

## First validation of devices communicating according to IEC PAS 63023

*Nikkiso's new machine DBB-EXA was introduced 1st of June 2015 and has now been validated to be used together with Redsense as per the new standard IEC PAS 63023. This means that the dialysis treatment will pause if the needle dislodges. The new Nikkiso dialysis machine, and Redsense, represents the first dialysis equipment world-wide that has validated connectivity following the IEC PAS 63023.*

- Nikkiso is one of the largest dialysis service companies in the world and it is a strong message when they choose to move forward with the PAS 63023 and validate together with Redsense, comment Patrik Byhmer CEO Redsense Medical.

IEC PAS 63023:2016 establishes a unique input interface for connection of an external alarming device to hemodialysis equipment. The input interface of the hemodialysis equipment is designed as a simple solution, which takes a single fault condition of the input interface into account, to stop the extracorporeal blood flow in case of needles slipping out from the fistula or graft detected by the external alarming device.

### More on Venous Needle Dislodgement (VND)

When the venous needle pulls out of the access site, it is referred to as venous needle dislodgement, or VND. Instead of the cleansed blood returning back to the patient's bloodstream, it is pumped into the chair, bed, or floor. This can lead to a rapidly declining blood volume, and may cause morbidity and mortality if not discovered quickly<sup>[1]</sup>. VND may range from minimal blood loss, if it is discovered as soon as the needle dislodges, to a fatal hemorrhage if not recognized in the first minutes. Time is of the essence because a patient will lose blood rapidly. Up to 40% of the total blood volume may be lost in a matter of minutes<sup>[2]</sup>. The challenge is that VND is very unpredictable. It can occur at anytime, to anyone. Even under ideal conditions<sup>[3]</sup>. It has been estimated that less than 29% of fistulas have the chance of initiating a pressure alarm.

<sup>[1]</sup> Axley, B., Speranza-Reid, J., & Williams, H. (2012). Venous Needle Dislodgement in Patients on Hemodialysis. *Nephrology Nursing Journal*, 39(6), 435-445

<sup>[2]</sup> Hurst J. It Can Happen Without Warning: Venous needle dislodgement. *Renal Business Today*, 4(9), 18- 22

<sup>[3]</sup> Hurst J. It Can Happen Without Warning: Venous needle dislodgement. *Renal Business Today*, 4(9), 18- 22