

Urgent Field Safety Notice

Restriction of the APEX time calculation use in the PatientOnLine software version 6.2

Date: December 17th, 2019

Dear customer,

As part of our continuous quality assurance process it was identified that the used method of APEX (Accelerated Peritoneal Equilibration Examination) time calculation in the PatientOnLine (POL) software version 6.2 can lead to deviating results for the APEX time. The calculation of the APEX time in POL 6.2 is not based on the original APEX test as defined and published by Dr. C. Verger ¹.

An incorrect calculation of the APEX time can lead to an inappropriate prescription. Multiple, consecutive treatments may result in an underachievement in terms of solute clearance and ultrafiltration.

To avoid the risk of an inappropriate prescription we ask you to no longer use the APEX time calculation feature in the POL 6.2 software.

Please make sure that all POL 6.2 users and other concerned persons in your organization are informed about this Field Safety Notice.

We sincerely apologize for the inconvenience and we will correct the failure as soon as possible.

Sincerely yours,



i.A. Matthias Keil
Senior Product Manager
Technical Operations



i.V. Marco Zimmer
Corporate Safety Officer
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References

1. Verger C, Larpent L, Veniez G, Brunetot N, Corvaisier B. L'APEX ... description et utilisation. Bull Dial Perit 1991; 1(2): 36-40.