Eurotrol
Your Global Reference Point for Quality Control

# MEDICAL DEVICE RECALL

# Eurotrol Hemoglobin Controls

22nd of October 2018

## Attention to Customer

Customer Name
Device Name
Street Address
City, State, Postal Code

Dear Device Customer/Distributor,

## Purpose of this letter

The purpose of this letter is to advise you that Eurotrol is voluntarily recalling the following batches of Eurotrol Hemoglobin Controls.

| Product name | Catalogue number | Batch number |
|---|---|---|
| HemoTrol Normal (Level 2) | 022.002.002 | 81102 |
| HemoTrol High (Level 3) | 022.003.002 | 82403 |
| HemoTrol Normal (Level 2) | 202.002.002 | 81102 |
| HemoTrol High (Level 3) | 202.003.002 | 82403 |
| CueSee® tHb Level 2 | 253.002.002 | 25302811 |
| CueSee® tHb Level 3 | 253.003.002 | 25303824 |

## Reason for the Voluntary Recall

This recall has been initiated due to incorrect measurement results caused by microbial contamination of the product. The failure results in values lower than assigned values.

We are aware of 23 complaints associated with the problem.

Approximately 20% of devices with batch number 81102 and 25302811 is affected by this problem.

Devices with batch numbers 82403 and 25303824 are recalled as a precaution. No complaints have been received regarding these batches nor did testing show deviating measurements.



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ABN AMRO Bank No. 56.18.38.909, BIC ABNANL2A, IBAN NL92ABNA0561838909, Trade register Arnhem 09067367, VAT No. NL009139448B01

## Risk to Health

There are 2 scenarios possible that could lead to a hazardous situation:

1. The product is malfunctioning and thereby causes a fail on a proper functioning analyzer.
2. The product is malfunctioning and wrongfully passes a malfunctioning analyzer.

The user of the control material is not at risk due to deviating measurement results caused by microbial contamination when the product is handled according to the IFU. There is however an indirect health hazard to the patient.

Conclusion from following subsections: The product is not likely to cause any adverse health consequences.

Fail to Qualify a Proper Functioning Analyzer

If an IVD analyzer has wrongfully failed Quality Control (QC) test due to a quality control material which is malfunctioning, this could result in delayed examination results. Local regulation may require regular QC measurement of IVD analyzers in order to release these for use. If the IVD analyzer is wrongfully rejected it cannot be used for measurements on patient samples. In such cases an alternative quality control material is required to release the equipment. If not available a hazardous situation may occur when a physician solely relies on the result of the analyzer and not take into account other patient symptoms and test results.

Wrongfully Pass a Malfunctioning Analyzer

Only if multiple failures occur sequentially this could result in harm to the patient. When the IVD analyzer has a malfunction which compensates (same magnitude, opposite direction) the malfunction of the quality control material, the analyzer reports measurements results within the assigned range. Malfunction of the QC could, in this unlikely case, lead to a wrongful pass of a malfunctioning IVD analyzer. This, in turn, could result in an incorrect examination result when measuring a patient sample and as a possible consequence lead to incorrect medical treatment of this patient. Resulting incorrect treatment could cause harm to a patient. This hazardous situation is considered to be highly unlikely because a physician does not solely rely on the hemoglobin result of the IVD analyzer but takes into account other patient symptoms and test results.

**How to recognize that the device may fail**

Too low readings on the analyzer could be an indication of a malfunctioning quality control material. Increase in viscosity of the liquid and/or presence of particles indicates a malfunction.

## Actions to be taken by the Customer/User

Immediately discontinue use of the listed batches and discard the product according local regulation on medical waste. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

Contact you distributor for alternative batches of the product in order to replenish your stock.

Please complete and return the enclosed response form as soon as possible. The acknowledgement can be given through email or telephone.



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## Product and Distribution Information

| Product Names | Catalog Number | UDI | Lot Number | Manufacturing Date | Expiration Date |
|---|---|---|---|---|---|
| HemoTrol Normal (Level 2) | 022.002.002 | - | 81102 | March 2018 | October 2019 |
| HemoTrol High (Level 3) | 022.003.002 | - | 82403 | June 2018 | January 2020 |
| HemoTrol Normal (Level 2) | 202.002.002 | - | 81102 | March 2018 | October 2019 |
| HemoTrol High (Level 3) | 202.003.002 | - | 82403 | June 2018 | January 2020 |
| CueSee® tHb Level 2 | 253.002.002 | - | 25302811 | March 2018 | October 2019 |
| CueSee® tHb Level 3 | 253.003.002 | - | 25303824 | June 2018 | January 2020 |

## Type of Action by the Company

The products will be removed from the market to resolve the potential health hazard. Alternative batches are available to ensure uninterrupted use of the products.

### Other Information

Your assistance is appreciated and necessary to prevent failure to pass properly functioning Hb201 analyzers.

Please complete and return the enclosed response form as soon as possible.

If you have any questions, please contact:

Name: Eurotrol B.V.
Address: Keplerlaan 20
Zip code & city: 6716 BS Ede
Country: The Netherlands
Phone: +31 318 695777
E-mail: office@eurotrol.com

Authorized by:

Name: (Print) _____

Signature: _____

Title: _____



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# MEDICAL DEVICE RECALL RETURN RESPONSE
## Acknowledgement and Receipt Form

Response is Required

**Customer Information:**

Customer Name
Street Address
Town, State, Postal Code

## EuroTrol Hemoglobin Controls

**Lot numbers:**

81102, 82403, 25302811, 25303824

**Please check ALL appropriate boxes and sign the form:**

☐ I have read and understand the recall instructions provided in the 22nd of October 2018 letter.
☐ I have checked my stock and have destroyed inventory consisting of _____ product boxes.

Any adverse events associated with recalled product? ☐ Yes ☐ No
If yes, please explain:

_____
_____
_____

Please check the appropriate box(es) to describe your business
☐ wholesaler/distributor ☐ hospital/medical facility ☐ medical laboratory

Affected product information: Include information that is applicable for affected product.

| Product Names | Catalog Number | UDI | Lot Number | Quantity in inventory | Quantity discarded |
|---|---|---|---|---|---|
| HemoTrol Normal (Level 2) | 022.002.002 | - | 81102 | | |
| HemoTrol High (Level 3) | 022.003.002 | - | 82403 | | |
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**Return Response Box:**

| **Please provide any additional information, if applicable.** |
|---|
| |

**Distributors Only:**

☐ I have identified and notified my customers that were shipped or may have been shipped this product by (**specify date and method of notification in return response box**); or

☐ Attached is a list of customers who received/may have received this product. Please notify my customers.

**Signature:**

| | |
|---|---|
| Name/Title | |
| Telephone | |
| Email address | |

Signature: _____ Date: _____

PLEASE MAIL COMPLETED RESPONSE FORM TO: recall@eurotrol.com



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