

Urgent Field Safety Notice

Notice Ref No:	FSN RPD 2013_01
Document Date:	05-March-2013
Type of Action:	Field Safety Corrective Action required

PRODUCT AFFECTED:	<Glass syringe barrel>
SYSTEM AFFECTED:	< MODULAR ANALYTICS EVO>
MATERIAL NUMBERS:	Modular core with ISE (EVO) (material number 04998570001) Modular D module (EVO) (material number 04998618001)
LOT NO (IF APPLICABLE):	core unit serial number from 2269-10 to 2438-05 D module serial number from 2268-01 to 2490-06
SUMMARY OF ISSUE:	Some of the glass syringe barrels for the above mentioned serial numbers were not chamfered due to production failure. Accordingly, the seal piece of the syringe may get damaged leading to leakage.
ACTION REQUIRED:	Replacement of the glass syringe barrel for the affected serial numbers.
CONTACTS:	Technical Services: Country:

Reason for notice:

Some of the glass syringe barrels for the above mentioned serial numbers were not chamfered due to production failure which may lead to leakage.

Dear Customer,

We regret to inform you that some of the glass syringe barrels for the **MODULAR ANALYTICS EVO** core unit (serial number from 2269-10 to 2438-05) and D module (serial number from 2268-01 to 2490-06) were not chamfered due to production failure. On changing the seal pieces of the syringe during the preventive maintenance the affected glass barrels may lead to glass debris formulation which could damage the seal piece leading to leakage.

Actions required:

During the next regular scheduled preventive maintenance the syringe glass barrels for the affected serial numbers will be replaced by Roche field service engineer.

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