



**FRESENIUS
MEDICAL CARE**

Field Safety Notice

Fresenius Medical Care HD concentrates

Date: 14th Oct 2019

Our reference:

FSN201910HD

Affected article number / product name:

AP00250/F-A-21.5-G-34-5

Affected batch number:

A8ZG061

Dear customer,

During the continuous monitoring of our HD concentrates on the market, we became aware of increased reports of high conductivity alarm from our customers either during treatment or the self-test of haemodialysis machine with one single batch listed above. Following our complaint procedure for any suspected defect, our customers have contacted us and returned products from affected batch.

Based on the investigation, a deviation of sodium concentration in the solution was found which caused high conductivity alarm either detected during treatment or the self-test of the machine. We have included additional in-process control to guarantee product quality.

In order to avoid any potential risk, we ask you to immediately stop using the affected batch A8ZG061 and monitor patients who have used the affected batch.

Please provide this notice to all those who need to be aware of it and also complete the attached acknowledgement receipt.

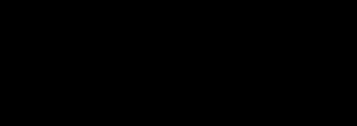
We sincerely apologize for the inconvenience and we will provide you with a replacement as soon as possible. You will be contacted by your local Fresenius Medical Care representative to organize the exchange.

In case of any further questions please do not hesitate to contact:

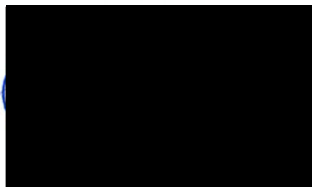
Name: Karen Ng



Sincerely yours,



Karen Ng
Business Director



cc: Chairman Medical Board and relevant Head of Departments