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ABL Radiometer 800 Series Maintenance Procedure

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

Routine maintenance is performed to monitor the instrument's performance and to keep the analyzer in operation. The purpose of this procedure is to provide staff with instructions and information on maintaining the Radiometer ABL 800 Series.

II. SUPPLIES:

A. Inlet Gaskets
B. Pump Tubing
C. H700 QUALICHECK Adapter
D. Ampoule Opener
E. ctHb Calibration Solution
F. Cal solutions 1 and 2
G. Cal Gases 1 and 2
H. Rinse solution
I. Waste Bottles
J. Membranes for each electrode
K. Hypochlorite solution
L. Cleaning solution
M. Valve key
N. Small red pO2 electrode brush

O. AutoCheck 5+

P. AutoCheck 6+

III. QUALITY CONTROL (QC):

QC is set to automatically run one level per shift via the AutoCheck Module. QC may also be initiated to run through the AutoCheck module, or QC may be manually run. QC should be repeated only once prior to performing troubleshooting techniques.

A. **Measurement using AutoCheck Module.**
AutoCheck Module holds 20 vials of Quality control material. The QC material is loaded into an autocheck carousel, which is manually loaded.

1. Quality control will automatically run at selected timed intervals
2. Once QC is complete a printout of results will follow or will be displayed on the screen
3. Any parameter that is not within acceptable range will have a "?" or an arrow next to it
4. QC will automatically transmit to the QC Review Program
5. QC that has an error or is marked with a "?" will not cross into the QC Review Program
6. Verify/Save the QC and enter actions for QC failures
7. A parameter that is out of QC range will flag as a failure or warning in the QC Review Program
8. QC will auto-rerun one time
9. Troubleshoot if QC is still out of range

B. **Manually initiate a QC program using the Autocheck Module**

1. Select **Analyzer Status > Quality Control**
2. Select the QC level to run
3. Select Run AC Ampoule
4. QC will automatically run
5. Follow steps 2-8 in the Measurement using AutoCheck Module section above (III-A).

C. **Manual Quality Control measurement**: Before analyzing the Quality Control material,

1. Place the ampoule fully into the H705 ampule holder
2. Holding the ampule in its holder between two fingers, shake it vigorously for at least 15 seconds
3. Place the H700 Ampule adapter over the ampule and press it down to open the ampule
4. Open the Syringe inlet flap
5. Place the adapter tip up into the syringe inlet

6. Press *"**Ampoule QC**"* to select the measuring program
7. Press: "***Start***"
8. When prompted by the analyzer, remove the adapter and close the syringe inlet flap
9. When analysis is complete, Click Result
10. Click QC ID
11. Select the lot number of QC that was tested
12. Click back
13. Results will print out or be displayed on the screen
14. Follow steps 3-8 in the Measurement using AutoCheck Module section above

IV. DAILY MAINTENANCE:

A. **Check Analyzer status:**
   1. Examine Inlet Gasket
   2. Replace or clean as necessary (see Weekly Maintenance)
   3. Resolve any messages pertaining to the function of the instrument including replacements or error codes.

B. **Check Solution Levels**
   1. **Cal 1 and Cal 2 Solutions**
      a. Select **Analyzer Status > Reagents**
      b. Observe the volume %'s of solution vials and observe how much liquid is actually in bottle
      c. Replace Calibrator solutions if less than 10% (See attachment C for reagent preparation)
      d. Replace if necessary for low volume solutions
      e. Select **Replace** touch key
      f. Remove low volume bottle
      g. Date new bottle with Open and Expiration Date
      h. Scan the upper barcode on new replacement bottle. Bottle that was scanned will show at the right side of screen
      i. Place new bottle onto analyzer
      j. "Press keyboard button and type initials in operator notes for documentation"
      k. Press **Restart**
   2. **Cleaning Solution**
      a. Select **Analyzer Status > Reagents**
      b. Observe solution volume percentage, compare to how much liquid is

actually in bottle

c. Replace cleaning solution if it is under 10% (See appendix C for reagent preparation)

d. Select **Replace** touch key.

   i. Unscrew the lid from the new solution container

   ii. Remove the used solution container by holding it on the sides and pulling

   iii. Scan the upper barcode of the new solution, using the barcode reader

   iv. Place the new solution container in position on the analyzer and push it firmly onto the connector

   v. Mark Open and Expiration date on container

   vi. "Press keyboard button and type initials in operator notes for documentation."

   vii. Press **Restart**

   (***Caution*** *– Do not breathe dust, avoid contact with skin. Irritating to eyes and skin. Wear suitable gloves. May cause sensitization by inhalation and skin contact. In case of accident or if you feel unwell, seek medical advice immediately. Show the label where possible.)*

3. **Rinse Solution**

   a. Select **Analyzer Status > Reagents**

   b. Observe the volume percentage of the rinse solution

   c. Change rinse solution when less than 5%

   d. Remove empty bottle by pulling bottle straight out of connection

   e. Date new bottle with Open and Expiration date

   f. Scan the upper barcode on the new bottle

   g. Place onto analyzer by pushing bottle into connection

   h. "Press keyboard button and type initials in operator notes for documentation."

   i. Press **Restart**

   NOTE: Always keep empty Rinse bottles, these empty Rinse bottles are to be used as Waste bottles. Peel rinse labels off and store with the empty waste containers.

C. **Waste Bottles**

1. Change the waste bottle only when prompted by the instrument

2. Instrument will prompt "Waste Container Full" and will go into an automatic Standby
3. Remove Waste bottle and replace with an empty Rinse Solution bottle or a new Waste bottle
4. Discard full waste bottle with cap from rinse bottle into biohazard
5. Choose "Exit Standby" and instrument will return to a Ready mode

D. **Check or Replace Calibration Gases**

1. Press Analyzer Status >Reagents
2. Remove the gas cylinder by turning it counterclockwise until it becomes free
3. Remove the cap covering the valve on the new gas cylinder. Check that the valve is clear of any debris
4. Mark Open and Expiration date on container
5. Scan the barcode on the new gas cylinder
6. Place the gas cylinder valve into position on the socket of the regulator. To ease alignment, use the analyzer enclosure as a guide
7. Press keyboard button and type initials in operator notes for documentation
8. Press Restart

Caution: Risk of personal injury. Pressurized container. Non-Flammable compressed gas. Do not breathe gas. Gas mixtures containing less than 19.5% Oxygen may cause suffocation. Protect from sunlight. Do not expose to temperatures exceeding 50 C. Store and use with adequate ventilation. Keep away from oil and grease. Do not refill.

Caution: Removal of safety valve. Before discarding an empty cylinder, remove the safety valve using the valve key.

E. **Check Paper Supply**

1. Lift lid on paper cover.
2. Observe paper supply.
3. Change paper if necessary: Paper supply is low when pink lines appear on the side of the paper.
    a. Move the release lever fully back to the nearly horizontal position
    b. Remove any leftover paper from the printer
    c. Move the release lever forward
    d. Make sure that the paper edge is cleanly cut. Place the new roll into position in the printer so that the paper unreels from underneath the roll. The thermal side of the paper is on the outside of the roll.
    e. Aligning the leading edge of paper straight, feed it behind the drive roller. The paper will feed through the printer automatically once the internal sensor detects the edge of the paper.

f. Check that alignment is satisfactory. Realign as required.

g. Close the printer cover, making sure the paper feeds out of the printer

F. **Document Daily Maintenance according to site specific method**

V. WEEKLY MAINTENANCE:

A. **Clean and Replace Inlet Gasket**

1. Remove blue syringe and capillary inlet flaps
2. Wait for instrument to drain
3. Push inlet probe upward and out of inlet gasket pathway (if necessary)
4. Lift inlet gasket straight up
5. Set aside old gasket for cleaning. Discard if damaged.
6. Obtain new or previously cleaned gasket from the storage area and place the new gasket onto the ABL firmly, making sure it is well secured into place
7. Document the inlet gasket replacement manually or Scan the barcode on the packaging of a new inlet gasket
8. Type initials in operator notes
9. Replace the syringe and capillary inlet flaps
10. Choose "Restart" touch key
11. Soak old inlet gasket in Deconex or a similar detergent then soak in water for 30 minutes
12. Dry clean gasket and place in the designated storage area
13. Inlet gaskets should be discarded after site specific usage schedule

B. **Protein Removal (Deproteinization)**

1. Obtain Hypochlorite Solution, stored at 2-8 C
2. Pull 1 mL of solution into syringe provided
3. On Radiometer screen: Press *Menu – Start Programs*
4. Choose *Auxiliary Programs*
5. Select *Protein Removal*
6. Open Inlet
7. Place syringe at inlet gasket
8. Press Start
9. Remove syringe when prompted
10. Instrument will return to Ready mode when completed
11. Document running protein removal by doing the following: Analyzer Status>Electrodes and Other>Highlight Run Protein Removal>Log Activity>Enter Operator's Initials>Choose Done

C. **Document Weekly Maintenance according to site specific method.**

VI. BI-WEEKLY MAINTENANCE (IF APPLICABLE):

A. **Replace Crea A and Crea B Membrane**

1. Lift electrode cover
2. Wait for instrument to drain and enter the Hold mode
3. Press the tab on the electrode housing cover to release the housing cover and expose electrode
4. Remove the electrode from the analyzer
5. Creatinine membranes are stored at 2-8˚C.
6. Always replace both Crea A and Crea B membranes at the same time
7. To remove the used electrode jacket, press the tabs on the sides of the jacket and pull
8. Rinse the electrode with water, then shake it to remove the excess water. Do not dry the electrode. Verify that the Sealing Ring on the bottom of the electrode is in place.
9. Remove the protecting foil of a sealed electrode jacket in the Membrane Box by pulling upward
10. Open a capsule of electrolyte solution and empty contents into the electrode jacket
11. Press the electrode firmly into the electrode jacket until it clicks into place
12. Remove the membraned electrode from the Membrane box
13. Dry the electrode contact and install the electrode in the analyzer
14. Push the electrode housing closed gently; yet firmly, until you hear a click
15. Close the electrode cover
16. Scan the barcode on the membrane box to document the replacement
17. Choose the **Restart** touch key
18. Perform a 2-point calibration and QC if no other maintenance is needed

B. **Document Bi-weekly maintenance according to site specific method.**

VII. MONTHLY MAINTENANCE:

A. **Replace Glucose and Lactate Membrane**

1. Lift electrode cover
2. WAIT for instrument to drain and enter the Hold mode
3. Press the tab on the electrode housing cover to release the housing cover and expose electrode
4. Remove the electrode from the analyzer

5. Lactate membranes are stored at 2-8˚C
6. Glucose membranes are stored at 2-25 C
7. To remove the used electrode jacket, press the tabs on the sides of the jacket and pull
8. Rinse the electrode with water, then shake it to remove the excess water. Do not dry the electrode. Verify that the Sealing Ring on the bottom of the electrode is in place.
9. Remove the protecting foil of a sealed electrode jacket in the Membrane Box by pulling upward
10. Open a capsule of electrolyte solution and empty contents into the electrode jacket
11. Press the electrode firmly into the electrode jacket until it clicks into place
12. Remove the membraned electrode from the Membrane Box
13. Dry the electrode contact and install the electrode in the analyzer
14. Push the electrode housing closed gently; yet firmly, until you hear a click
15. Close the electrode cover
16. Scan the barcode on the box and document with operator's initials
17. Choose the "Restart" touch key
18. Perform a 2-point calibration and run all levels of QC if no other maintenance is needed

B. **Replace Reference Membrane**

1. Lift electrode cover
2. WAIT for instrument to drain
3. Enter the Hold mode
4. Press the tab on the Reference Electrode housing cover to release the housing cover and expose the electrode
5. Remove the electrode from the analyzer
6. To remove the used electrode jacket, hold firmly on the sides of the jacket and pull
7. If the used O-ring remains on the electrode, remove it
8. Rinse the electrode with warm water and dry with a lint-free tissue
9. Remove the protecting foil of a sealed electrode jacket in the Membrane Box by pulling upward
10. Press the electrode firmly into the electrode jacket, through the protective film, as far as possible
11. Remove the membraned electrode from the Membrane Box
12. Rinse the membraned electrode with water and dry with lint-free tissue
13. Dry the electrode contact and install the electrode in the analyzer
14. Push the electrode housing closed gently; yet firmly, until you hear a click

15. Close the electrode cover
16. Scan the barcode on the box and document with operator's initials
17. Choose the "Restart" touch key
18. Perform a 2-point calibration and run all levels of QC if no other maintenance is needed

C. **Document monthly maintenance according to site specific method.**

VIII. QUARTERLY MAINTENANCE:

A. **Perform tHb Calibration**

1. Perform Protein Removal procedure (see Weekly Maintenance)
2. Perform a 1 point or 2 point calibration
3. Select Analyzer Status touch key
4. Select Calibration touch key
5. Select tHb Cal touch key
6. Enter the bar code from the tHb Calibration Solution insert, using the bar code reader or the keyboard
7. Tap the top of the tHb Calibration Solution ampoule to collect the liquid at the bottom and break off the ampoule neck, using the ampoule opener
8. Put the ampoule in the black H700 ampoule adapter
9. Open the syringe inlet flap and place the adapter tip into the inlet
10. Press the Start touch-key to aspirate the calibrating solution
11. When prompted by the analyzer, remove the adapter and close the syringe inlet flap. Do not discard the calibrator ampoule, as it will be used for the calibration verification.
12. After measurement, a rinse is performed and then the analyzer returns to the Ready mode
13. Verify the tHb Calibration:
    a. Open the syringe inlet flap and place the adapter with the tHb calibrator solution into the inlet
    b. Select Syringe-S195 µL or Short Syringe-S95µL touch key
    c. Press the Start touch-key
    d. Remove the ampoule when prompted and close the inlet
    e. If the ctHb value is within the insert limits, the tHb calibration is accepted
    f. If the ctHb value is outside the insert limits, repeat the tHb calibration

B. **Replace the Ca++, Na, K and Cl Electrode Membranes**

1. Lift the electrode cover

2. WAIT for instrument to drain and enter the Hold mode
3. Press the tab on electrode housing cover to release the housing cover and expose the electrode
4. Remove the electrode
5. To remove the used electrode jacket, press the tabs on the sides and pull
6. If salt deposits are present on the O-ring, rinse the electrode with water, then shake it to remove excess water. Do not dry the electrode.
7. Remove the protecting foil of a sealed electrode jacket in the Membrane Box by pulling upward
8. Press the electrode firmly into the electrode jacket until it clicks into place
9. Remove the membraned electrode from the Membrane Box
10. Dry the electrode contact and install the electrode in the analyzer
11. Push the electrode housing closed gently; yet firmly, until you hear a click
12. Close electrode cover
13. Scan the barcode on the box and document with the operator's initials
14. Choose the "Restart" touch key
15. Perform a 2 point calibration and run all levels of QC if no other maintenance is needed

C. **Replace pO2 Electrode Membrane**

1. Lift electrode cover
2. WAIT for instrument to drain and enter Hold mode
3. Press the tab on the electrode housing cover to release the cover and expose the electrode
4. To remove the used electrode jacket, press the tabs on the sides and pull
5. If the sensitivity (found on Calibration Status) exceeds 30pA/mmH then brush the electrode tip with small red brush per package insert
6. Rinse the electrode with water, then shake it to remove excess water. Do not dry the electrode. Verify that the Sealing Ring on the bottom of the electrode is in place
7. Remove the protecting foil of a sealed electrode jacket in the Membrane Box by pulling upward
8. Press the electrode firmly into the electrode jacket until it clicks into place
9. Remove the membraned electrode from the Membrane Box. IMPORTANT: If air bubbles exist between electrode tip and membrane remove them by pressing tabs on electrode jacket and moving electrode slightly up and down until they disappear. Then press electrode firmly into electrode jacket.
10. Dry the electrode contact and install the electrode into the analyzer
11. Push the electrode housing closed gently, yet firmly, until you hear a click

12. Close electrode cover
13. Scan the barcode on the box and document with the operator's initials
14. Choose the "Restart' touch key
15. Perform a 2 point calibration and run all levels of QC if no other maintenance is needed

D. **Replace pCO2 Electrode Membrane**

1. Lift electrode cover
2. WAIT for instrument to drain and enter the Hold mode
3. Press the tab on the electrode housing cover to release the cover and expose the electrode
4. To remove the used electrode jacket, press the tabs on the sides and pull
5. Rinse the electrode with water, then shake it to remove excess water. Do not dry the electrode. Verify that the Sealing Ring on the bottom of the electrode is in place.
6. Remove the protecting foil of a sealed electrode jacket in the Membrane Box by pulling upward
7. Press the electrode firmly into the electrode jacket until it clicks into place
8. Remove the membraned electrode from the Membrane Box. IMPORTANT: If air bubbles exist between electrode tip and membrane, remove them by pressing tabs on the electrode jacket and moving electrode slightly up and down until they disappear. Then press electrode firmly into jacket.
9. Dry the electrode contact and install the electrode in the analyzer
10. Push the electrode housing closed gently; yet firmly until you hear a click
11. Close the electrode cover
12. Choose "Restart" touch key
13. Scan the barcode on the box and document with the operator's initials
14. Perform a 2 point calibration and run all levels of QC if no other maintenance is needed

E. **Document Quarterly maintenance according to site specific method.**

IX. 6 MONTH MAINTENANCE:

A. **Clean/Replace Fan Filter**

1. Locate the fan filter on the back right side of the analyzer
2. Remove and clean or dispose of the old filter
3. Obtain new fan filter from the ABL Storage area
4. Place new or cleaned fan filter into position on the back of the analyzer
5. In the Hold mode, filter replacement may be documented manually or by scanning the barcode on the package

6. Press keyboard button and type initials in operator notes for documentation.

B. **Replace Electrode Module Pump Tubing**

1. Enter the HOLD mode by lifting the electrode cover
2. WAIT for the instrument to drain
3. Disconnect the ends of the tube from the connectors
4. Gripping one end of the tube, free the fastener from the fastener slot by pulling upward
5. Pull upward to free the remainder of the tube from around the pump rotor and the other fastening slot
6. Place a new pump tube around the pump rotor
7. Secure the upper fastener of end of tube in the fastening slot
8. Gripping the other fastener, wrap the tube around the pump rotor. Secure the other fastener in the other fastening slot
9. Press the Rotate Pumps touch-key to turn the pump and seat the tubing into position
10. Attach the ends of the tube to the connectors, pushing the tube onto the connector as far as possible
11. Scan the barcode on the tubing package and document with the operator's initials
12. When all tubing has been replaced, close the lid on the electrode cover
13. Select the Restart touch-key. The instrument will automatically perform a Pump Calibration and Liquid Sensor Adjust.

C. **Replace Solutions Pump Tubing**

1. Enter the HOLD mode by lifting the electrode cover
2. WAIT for the instrument to drain
3. Remove the pump clamp and disconnect the ends of the old tube from the connectors
4. Gripping one end of the tube, free the right fastener from the fastener slot by first pulling outward and then lifting upward
5. Pull upward to free the remainder of the old tube from around the pump rotor and out of the other fastening slot
6. Secure the fastener of the left-short-end of the new tube in the fastening slot. The short end of the tube is to be on the left, the long end on the right.
7. Gripping the longer fastener, wrap the new tube around the pump rotor. Secure the fastener in the other fastening slot.
8. Press the Rotate Pumps touch-key to turn the pump and seat the tube
9. Attach the ends of the tube to the connectors, pushing the tube onto the connector as far as possible
10. Slide a new pump clamp (supplied with the pump tubes) over the right side

connector so that it is seated over the enlarged portion of the tube end, then clamp it shut

11. Scan the barcode on the tubing package and document with the operator's initials
12. When all tubing has been replaced, close the lid on the electrode cover
13. Select the Restart touch-key. The instrument will automatically perform a Pump Calibration and Liquid Sensor Adjust.

D. **Replace the Waste Pump Tubes**

1. Enter the HOLD mode by lifting the electrode cover
2. WAIT for the instrument to drain
3. Gripping one end of the tube, free the right fastener from the fastener slot by first pulling outward and then lifting upward
4. Pull upward to free the remainder of the old tube from around the pump rotor and out of the other fastening slot
5. Remove the lower tube in the same manner
6. Take the short end of the one of the new tubes and place the fastener into the lower right side fastening slot
7. Gripping the other fastener, wrap the tube around the pump rotor, making sure that the tubing is going into the bottom tubing slot Secure the fastener in the lower left side fastening slot
8. Select the Rotate Pumps touch-key
9. Connect the right end of the new tube to one of the right-side connectors and the left end of the tube to one of the left-side connectors. Ensure that tube ends are pressed completely onto the connectors.
10. Repeat steps 6-9 with the other tube except securing the tube fasteners in the upper fastening slots
11. Scan the barcode on the tubing package and document with the operator's initials
12. When all tubing has been replaced, close the lid on the electrode cover
13. Select the Restart touch-key. The instrument will automatically perform a Pump Calibration and Liquid Sensor Adjust.

E. **Document 6 month maintenance according to site specific method.**

X. AS NEEDED MAINTENANCE:

A. **Inlet Probe Replacement**

1. Remove the upper cover of the instrument. The instrument will enter the Hold mode.
2. Remove the blue inlet flaps
3. Remove the inlet gasket by lifting it straight up
4. Lift clip holding probe in place in the attachment

5. Lift the inlet probe out of the attachment
6. Connect the new inlet probe to the tubing
7. Place the new probe (flat side up) onto the attachment
8. Close the clip to hold the probe in place
9. Replace the inlet gasket and blue inlet flaps
10. Replace the upper cover of the instrument
11. Scan the barcode to document the probe replacement
12. Press keyboard button and type initials in operator notes for documentation.
13. Choose **Restart** touch-key

B. **Cleaning Procedure**

1. Select Auxiliary Programs touch key
2. Select Cleaning touch key
3. Analyzer will return to Ready mode when finished

NOTE: Cleaning procedure MUST be done immediately after a cord blood sample has been analyzed.

C. **Document any "As Needed" maintenance according to site specific method.**

XI. TROUBLESHOOTING TECHNIQUES:

A. **Clots**

The following problems are due to clots from specimens

1. Rinse dripping out of the inlet gasket
2. "Sample error" on printout when trying to analyze a sample
3. "Sample integrity" on printout when trying to analyze a sample
4. Failed membrane, indicated in "yellow' on the instrument. If there is a failed membrane, clean the membrane chamber first before performing the clot removal procedure.
    a. Enter the HOLD mode by lifting the electrode cover
    b. Remove the failed membrane from the chamber
    c. Using a cotton applicator stick, moisten with water and clean inside the chamber
    d. Using a dry cotton applicator stick, dry the chamber
    e. Put the electrode back into the chamber
    f. Close the cover and choose "Restart" touch key
    g. Once in "Ready " mode, perform the Clot Removal procedure as follows;

B. **Perform Clot Removal Procedure**

1. Check inlet nipples and tubing for clots. Clean and replace as necessary
2. Perform a Protein removal
3. Perform a Cleaning procedure
4. Perform a Tube refill
5. Perform a Liquid sensor adjust
6. Perform a Pump calibration
7. Perform a 2 point calibration
8. Run 3 levels of QC

Once all of the clot removal procedure has been completed and the instrument still fails, call Radiometer customer support. The phone number is located on the front of the instrument.

XII. REFERENCES:

A. Radiometer Medical A/S, ABL 800 Series Operator's Manual, 2017
B. Radiometer Medical A/S, ABL 800 Series Reference Manual, 2017

Approval Signatures

Step Description	Approver	Date
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