



Technical Update

from Radiometer Medical ApS

RADIOMETER

Mandatory Field Action

Recommended Field Action

Product: ABL90 FLEX

Scope: Release of Software V2.8

Background: We have released a new software version for the ABL90.

The following improvements have been implemented in the software:

Linearity of Glucose

The linearity of the glucose is dependent on the oxygen tension of the sample. This dependence is due to the co-reaction of glucose and oxygen by the enzyme glucose oxidase. Very low pO_2 levels can influence the linearity of the glucose sensor. As a consequence of this Glu results will no longer be reported when the pO_2 value is below 25 mmHg. Instead the following message will be reported.

No.	Message	Interpretation
1387	Glu not usable	Glu is not usable as pO_2 is below 25 mmHg

Result Outside Reportable Range

Measured results outside the reportable range were previously shown as blank results. With the new software the analyzer may be set to indicate ">x.xx" or "<x.xx" where x.xx is the high or low limit of the reportable range that has been exceeded. See Notes below.

Expansion of reportable range

Radiometer has tested and verified the performance of pO_2 and cNa^+ at extended lower levels and as a consequence thereof expanded the reportable range.

Composed by: Mogens Thomasen
Senior Specialist,
Technical Product Support

Date: August 30, 2012

Ref.: TU0092

Sensor	New lower limit
pO ₂	10 mmHg
Na ⁺	95 mmol/L

tHb offset

It is now possible to adjust both the offset and slope for the tHb. Previous versions only allowed adjustment of the slope.

User interface

A general update of the user interface has been made. This means that most of the animated videos are now replaced with "live" videos.

The sample process has also been updated with a three step process and video, in order to better guide the operator through the sample aspiration process.

Furthermore, a number of corrections have been implemented in the software, e.g.:

- Video with paper replacement was shown during SP replacement
- OIR replacements not restricted by access rights as set up for Guided Troubleshooting
- Inlet gasket replacement shown in "Other activities" window when overdue.

Action: **The actions below are mandatory because of the linearity issue with Glucose.**

1. Translate the customer letter into your local language, as necessary, and print on your official company paper.
2. Upgrade the software in all ABL90 FLEX analyzers to **V2.8**
3. Provide each customer with the customer letter as well as a copy of the Update kits for the Operator's and Reference Manuals

Completion Date: The confirmation fax must be returned by **January 31, 2013** to confirm that the actions have been completed.

Inquiries: Please refer all inquiries related to this Technical Update to RMED Technical Support:

Email: technical.support@radiometer.dk or

Telephone: +45 4010 8827

Tools:

Software:

Please refer to separate email including a link for download of the software.

Additionally, the software will become available on CD under part number 933-265.

Update kit for the Operator's Manual

Language	Code no.	Edition
English	995-411	201207A
Chinese	995-303	201208A
French	995-415	201208A
Russian	995-316	201208A
Spanish	995-414	201208A

Update kit for the Reference Manual

Language	Code no.	Edition
English	995-427	201207A
French	995-430	201208A
Spanish	995-428	201208A

More information: Please refer to separate email including the external release note.

Notes: To enable "Result Outside Reportable Range" add the following to roma.ini under System Settings:

[SystemSettings]
ShowValuesOutOfReportableRange=1



TU0092
Complete.doc



TU0092 Customer
Letter.doc

Submitted by:

6.12/14
[Signature]
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(Note as received from our Supplier)



Dear all

ABL90 software version 2.8 (933-265) contains new features, improvements to existing functionality and error corrections

This software upgrade is mandatory please refer to TU 0092

- *This software will not at the moment be installed on ABL90 analysers shipped from Radiometer.*

1. New features and changes

1.1 Reportable range

Radiometer has added the possibility of showing the exceeded reportable range instead of a blank result if the measured parameter is outside of the reportable range.

By default this is not enabled, but by adding the following to the ROMA.INI file, this will be enabled:

[SystemSettings]

ShowValuesOutOfReportableRange=1

If so enabled, results below Reportable Ranges will be shown as '< x.xxx' and result above Reportable Ranges will be shown as '> x.xxx' where 'x.xxx' is the actually exceeded limit.

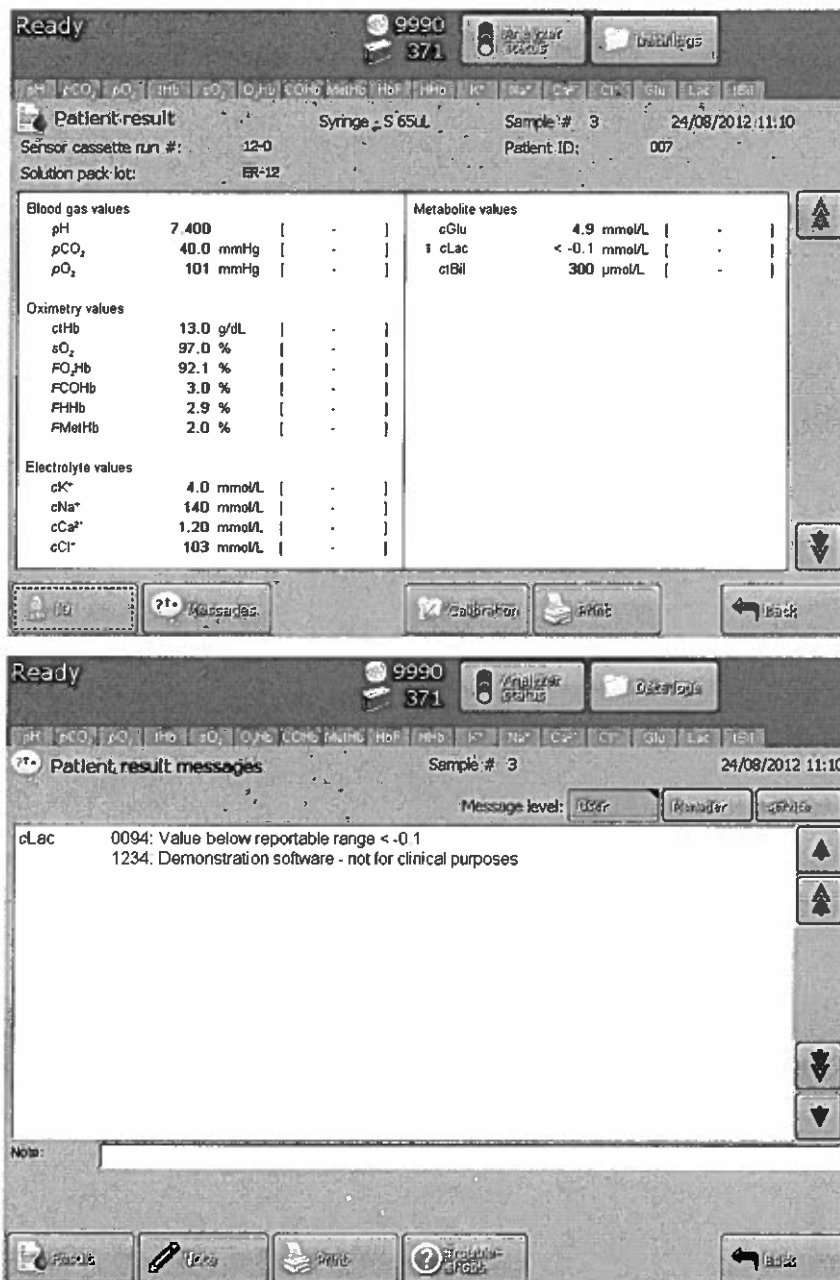
Furthermore error messages 0093 and 0094 will now have the range in the text:

0093 Value above the reportable range >10

0094 Value below the reportable range < -0.1

The triple up or down arrow will still be tagged to the parameter

See example below where the measured Lactate is below the reportable range of -0.1 mmol/L.



This will also be on the printout of the patient result.

< -0.1 will also be transmitted as the result to HIS/LIS systems and Radiance / AQUIRE. Error message 0093 and 0094 will still be transmitted as the message number only, No text is transmitted.

1.2 Reportable range expansion

Radiometer has tested and verified the performance of pO₂ and cNa⁺ at extended lower levels and as a consequence thereof expanded the reportable range.

Sensor	New reportable range
pO ₂	10 mmHg
Na ⁺	95 mmol/L

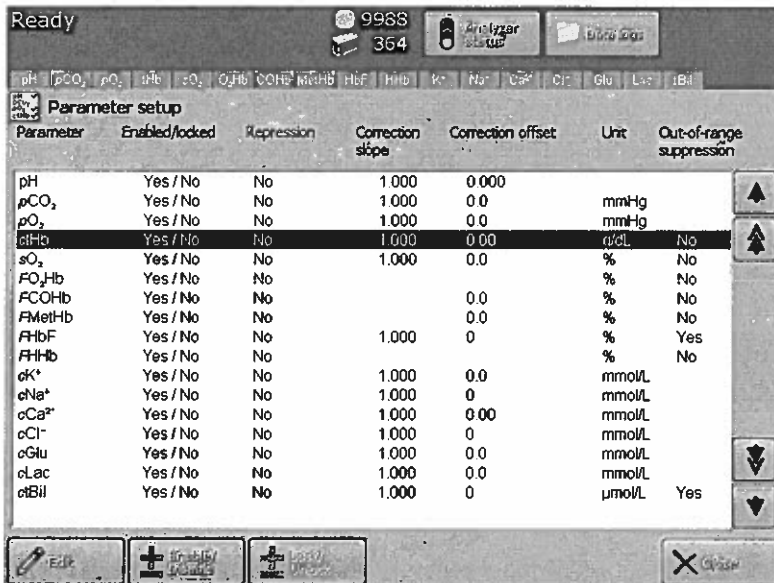
1.3 Blanking of Glu results when pO₂ is low.

The linearity of the glucose is dependent on the oxygen tension of the sample. This dependence is due to the co-reaction of glucose and oxygen by the enzyme glucose oxidase. Very low pO₂ levels can influence the linearity of the glucose sensor. As a consequence of this Glu results will no longer be reported when the pO₂ value is below 25 mmHg. Instead the following message will be reported:

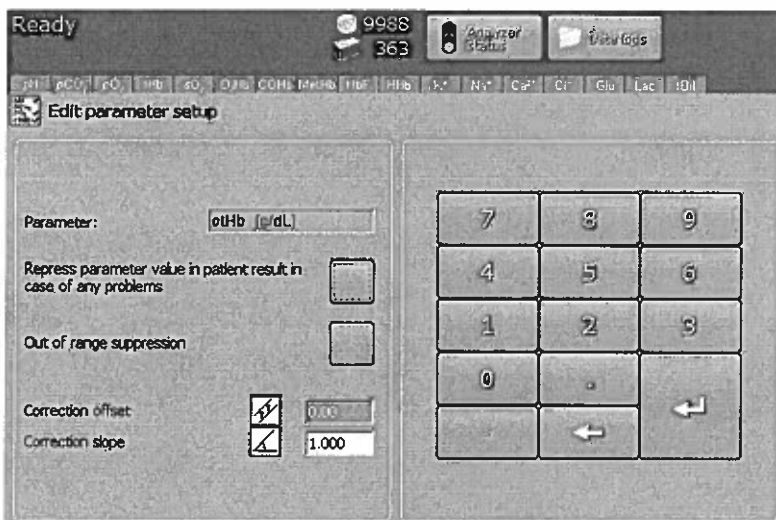
No.	Message	Interpretation
1387	Glu not usable	Glu is not usable as pO ₂ is below 25 mmHg

1.4 tHb offset

It is now possible to adjust both offset and slope for the tHb, previous versions only allowed correction of the slope. See example below.



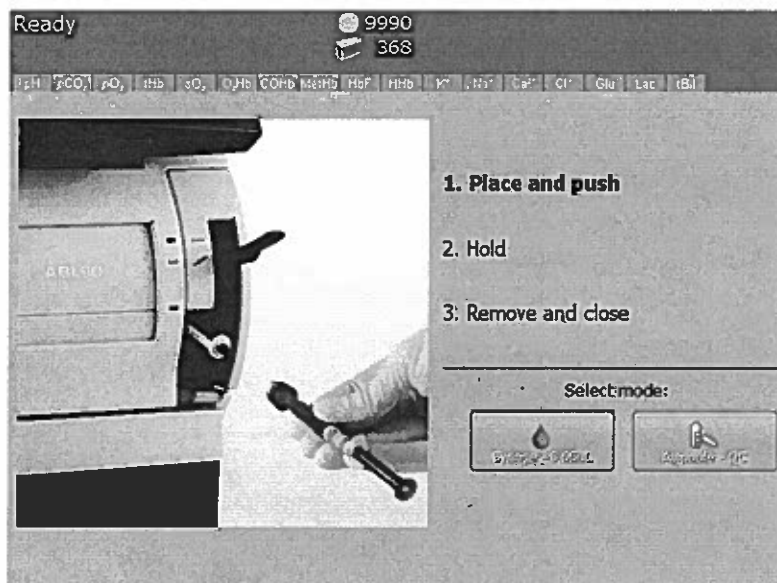
Please note that how much the offset can be changed is limited to +/- 2 mmol/L.



1.5 User interface

A general update of the user interface has been made. This means that most of the animated videos are now replaced with "live" videos.

The sample process has also been updated with a three step process and video, in order to better guide the operator through the sample aspiration process.



2. Errors corrected in this version

The following has been corrected in this software version:

TEP # (Techline #)	Error description	Status
TEP 2180	Print to internal printer fails when external printer is also selected for print	Corrected
TEP 3271	Language - Romanian – discrepancy Discrepancy in spelling of "Grafic acid - baza" and "Grafic acid - baze"	Corrected
TEP 3346	Video with paper replacement is shown in SP replacement	Corrected
TEP 3365	Icon mismatch between RilibÄK entry menu and Rilibäk range setup.	Corrected
TEP 3377 RAME 588248056	Report Layouts using 3 or more 'new page' not shown on ABL display. Performing a measurement using that layout will only show the first two pages of the result. Printing the result will show it all!	Corrected
TEP 3428 RLTD 580624380	OIR - barcode logons gets logged off very fast	Corrected

TEP # (Techline #)	Error description	Status
TEP 3517	OIR replacements not restricted by access rights When in the OIR screen it is possible for all operators, regardless of their access rights to perform replacements of solution pack and sensor cassettes.	Corrected
TEP 3536	Analyzer reacts on tap when screensaver is displayed. If there is a button on the screen exactly where the user taps then it will be activated.	Corrected
TEP 3580 RAME 624861855 RAME 625229620	Omitting mandatory QC input blocks QC ID. Mandatory QC temp is enabled. Run an ampoule QC without entering temp - exit. Repeat the process. Enter the QC log, select a result and try to enter the ID screen. QC ID is blocked and so are the rest of the buttons on the QC log screen.	Corrected
TEP 3595 RAME 623046297	QC default temp is wrong (89.6) when using Fahrenheit. Using F for temperature unit will cause the default QC temp to be 'locked' at 89.6 °F (= 32 °C). You can edit the field but the change will not be stored. The correct temp can be entered during QC measurement.	Corrected
TEP 3668	Inlet gasket replacement shown in "Other activities" window when overdue. The "inlet gasket" is shown in the "Other activities" window when replacement is overdue. Since the inlet gasket is re-categorized as a consumable it should no longer appear in the "Other activities" window.	Corrected
TEP 3681	Language: Danish 2 string errors. The error message for expired internal QC is written as: "0329: QC datou dløbet". The spacing is placed wrong. It should be: "0329: QC dato udløbet". Also the error message: "0090: QC er uden for kongrolgrænse" There is a spelling mistake in the last word. The string should read: "0090: QC er uden for kontrolgrænse"	Corrected

Please note that we have started including information about TEP number and Techline number if the corrected error was reported by a Techline case.

Please note:

- The previous version of servicedump.exe cannot be used on ABL90 with software version V2.5.1930.18 (or higher).
- The new version of servicedump.exe cannot be used on ABL90 with a previous software version (2.5.1930.13 or below).

3. Known issues in version 2.8

The following are issues Radiometer is aware of but so far have not found a solution for.

TEP #	Error description	Status
2868	<p>External barcode reader default enabled: As informed earlier the external barcode reader is per default enabled in ROMA.INI, preventing the setup of a serial ASTM connection. Due to production issues we will not change this default setting. The workaround is to change this in the ROMA.INI. Please see service tip 499846712 on how to do this. On existing installations do not select upgrade setup files (ROMA.INI) during installation of this new software, to preserve the changes already made to ROMA.INI.</p>	Will not be changed
3275	<p>Software shuts down when disconnecting from the QA portal In certain circumstances the ABL90 software will shut down when trying to disconnect from the QA portal. When doing as described below: 1. Start a Built in QC 2. Connect to QA Portal 3. Try disconnecting from QA portal 4. Press Close button while the pop-up message appears. The ABL90 software will shut down and the analyser needs to be rebooted.</p>	Root cause and counter measure to be determined
3562	<p>Wrong parameter names transmitted via ASTM The parameter names for the calibration parameters pO_2 sensitivity and pO_2 status are transmitted wrongly R 33 ^^^pH^Status^M 69.6 mV F R 34 ^^^pH^Sens^M 94.0 % F R 35 ^^^pO2^1^M 181.5 mmHg F R 36 ^^^pO2_CAL_SENS_Pct^M 94 % F R 37 ^^^pO2_CAL_STATUS_90^M -1.2 Text marked red is wrong. These descriptions are not supported by the ASTM standard.</p>	Root cause and counter measure to be determined

4. Manuals

New Operator and Reference manuals are available. See the list below for item and version numbers for the different languages:

Please note:

Some languages have gotten new part numbers for the Operator and/or Reference manuals with this software release.

New versions of the Operator's manual

Language	Code no.	Edition
English	995-420	201207A
Chinese	995-643	201208D
French	994-423	202108A
Russian	995-652	201208D
Spanish	995-421	201208A

Update kit for the Operator's manual

Language	Code no.	Edition
English	995-411	201207A
Chinese	995-303	201208A
French	995-415	201208A
Russian	995-316	201208A
Spanish	995-414	201208A

New versions of the Reference manual

Language	Code no.	Edition
English	995-435	201207A
French	995-438	201208A
Spanish	995-436	201208A

Update kit for the Reference manual

Language	Code no.	Edition
English	995-427	201207A
French	995-430	201208A
Spanish	995-428	201208A

5. Action:

The software has Thursday August 30 been sent to relevant service managers in a separate E-mail with a download link. Please download the software and copy it to a media of your choice (CD or USB memory stick).

It can also be ordered through Axapta (933-265) from Thursday August 30.

Installation procedure is as described in the service manual.

Best regards
Christian Knudsen
Technical Product Manager

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(Note as received from our Supplier)