



REDSENSE
medical

Let Redsense help
keep an eye on your
venous needles

- Reduce risk and cost

www.redsensemedical.com

Venous Needle Dislodgement

-A serious complication

Hemodialysis 15 hours per week

During Hemodialysis blood is cleared from waste products when our kidneys fail to do so. A typical dialysis session lasts 4-5 hours and is completed 3 times weekly. Throughout the world 2.5 million patients receive hemodialysis.

Blood access

During each dialysis session the blood access site is punctured with two needles. The blood is pumped through an artificial kidney where the blood is cleared from waste products before being returned to the patient in a loop.

A serious complication

Venous needle dislodgement, VND, is when the needle slips out and the returning blood is pumped onto the bed or chair instead of back to the patient's blood-stream. As much as 400-500 ml of blood is lost every minute and if not detected immediately the consequences may be catastrophic and in some cases fatal.

Equipment limitation

The hemodialysis equipment used today are not equipped to machines detect VND reliably. The method of detection is limited to pressure measurement. When the venous needle



is dislodged the pressure drop is too small to activate the system.

Measures for detection

VND can happen to anyone. Every attempt should be made to minimize the risk, and protection such as Redsense can be used to detect blood loss.

Venous Needle Dislodgement

-A safety problem



Dr. Sandroni published in 2009 that 0.0003% of VND incidents are fatal and 0.0008% are serious.⁴ The Department of Veteran Affairs presented similar data in 2008, showing 0.0016% of VND's are serious.¹⁷ VND incident rates, from RPA in 2007 show 0.1282% incident rate and data from Dr. Ahlmén in 2008 show 0.1736%.^{20,7}

Globally this would mean that:

21 patients die due to VND every week

21 patients are seriously injured every day due to VND

21 | 21 | 2100

2100 needles are dislodged every day

EDTNA/ERCA questionnaire recordings of 283 VND incidents indicate that 23% of VND's are serious and severe needing resuscitation to save patients lives and 5% either died or suffer from long term sequelae.

Avoid unnecessary risk by saving cost in healthcare

-Patients trust and safety

• Patient trust and safety

VND is one of the most serious complications in hemodialysis which can have tragic results if the dislodgement is not recognized immediately. Prompt recognition and response may prevent VND from developing into a disaster for everyone involved. Utilizing all resources available, from procedures to monitoring the access site by a blood loss detector such as Redsense, will provide a much needed security.²³

Globally VND incidents per year

Patients with VND, mean:		423 750
Ahlmén ⁷ (5/2880)	0,1736%	487 500
RPA* ² (1/156/4/0,05)	0,1282%	360 000
Patients with serious VND, mean		3 357
Veterans Affairs ¹⁷ (1/62500)	0,0016%	4 493
Sandroni ⁴ (1/126718)	0,0008%	2 216
Patient deaths due to VND, mean		650
Sandroni ⁴ (1/3*126718)	0,0002%	739
Gambro ²¹ (1/500000)	0,0002%	562

* Needle Dislodgement



Avoid unnecessary risk by saving cost in healthcare

-Healthcare savings

• Healthcare savings

Reduce the risk and reduce costs, the use of Redsense can save millions.

Cost savings, the use of Redsense can save millions:

Estimating the cost of Redsense 2.7 € per treatment (3 patients per device).

By using Redsense on 20% of the HD patients:

- Healthcare savings close to 200 000 000 € can be made annually.

Cost for a VND incident:²³

-VND minor:

Limiting intervention to blood transfusion and extra EPO dose which all can be carried out at the dialysis clinic and an extra day for observation:

Blood transfusion	970 €
Extra EPO	745 €
Extra day in hospital	2 980 €
<hr/>	
Total:	4 695 €

Based on Ahlmén study about 40% of the VND's need blood transfusion and two extra days in the hospital'

-Serious event with hospitalization:

Regular hospitalization for blood loss anemia (4 days) 170 000 €

1 day of anemia therapy includes EPO, blood transfusion, iron and possibly plasma expanders or albumin 42 500 € / day

Emergency Room (ER) 22 350 € or more

Intensive Care Unit (ICU), hospitalization (1 day) 14 900 € - 29 800 €

Thus cost range from 170 000 € to 223 500 € and up

Example: A patient in the ER for 4 h received oxygen at 2 L/min, blood drawn for routine panel, an abdominal CT scan; the bill was 24 700 €

Implementing Redsense is in alignment with the EU directive

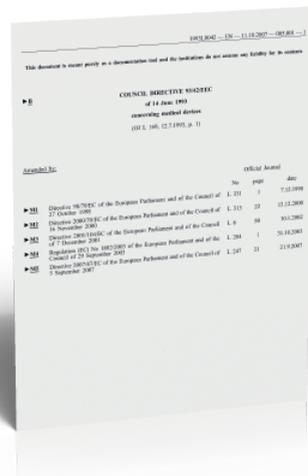
Council directive 93/42/EEC concerning medical devices

"The solutions adopted by the manufacturer for the design and construction of the device must confirm to safety principles, taking account of the generally acknowledged state of the art.

In selection of the most appropriate solutions, the manufacturer must apply the following principles in the following order:

- eliminate or reduce risks as far as possible (inherent design and construction)
- where appropriate take adequate protection measures including alarms if necessary, in relation to the risks that cannot be eliminated,
- Inform the user on the user of the residual risks due to any shortcomings of the measures adopted.^{1/32}

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1)



US Government

-Veteran Affairs, mandate Redsense

As of November 2010, The Department of Veteran Affairs Patient Safety Alert mandate the use of Redsense alarm.

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL10-13 July 7, 2010

Item: Redsense® Dialysis Alarm for Patients Undergoing Needle Access Procedures

Specific Incident: VHA issued a Patient Safety Advisory, AD09-02, on October 21, 2008, and a Patient Safety Alert, AL10-05, on February 3, 2010, that addressed bleeding during dialysis. This Patient Safety Alert adds an additional control measure aimed at the early detection of blood loss due to venous needle dislodgement (VND) using the Redsense® Alarm. The prior documents are available at the NCPS website, www.patientsafety.gov.

The Redsense® alarm (www.redsensemedical.com) is an FDA approved device for the early detection of venous needle disconnections. Usability issues initially noted with this device by NCPS in 2008 have been resolved with manufacturer redesign.

General Information: The VA National Center for Patient Safety (NCPS) has analyzed forty nine (49) RCAs (Root Cause Analysis) and Patient Safety reports of bleeding during dialysis which occurred in VA dialysis units from March 1, 2002, through March 31, 2010. Forty two (42) of these events were serious bleeding episodes. Ten (10) incidents resulted from disconnection of the blood line at the dialysis catheter connection and thirty two (32) incidents resulted from VND. In the most severe bleeds, the dialysis machines did not alarm until significant blood loss had occurred or they did not alarm at all.

VA dialysis units are part of the program

Renal Physicians Association recognizes VND to be one of the top areas needing improvement and is part of the program "Keeping Kidney Patients Safe"

The European nurses association -Initiatives to minimize the risk of VND



Poster

Although hemodialysis has become a routine treatment, adverse side effects, and occasionally life threatening clinical complications, still happen. The EDTNA and ANNA have produced 12 practice recommendations to help reduce the risk and detect blood loss as early as possible.¹⁰

Risk Assessment Tool

Each patient should be assessed for the risk of VND. Minimizing the risk of VND requires a combination of skills, vigilance and technology. The assessment tool allows staff to identify the highest risk patients for whom devices intended to detect blood loss to the environment can be used to ensure that an alarm is raised if VND occurs.²⁸



Can be downloaded from
www.redsensemedical.com

Redsense

-The only to The first clinically tested alarm system for detection of VND

CE Marked according to MDD, FDA Cleared & Listed.



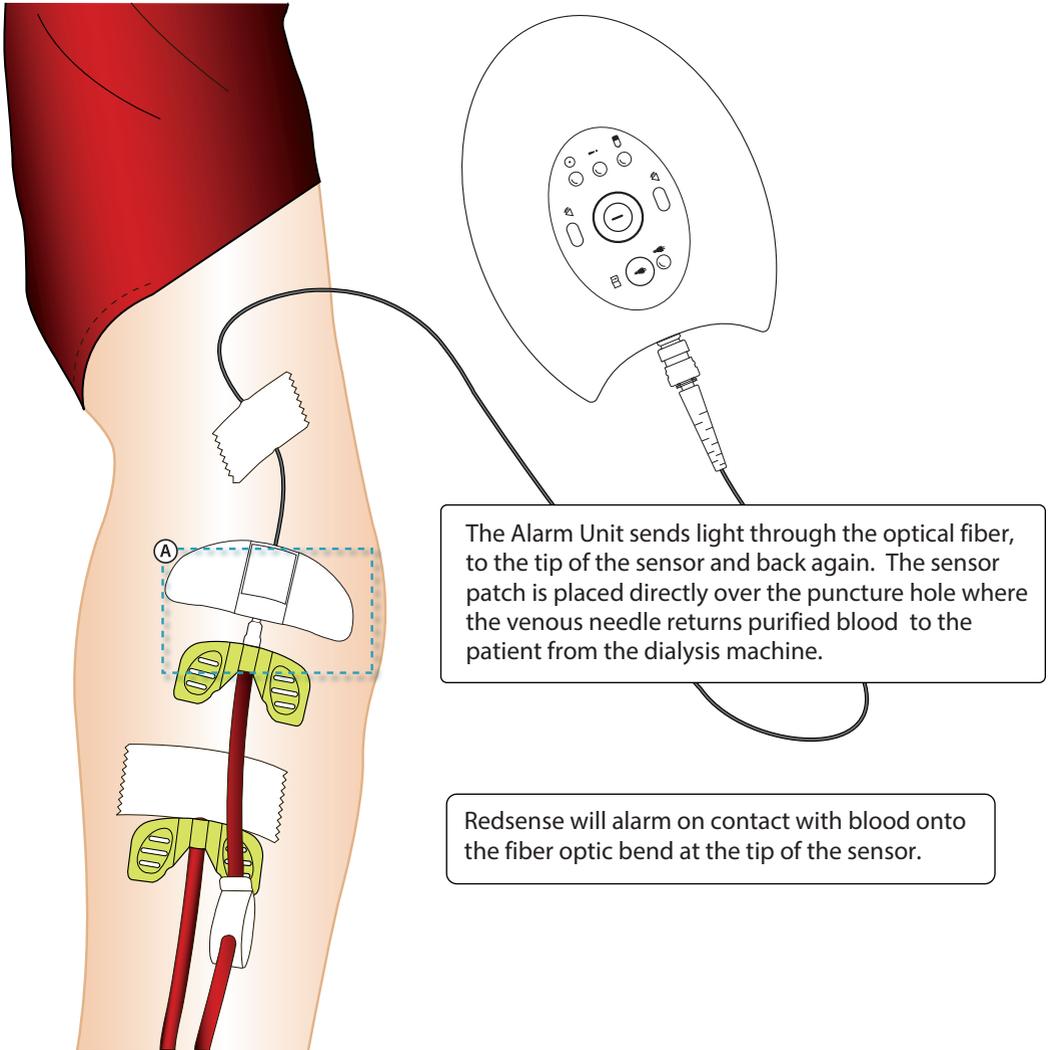
Intended use:

The Redsense device is intended to monitor for potential blood loss from the hemodialysis access site in hemodialysis patients undergoing hemodialysis treatment.

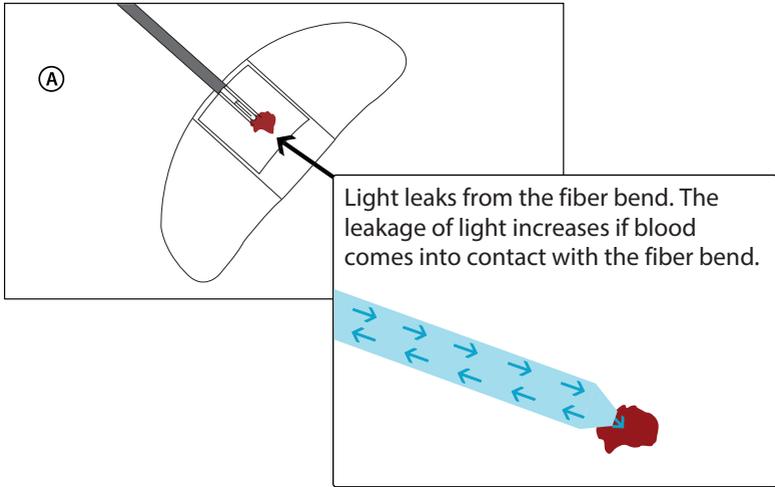
The device includes a blood sensor incorporated into a sensor patch. The sensor monitors potential blood leakage from the venous needle blood access via a light signal and will alarm if blood leakage is detected by the device's sensor.

All use must be administrated under physician's prescription, and must be observed by a trained and qualified person considered to be competent in the use of this device by the prescribing physician.

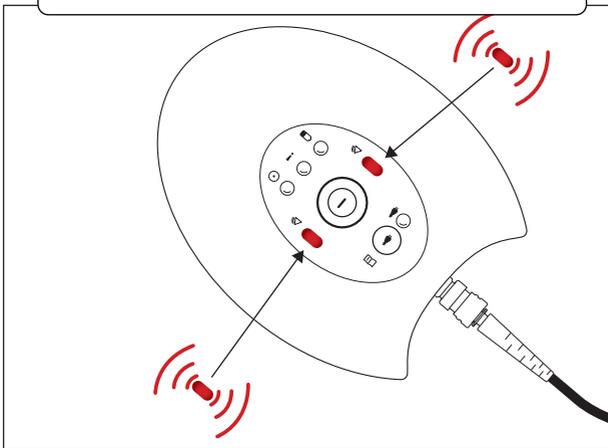
How Redsense works



Advanced technology embedded in an easy to use patch



The Alarm Unit measures the returning level of light. If the level of light is suddenly reduced, the Alarm Unit sounds the alarm immediately.



Literature review list

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