DADE BEHRING

To whom it may concern

Unser Zeichen	☎ *Durchwahl*	*Fax*	*Datum*
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Field Correction
on
BEP® 2000 / BEP® 2000 Advance System Software

Dear Customer,

Our records indicate that you are using a BEP 2000® / BEP® 2000 Advance System. Dade Behring was informed by its supplier that BEP 2000® / BEP® 2000 Advance System software version 1.23 and all previous versions have a software error that can affect the alert function in case of insufficient volume pipetting under certain unusual circumstances.

Please be informed that in case only original Dade Behring assay definitions are used your system is not affected by the software error.

An exceptional combination of system settings combined with non-Dade Behring assay definitions can lead to the situation that an incorrectly pipetted sample will not be flagged accordingly.

Although up to now such an event has not been reported to us, in the following please find a problem description and an instruction on an appropriate workaround to avoid any problem.

The potential fault only occurs when the software switches from a „raise alarm and stop" to a „log and continue" pipettor error handling mode:

1. At the definition of a pipetting step for the function „Pipette -> Action On Error" „raise alarm and stop" was selected.
2. At the definition used for a pipetting step thereafter the function „Pipette ->Action On Error" „log and continue" was selected.

If an error occurs during the „raise alarm and stop" mode then the first error in the „log and continue" mode will not be reported. An example is given below:

- ·Option „raise alarm and stop" is activated for controls and standards
  and
- During pipetting of controls or standards there is insufficient volume
  and
- Option „log and continue" is activated for samples
  then

  No error flag is recorded in the „event log" for the first sample with insufficient volume after switching to a „log and continue" pipettor handling error mode. All subsequent samples with insufficient volume are recorded correctly.

Considering the conditions and sequence of events as described above the potential for an incorrect error code handling is considered as extremly rare.

However, in order to avoid the potential for an incorrect error flag recording please be advised to follow the instruction provided below:
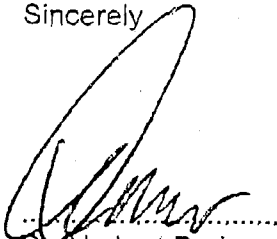
- The option „**Check reagent levels before a run**" (in accordance with Dade Behring's default settings in BEP® 2000 software) has to be activated

- Solely the „**log and continue**" pipettor error handling mode at all definitions of the pipetting steps under„Pipette -> Action On Error" has to be activated

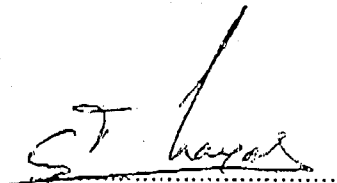If you have any questions or need assistance please contact your local Dade Behring representative.

Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you have transferred this product.

We apologize for the inconveniences this action causes and thank you for your continued support of Dade Behring Infectious Disease Diagnostics products.

Sincerely

Dr. Norbert Dedner
Director
Field Quality Assurance

Tarek El Nayal
Director
Global Product Marketing IDD