

Urgent Field Safety Notice

Notice Ref No:	FSN_SB_RPD_2012_12
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PRODUCT AFFECTED:	<cobas b 123 Fluidpack COOX , 200/400/700 >
SYSTEM AFFECTED:	< cobas b 123 POC system >
MATERIAL NUMBERS:	05169992001 05170036001 05170052001
LOT NO (IF APPLICABLE):	According to the table below
SUMMARY OF ISSUE:	Increased risk of OOB (out-of-box) failure rate for COOX calibration
ACTION REQUIRED:	Do not use and exchange the affected Fluid Pack
CONTACTS:	Technical Services: Country:

Reason for notice:

Recent investigation showed an increased risk of OOB failure rates of the listed lots of cobas b 123 POC system Fluid Packs COOX due to a layer thickness changes at the cuvette.

Dear Customer,

We regret to inform you that we identified an increased risk of OOB failure rates of certain lots of the cobas b 123 Fluidpack with COOX.

This OOB failure will lead to a non-calibration of the COOX parameters (Oximeter module: tHb, SO2, Hb derivatives and Bilirubin) and an exchange of the Fluid Pack must be performed.

All other parameters remain unaffected by this issue. There is no risk of incorrect measurements or results for any parameter.

As part of the root-cause analysis, a systematic and detailed testing was conducted. Please be informed that for the following 12 lots of cobas b 123 Fluid Pack COOX (**Lot number and GMMI/Ref. No. have to match**) there is a significantly increased risk of OOB failure rate:

GMMI / Ref. No.	Product Description	Lot No.
05169992001	cobas b 123 FLUID PACK COOX, 200	21426121 21426141 21426171 21426181
05170036001	cobas b 123 FLUID PACK COOX, 400	21426111 21426121 21426131 21426151
05170052001	cobas b 123 FLUID PACK COOX, 700	21426251 21426301 21426321 21426351

Please be aware that these packs can still be used for non-COOX measurements without any restrictions by deactivating the COOX parameter or using a non-COOX cobas b 123 POC system.

All lots which are now available in the Roche warehouse are tested and can be used without constraints. The same applies to all Fluid Packs without COOX and previous lots.

Actions required:

Please do not use the affected lots mentioned in the table above and immediately order new Fluid packs.

Until you will receive unaffected Fluid Packs please be aware that the use of the above mentioned lots is associated with a certain OOB failure rate.

Already calibrated in-use Fluid Packs can be used up as the failure only occurs at initial calibration.

Please be aware that the exchange of Fluid Packs from affected lots in an emergency situation should be avoided.

We apologize for any inconvenience caused by that issue.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency
(Closing paragraph)
Signature