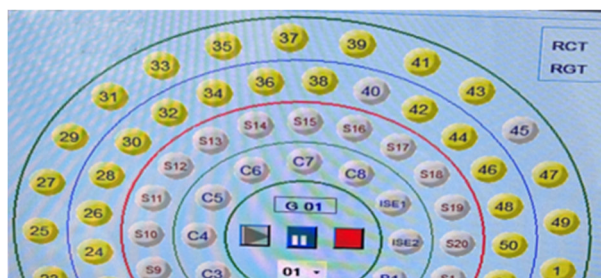


URGENT FIELD SAFETY NOTICE

Urgent directive for respons[®]940

Randomly incorrect allocation of a barcode to a sample on respons[®]940

Date	2024-10-01
Product	respons [®] 940 systems Cat. No.: 965900 (965400), 965910 (965500)
Explanation	DiaSys Diagnostic Systems GmbH has to inform you that in rare cases - when using the sample barcode reader to determine the positions of barcoded samples on the tray - a barcode may be accidentally allocated to the wrong sample position. In this case, the measurement results of the higher sample position number are assigned to the next lower sample position number and its corresponding patient. Additionally, the sample placed at that lower position number is not measured and not marked as pending. Manually allocated sample positions are not affected by the issue described above.
Impact on patient results	In above mentioned case, a reported result does not belong to the corresponding patient.
Measures	At the end of each run, the user must check whether the number of samples placed on the tray match with the amount of patient reports. In case of a mismatch, the skipped sample position (lower position number remains grey, e.g position 45 in picture below) and the subsequent sample (higher position number 46) must be re-measured.



Please immediately inform all involved users about this urgent directive, which is valid until further notice.

Previous and currently performed determinations with respons[®]940 using sample position detection via barcode reader that show the behavior described above shall be assessed with care and repeated if implausible results occur. Manually allocated sample positions are not affected.



URGENT FIELD SAFETY NOTICE

DiaSys has announced this field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

Under current regulations, we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we ask you to fill in and sign the attached confirmation of receipt as proof that you have received and communicated this information to all concerned customers. Please return it by fax or as scan until 2024-10-16.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.



CONFIRMATION OF RECEIPT

2024-10-01

Please confirm that the customer information mentioned below and attached to this mail, has been noted by the responsible person in your company:

Urgent Field Safety Notice – Randomly incorrect allocation of a barcode to a sample on respons[®]940

I confirm having forwarded the above-mentioned information to all customers using the mentioned DiaSys product.

Customer/Distributor name:

Contact:
(see signature)

Date and signature:

Please return this confirmation via fax +49-6432-9146 410 or via e-mail to qm@diasys.de until 2024-10-16

Thank you for your cooperation.