

Why Redsense?

First of all, it is a regulatory must to use state of the art safety precautions following European and North American Medical Device Directive (MDD) and dialysis standards.

However, to break it down:

The issue

Venous needle dislodgement (VND) is a potential life-threatening incident. ¹ Both American ² and Swedish ³ studies have shown that 1 in approximately 720 needles dislodge during hemodialysis treatment.

Following regulations, dialysis machines are equipped with blood pressure monitors. However, it has been shown that they are notoriously unreliable and cannot successfully trigger an alarm when the needle dislodges. ⁴

The importance

If a needle were to dislodge, completely or partially, the patient may lose 50% of total blood volume within 5 minutes due to the pressure in the venous access site.⁵ It has been shown that globally 21 patients die due to VND every week. Moreover, every day 21 patient get severely injured due to VND, and 2100 needles dislodge; and this EVERY SINGLE DAY.⁶

The solution

The go-to solution is monitoring hemodialysis for VND with the help of an external alarm. While enuresis alarms address the risk of blood loss, they introduce the risks of a non-sterile open wound in direct contact with an electric current. Redsense takes these risks out of the equation; fiber optics and light offer a safe alternative ⁷ for detecting blood leakage without introducing new hazards during the treatment. ⁸ The International Electrotechnical Commission's committee for dialysis has clearly stated in the standard for dialysis equipment (IEC 60601-2-16) that the pressure alarm isn't sufficient to detect VND. Therefore PAS63023 was released, which allows a dialysis machine to communicate with an external alarm such as Redsense and stop the blood flow when blood is detected.

Notable customers

The top 5 largest dialysis providers in the US use Redsense:

- Fresenius Medical Care North America
- DaVita Kidney Care
- U.S. Renal Care
- American Renal Associates
- Dialysis Clinic inc.

<https://www.healio.com/news/nephrology/20190723/large-providers-continue-strong-growth-in-home-dialysis>

Three in the top 5 best nephrology hospitals in the US use Redsense:

- Mayo Clinic
- New York Presbyterian
- Cleveland Clinics

<https://health.usnews.com/best-hospitals/rankings/nephrology>

Veteran affairs, USA – governmental mandate to use Redsense during hemodialysis treatments

Crosshouse, UK – PAS63023 connection to the machine

Dianet, NL – PAS63023 connection to the machine and connection to unit nurse call system

Vivantes, DE

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