



3240 Whipple Rd, Union City, CA 94587

June 15, 2009

SOFTWARE UPGRADE NOTIFICATION

Dear Piccolo[®] Xpress[™] Customer:

Enclosed is Piccolo Xpress[™] software version 2.1.19. Significant improvements have been made, therefore installing this latest version of software is highly recommended for optimal use of your Piccolo Xpress. The software upgrade does not impact ASTM connectivity or stored information. Please be sure to notify your LIS/EMR provider.

Updating to version 2.1.19 software provides such benefits as:

- estimated Glomerular Filtration Rate (eGFR)
- Upgraded connectivity and communications
- Algorithm modification for advanced analyte precision

Included in this package are:

- Piccolo Xpress software version 2.1.19 CD
- eGFR description and operation
- Software installation instructions

Software installation instructions can also be found in the Piccolo Xpress Operator's manual; section 9.4, pages 9-3 to 9-4.

If you have questions, need assistance with the software installation or **you are not the main Piccolo Xpress operator for your facility**, please call Abaxis Medical Technical Support at 1-800-822-2947.

Ron Blasig

Director of Medical Technical and Customer Support



eGFR Description and Operation

eGFR:

Abaxis has responded to the many physicians that have requested an automatic eGFR calculation from the Creatinine values on the Piccolo Xpress™. You will see this calculation on all results printouts for panels that include creatinine, if the eGFR option has been selected through the advanced options menu.

Creatinine is commonly measured as an indicator of kidney disease and is filtered from the blood by the glomerulus network in the kidney, then excreted into the urine. Individuals with kidney disease slowly lose the ability to remove creatinine from the blood, resulting in increased blood creatinine. As kidney function worsens, due to diseases such as diabetes, hypertension, or cardiovascular disease, the GFR decreases or the ability of the kidney to remove the waste products decreases. Measurement of GFR provides a good assessment of the magnitude of kidney disease. In addition, following the rate that the GFR decreases over time allows physicians to predict at what point an individual will require dialysis due to renal failure. eGFR, has been recommended to be reported by all laboratories whenever a serum creatinine is measured.

The Xpress™ uses the built in equation, Modification of Diet in Renal Disease (MDRD) currently recommended for estimating the GFR based on measured creatinine calibrated to be traceable to Isotope Dilution Mass Spectrometry (IDMS). eGFR calculation should only be used in individuals 18 years of age or greater, but not over 70 years of age. The equation should not be used in pregnant women, individuals with cancer, amputees, and individuals with extremes in body size, muscle mass or nutritional status. Compared to serum creatinine, the eGFR more reliably detects kidney disease in its early stages because the eGFR is calculated using creatinine as well as patient age, sex and race. The National Kidney Foundation (NKF) suggests only reporting actual results once values are <60 ml/min (normal values are 90-120 ml/min, according to the NKF). An eGFR below 60 ml/min suggests that some kidney damage has occurred. The NKF recommends that your eGFR result be interpreted in relation to your clinical history and presenting conditions.

eGFR Xpress™ Operation:

eGFR is turned off by default. It will still show on the print card directly below CRE with a result of N/C (for Not Calculated). To turn on eGFR the user needs to select eGFR under the advanced icon (light bulb). Or, they need to manually enable the Age, Race and Gender prompts under the advanced icon. The user may enable DOB (Date of Birth) under the Alternate ID section of the advanced icon instead of, or in addition to, the age prompt. If both are enabled the Age prompt takes precedence. If eGFR is enabled, the prompts are always there regardless of the rotor that is run. Even if the rotor doesn't include CRE. If the user fails to enter one of the 3 items necessary to perform the calculation, the results will not be calculated. The displayed results will be N/C. If the calculation is enabled using the eGFR choice under the advanced icon, no error report will be automatically printed when the operator doesn't enter all the information. If the operator enables the prompts individually, an error report will be automatically generated.

The official units for eGFR are mL/min/1.73 m (squared). We are using the alternate units of mL/min (so we can print them).

installation instructions

Update the analyzer software as follows:

1. In the Home screen, press the **Settings** icon.



2. Press the **More Settings** icon.

Note: If you have enabled the security settings for an administrator password, this security feature will be in effect.



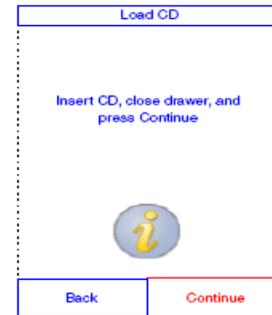
3. Press the **Software Update** icon.



From the back side of the analyzer-

4. Place the CD in the drawer, press the drawer inward to close it, then press **Continue**.

(Press the information icon  for additional help.)



5. The software update then begins.

When the update is complete, the analyzer automatically shuts down and restarts.

You can then remove the CD from the drawer.



CAUTION: *Do not remove the CD or remove power until after the analyzer shuts down and restarts to complete the software update, or you could damage the analyzer.*

6. To verify the software has been successfully updated, see the Operator's Manual, Section 4.6, page 4-17.