shut down, push the analyzer power switch to the Off position (O).
- 3. Restarting the Analyzer after a temporary shutdown.
  - a. Push the power switch to the On position (I).
  - b. If the analyzer does not restart, press the standby button on the back of the analyzer
  - c. The analyzer is ready for use when it is **Ready**.
- Long-term shutdown of the analyzer It is usually only necessary to do a long-term shutdown when the analyzer is stored. Refer to operator manual for long-term shutdown.
- 5. Moving the analyzer that has a charged battery The charge level of the battery must be high enough to be able to move the analyzer and connect it to the main power supply before the charge level drops below 11 %.
  - a. Disconnect the power cable and peripheral devices.
  - b. Lift the analyzer by its handle, keep it vertical and move it to its new location.
  - c. Connect the power cable and peripheral devices to the analyzer.
  - d. Connect the analyzer to the main power supply before the analyzer charge-level falls below 10 %.
- 6. Moving an analyzer that does not have a battery
  - a. Do a temporary shutdown.
  - b. Disconnect the power cable and peripheral devices.
  - c. Lift the analyzer by its handle, keep it vertical and move it to its new location.
  - d. Connect the power cable and peripheral devices.
  - e. Switch on the mainspower supply.
  - f. Push the power switch to the On position (I).
  - g. If the analyzer does not restart, press the standby button on the back of the analyzer.
- 7. Restarting the analyzer after a long-term shutdown. Required items needed:
  - Solution Pack and A Sensor Cassette
    - a. Use the power cable to connect the analyzer to the mains power supply.

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- b. Push the power switch to the On position (I) and wait until the **Operator-intervention** required screen is shown.
- c. If the analyzer does not restart, press the standby button on the back of the analyzer.
- d. Install a Solution Pack.
- e. Install a Sensor Cassette.
- f. Run external Level 1 and Level 3 QC.
- g. Tap the **Test again** button.
- h. The analyzer is ready for use when it is **Ready**.

#### XI. REFERENCES

- A. ABL90 Flex Plus Instruction for use manual from software 3.4, Version 2018051.
- B. ABL90FLEX Troubleshooting Guide, Radiometer Medical ApS, Copenhagen, Denmark, 2012.

#### Effective Date: September 16, 2018 Date Reviewed/ Date Revised:

Pekin Laboratory is a CAP accredited facility, as of 7/1/11 the responsibility of new and/or substantially revised policies and procedures will be restricted to the Laboratory Director whose name appears on the CLIA certificate, whose signature appears below. The biennial review will be completed by the Lead, Coordinator or Manager.

| Policy Created by: Cindy Schroeder MT (ASCP) | Date:09/03/18 |
|--|---------------|
| Medical Director Approval:                   | Date:         |
| Change of Medical Director:                  | Date:         |

| REVISION HISTORY |                       |        |                |  |  |
|------------------|-----------------------|--------|----------------|--|--|
| Rev              | Description of Change | Author | Effective Date |  |  |
| 0                | Initial Release       |        |                |  |  |
|                  |                       |        |                |  |  |
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|                  |                       |        |                |  |  |

#### **Reviewed by**

| Lead | Date | Coordinator/ Manager | Date | Medical Director | Date |
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