[redacted]

SIEMENS

**Urgent Field Safety Notice**

**BR-01212**

**January 2012**

**Syringes for BEP® III (OVDS21), lots DB0100, DB0101, DB0102, DB0103, DB0104**

**Leakage of syringes for BEP III in very rare cases**

Dear valued Customer,

Our records indicate that you have received one of the above mentioned lots of syringes for BEP III.

During recent investigations, Siemens Healthcare Diagnostics has observed that in very rare cases syringes of the affected lots may show a leakage. This may lead to a transfer of reduced volumes of conjugate, chromogen or stopping solution at the end of a pipetting sequence. In our internal investigations we have not observed wells into which absolutely no liquid was dispensed.

Please note that leaking syringes will not automatically lead to incorrect results. According to recently established data even a reduced volume that is pipetted will not negatively impact the result. Furthermore, controls at the end of a run will indicate a potential pipetting issue. In case of a competitive assay there is no risk of false negative results due to the test principle.

Siemens Healthcare Diagnostics is conducting a voluntary field corrective action to avoid the usage of leaking syringes. Therefore, as an immediate work-around a test procedure has been developed to detect potentially leaking syringes. This test procedure must be applied before using syringes for BEP III of the affected lots. Details on the test procedure are provided in Attachment 1. Please note that this test procedure was optimized for sensitivity and will sort out significantly more syringes than necessary.

Blood Donor Screening:
Due to our assessment based on the very rare cases of occurrence of leaking syringes and the low disease prevalence, it is not recommended to review previous test results or to repeat testing.

**Siemens Healthcare Diagnostics Products GmbH**

Emil-von-Behring-Str. 76
35041 Marburg, Germany

Phone: +49 6421 39-4511
www.siemens.com/diagnostics





[Tracking Number]

Non-Blood Donor Testing:
If no controls were used at the end of a run and the diagnosis is based on a single test result, we recommend discussing the content of this letter with your laboratory director regarding the need to review previous test results, conduct patient follow up, and/or repeat testing for tests conducted with the affected lots of syringes for BEP III as shown in the table below:

___First shipment dates for affected lots

| Lot No. Syringes for BEP III | First shipment |
|---|---|
| DB0100 | 2011-09-12 |
| DB0101 | 2011-09-30 |
| DB0102 | 2011-11-24 |
| DB0103 | 2011-11-23 |
| DB0104 | 2011-12-01 |

If valid control results were found at the beginning and end of a test series, it is not necessary to review previous test results or to repeat testing to exclude the risk of a leaking syringe having affected patient results.

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 may have transferred the affected lots of syringes for the BEP III.

The Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) has been notified of this action.

We apologize for any inconvenience that this situation has caused. Thank you for your patience and continued support.

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**FIELD CORRECTION EFFECTIVENESS CHECK**

Syringes for BEP III

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice dated January 2012 regarding leakage of syringes for BEP III in very rare cases. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare diagnostics at the fax number indicated at the bottom of this page.

| | | |
|---|---|---|
| 1. Did your facility receive a field correction letter from Siemens Healthcare Diagnostics regarding _____<br>[This question is necessary only if the Effectiveness Check Letter is mailed separately from the FCA Letter] | Yes | No |
| 2. Did we effectively communicate all necessary information? | Yes | No |
| 3. Do you now have any of the noted product on hand? (Please check inventories before answering.) | Yes | No |
| 4. If the answer to the question above is Yes, do you intend to take the recommended action as requested? | Yes | No |

Name of person completing questionnaire:

Title:

Institution: Instrument Serial Number:

Street:

City: State: Phone:

PLEASE FAX THIS COMPLETED FORM TO THE TECHNICAL SOLUTIONS CENTER AT (###) ###-####

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35041 Marburg, Germany

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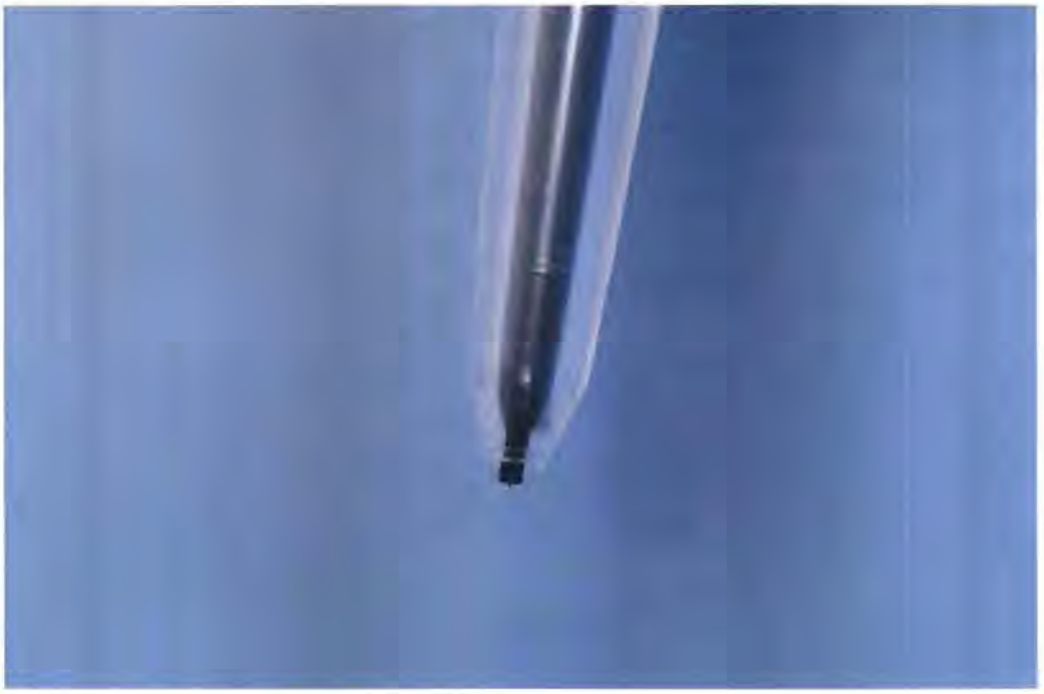
## Instruction to test BEP® III syringes

**Preparation:**

For the test you need an elastic sealing surface. We recommend using the rubber stops from the screw caps of Enzygnost glass bottles.

1. Clean the sealing surface with water to avoid contamination of the syringe tip.
2. Dry the rubber.
3. Ensure that the rubber is clean and free of particles.

**Note**
Ensure to protect the little tip of the plunger. When the plunger is fully in place its tip protrudes out of the syringe by 0.8 mm. It shall not be destroyed. The tip of the plunger is essential for the level detection.



Pict. 1: Syringe tip.

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**Creation of vacuum**

1. Pull the plunger half way up and back to its original position.
2. Pull the plunger for approx. 1 mm (the tip of the plunger must be fully in the syringe)

Pict. 2: Start position

3. Set the tip of the syringe on the sealing surface.

**Note**
Press the syringe with enough force onto the sealing surface to ensure that the syringe is safely sealed.

We recommend practicing a few times.

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Hold the syringe at the flange at the upper end of the cylinder (see video)

**Note**
This avoids an impact on the test result by holding and compressing the cylinder of the syringe.

4. Pull and turn the plunger half way up within the cylinder.

Hold the plunger safely and let it glide back.

**Note**

The created vacuum shall pull the plunger back.

5. Repeat three times.

**Note**

Ensure that the plunger is turned upon each repeat.

**Assessment**

1. After the third conducted gliding back of the plunger, measure its distance to the original position.
    - The syringe can be used, if the original position and the last position deviate by ≤ 3 mm (see pict. 3)
    - Dispose the syringe, if the distance is greater than 3 mm (see pict. 4)

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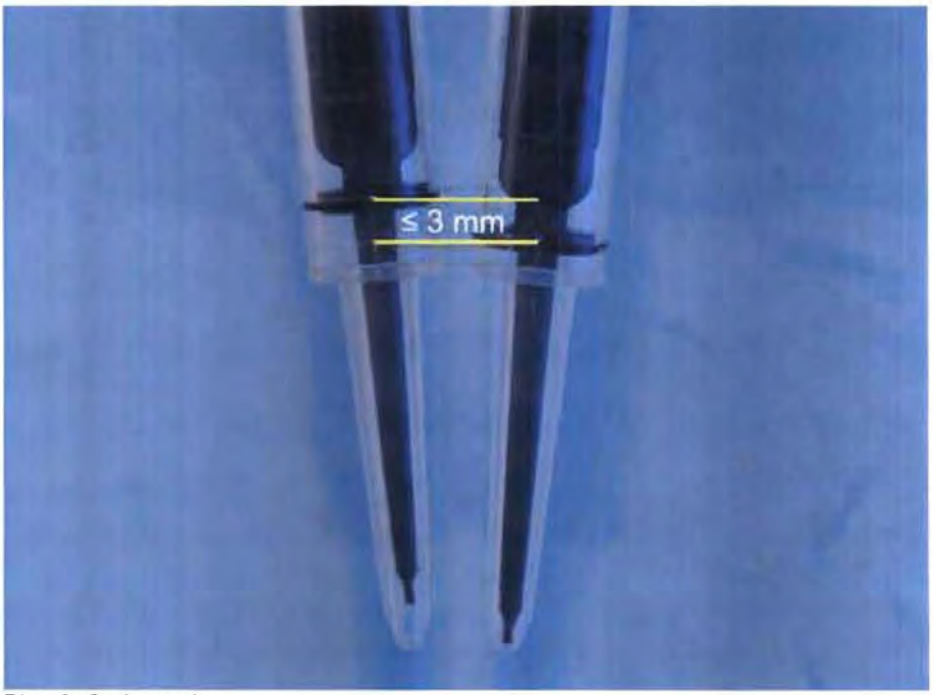
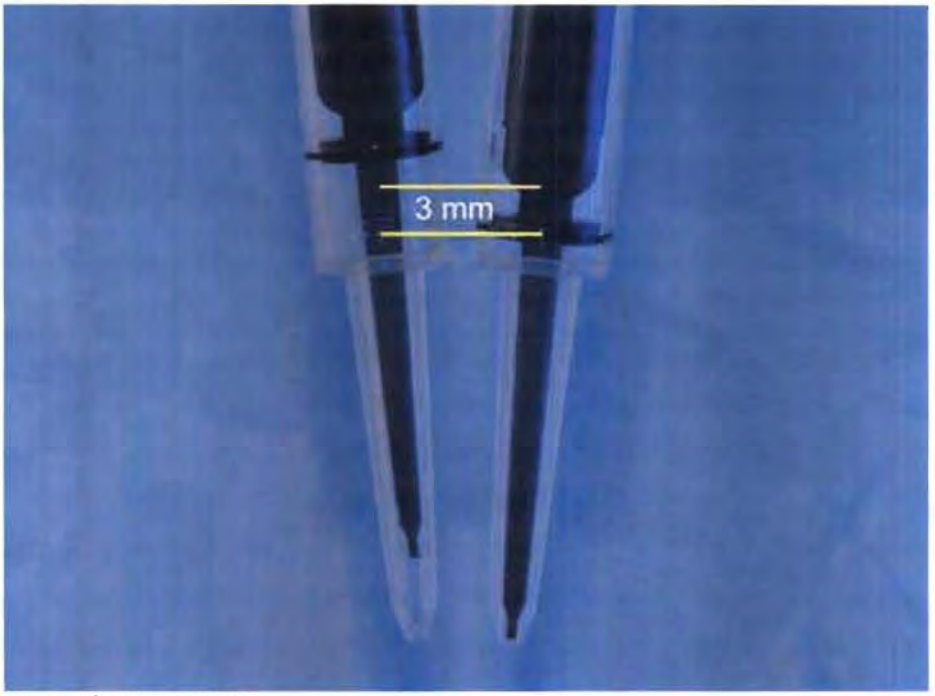


Pict. 3: Syringe ok



Pict. 4: Syringe not ok