



Redsense Medical AB (publ)

Interim Report January – March 2023



6,824

NET SALES, kSEK

118%

SALES GROWTH

104

OPERATING LOSS, EBIT, kSEK

10,429

CASH, kSEK

87%

SOLIDITY

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Profitable quarter and continued growth

January – March 2023

- Net sales amounted to kSEK 6,824 (3,127), an increase by 118%.
- Operating loss, EBIT amounted to kSEK 104 (2,076).
- Result after tax amounted to kSEK 413 (-1,549).
- Earnings per share was SEK 0.03 (-0.11) before and after dilution.

Significant events during the period

- On January 3, Redsense Medical announced that MSEK 4.75 of the previously disclosed record order had been delivered in December 2022, with the balance of the order planned for delivery in Q1.
- On January 20, Redsense Medical announced that Jennie Kardell will join the company as new Chief Financial Officer as of March 2023.
- On January 26, Redsense Medical announced that ECRI (Emergency Care Research Institute) included Venous Needle Dislodgement as number 4 on its 2023 list of Top Technology Hazards.

Significant events after the reported period

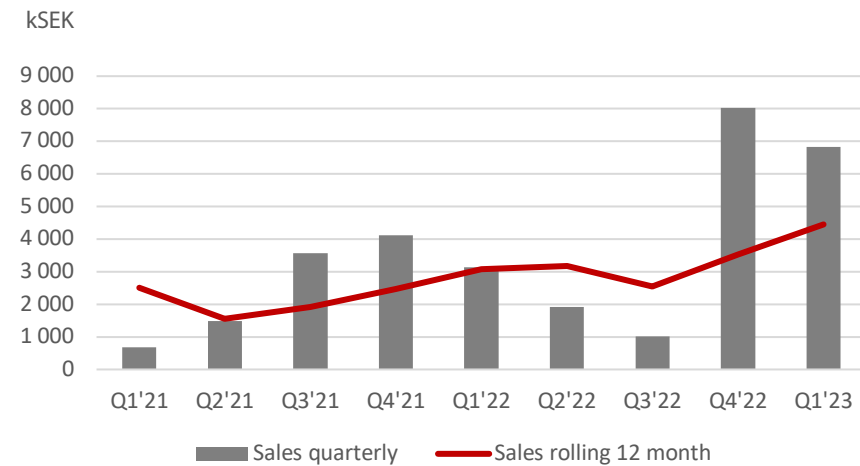
- On April 28, Redsense Medical announced that it held a 510(k) Pre-Submission meeting with the United States Food and Drug Administration (FDA) concerning the 510(k) premarket submission for the Redsense Clamp.
- On May 8, Redsense Medical announced that the Home Dialysis Risk Prevention Act has been introduced by the US House of Representatives.

Financial overview

kSEK	First quarter		Full Year
	Q1 2023	Q1 2022	2022
Net sales	6,824	3,127	14,340
Net sales, change	118%	356%	53%
Gross profit	4,140	1,557	8,851
Gross margin	61%	50%	62%
Operating profit (EBIT)	-104	-2,076	-10,208
Earnings per share	0.03	-0.11	-0.62
Cash flow from operating activities	20	-3,326	-9,783
Solidity	87%	94%	88%

See definitions on page 17

Breakdown of net sales by quarter



Strong start with 118 percent sales growth

We started 2023 with an excellent quarter where net sales increased by 118 percent to kSEK 6,824 (3,127) being the second-best quarter in the history of the company. The increase growth generated profit for the first quarter, which we are pleased with.

The US market is still the driver of our business. During the first quarter we continued to make part deliveries of the record order of MSEK 15.2 from December 2022, from one of our US distributors. In addition, we delivered a new order from our other US distributor.

Moving into the second quarter, we plan for additional deliveries of the large order from December last year, which will cater for another good quarter revenue wise.

The US in focus

The underlying demand for the sales growth in the US is driven by the development of the home hemodialysis market where Redsense has a unique position as the only blood leakage system being FDA cleared. Around 12,000 patients are currently treated in home settings with hemodialysis and this modality is expected to grow faster than other modalities.

Most of our products in the US are used for home hemodialysis, where we have a strong position. In terms of patients and number of treatments, the large market is however hemodialysis in the clinics. Close to 500,000 patients are currently treated by hemodialysis several times a week in clinics. The key to an introduction in a broader scale in the clinics, is legislation and Medicare reimbursement. Therefore, we are continuing our work in this area. During the quarter we meet with stakeholders in Washington D.C. to increase the awareness of VND (Venous Needle Dislodgement) and the opportunities to increase patient safety by using a blood leakage detection system.

Speaking about VND, ECRI (Emergency Care Research Institute), a global independent, non-profit organization devoted to improving safety, quality, and cost-effectiveness of care across all healthcare settings, is also highlighting the risks with VND. Ranking # 4 on the 2023 list of Top 10 Technology Hazards, ECRI's spotlight brings attention to the gravity VND and Access-Bloodline Separation, a potentially life-threatening but preventable complication of hemodialysis that can happen to any dialysis patient at any time.

For implementation of the Redsense system in home settings, nurses, technicians and other supporting personnel play an important role. In March we exhibited at the DTX40 conference in Las Vegas arranged by the National Association of Nephrology Technicians/Technologists. Participants from the major US dialysis providers showed a large interest in the Redsense solution. Home hemodialysis came into the spotlight in the session "Growth in Home Modalities", clearly indicating the focus the major dialysis providers have in this area.

Innovation to increase patient safety

One of our focus areas for 2023 is the launch of our new Redsense Clamp, an accessory to the alarm unit enabling automatic stop of the flow in the blood line in case of an incident, independently of the type of dialysis machine. The final step before launching the Clamp, is a user study to complete the CE-mark and preparations to start the study at the Toronto General hospital in Canada is underway. Key markets for initial launch of the Clamp will be Canada and Australia and selected countries in Europe. The Clamp are also of interest for the US market and preparations for the required regulatory activities is on-going.

Looking ahead

After concluding a strong first quarter, and with an excellent team in place, I look forward with confidence to the rest of the year. Our new CFO, Jennie Kardell, joined in March and I am very pleased to have Jennie onboard. She is a valuable addition to the team and will play an important role in the development of the company.


We will continue our activities to execute on the main strategic goals in 2023; further grow our position in the US home hemodialysis segment as well launch of the Clamp. Furthermore, our efforts to increase awareness about VND as the foundation for legislation and reimbursement in the US, will also be on the agenda.

In the short term, customer focused activities will be important to increase the sales pipeline. The promotional activities will be high going forward, and we will be exhibiting at conferences in the US and Europe. In June we will exhibit at the largest nephrology congress in Europe, the 60th ERA Congress in Milan.

I look forward to getting back to you on our progress and would like to express my appreciation to the team for their dedication and contributions. Our journey to improve patient safety and saving lives continues!

Pontus Nobréus
CEO, Redsense Medical





"We have presented two strong quarters in a row and look forward to continue the year in the same spirit."

Net sales and result

Net sales in the first quarter amounted to kSEK 6,824 (3,127), an increase by 118 percent compared to last year. The US was the biggest market with 99 percent (98) of the net sales. The increase is driven by deliveries of the US order stock as well as a new order from one of our US distributors.

Gross profit for the first quarter amounted to kSEK 4,140 (1,557), corresponding to a gross profit margin of 61 percent (50).

Other external expenses for the quarter amounted to kSEK 2,675 (3,234). The decrease is mainly due to reduced consulting services for the development of the Redsense Clamp.

Personnel expenses for the quarter amounted to kSEK 1,777 (1,989).

Operating loss for the quarter, before and after tax, amounted to kSEK 104 (2,076).

Net financial items for the quarter amounted to kSEK 517 (526) and primarily consist of change in value and net gains in short-term deposits.

Balance sheet items

On March 31 the Group's cash and cash equivalents amounted to kSEK 10,429 (3,672). Deposits of kSEK 0 (6,909) relate to short-term investments. The company has a credit facility of kSEK 2,000, which as per March 31 remains undrawn.

Intangible fixed assets amounted to kSEK 12,526 (12,354) which is fully capitalized development cost.

As of March 31, the equity amounted to kSEK 27,758 (27,149).

Cash flow

The cash flow from operating activities in the quarter amounted to kSEK 20 (-3,326).

Total investing activities for the twelve-month period amounted to kSEK 6,737 (10,782).

Financing activities for the period amounted to kSEK 0 (-2,572). It hasn't been any financing activities this quarter since the credit facility remains undrawn.

Parent company

The Group's parent company, Redsense Medical AB, has one wholly owned subsidiary in the United States.

The parent company's net sales amounted to kSEK 4,687 (2,330) in the first quarter, and the total operating expenses amounted to kSEK 7,247 (6,904). Operating loss was kSEK 104 (2,971) for the first quarter.

The parent company's net financial items for the quarter amounted to kSEK 517 (526) and primarily consist of change in value and net gains in short-term deposits.

The result after financial items amounted to kSEK -1,823 (-2,445), and the result before and after tax amounted to kSEK -1,823 (-2,445) for the first quarter.

The parent company's cash and bank balances amounted to kSEK 6,356 (8,527) on March 31. The company has a credit facility of kSEK 2,000, which as per March 31 remained undrawn.

Risks and uncertainties

As an international Group, Redsense is exposed to various risks that affect the possibilities to achieve the established targets. There are operational risks, such as the risk that competitive situations affect price levels and sales volumes, and the risk that the economic development in the markets and segments where the Group operates could develop unstable. There are also financial risks, such as currency risks, interest risks and credit risks.

No major changes in significant risks or uncertainty factors have occurred during the period, regarding geopolitical and other events. Other risks are unchanged compared to the description of Redsense's risks, uncertainty factors and the handling of these in the company's Annual Report for 2022.

Transactions with related parties

Transactions have taken place during the period within the Group. No other transactions have taken place during this quarter.

Human resources

The Group had 5 employees (full time equivalents) on March 31, compared to 5 the previous year.

Audit review

This report has not been reviewed by the company's auditors.

General information

In this interim report, the Group is referred to, unless otherwise stated. Figures in parentheses indicate the outcome for the corresponding period the previous year, apart from balance sheet items where figures in parentheses refer to December 31 the previous year. Unless otherwise stated, amounts are given in kSEK.

Calendar

Interim report Q2 January – June 2023
Interim report Q3 January – September 2023
Year-end report Q4 January – December 2023

August 29, 2023
November 9, 2023
February 27, 2024

All financial reports are published at www.redsensemedical.com

Declaration by the board of Directors and CEO

The board of Directors and the CEO certify that this interim report provides a true and fair overview of the Parent Company's and the Group's operations, financial position, results, and describes significant risk and uncertainties the Parent Company and the Group are exposed to.

Halmstad, May 9, 2023

Redsense Medical AB (publ)
The Board of Directors and CEO

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This information is information that Redsense Medical AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact persons set out above, on May 9, 2023, at 08:30 CET.

The share

The Redsense Medical share is listed on Spotlight Stock Market under the ticker REDS. The share was originally listed on Aktietorget (today known as Spotlight Stock Market) on June 5, 2015, relisted on the Nasdaq First North Stockholm on October 2, 2017, before relisting on Spotlight Stock Market on May 3, 2019. As of March 31, 2023, the company's market capitalization was MSEK 136.

The IPO share price of Redsense Medical in 2015 was SEK 5 per share. On the last day of trading in March 2023, the closing share price was 9.8 SEK. Thus, the total shareholder return since the IPO is 96 percent.

The Board of Directors intends to propose to the Annual General Meeting that no dividend be paid to the shareholders for the fiscal year 2023.

Share turnover

In total, 572 thousand shares were traded in the first quarter, for a value of MSEK 5.8.

Share capital

On March 31, 2023, the share capital of Redsense Medical amounted to SEK 1,404,081, divided on 14,040,810 shares, each with a quota value of SEK 0.10. All shares carry the same voting rights.

Ownership

At the turn of the quarter, the ten major owners represented 48 percent of the share capital and voting rights. The largest individual shareholder at the end of the first quarter was Patrik Byhmer with a 14 percent ownership via companies.

The ten major owners as of 2023-03-31

Patrik Byhmer*	14.03%
Discover Capital Gmbh	5.34%
Avanza Pension	5.22%
ÖstVäst Capital Management	5.08%
Nordnet Pensionsförsäkring	4.61%
Swedbank Robur Fonder	3.85%
Futur Pension	3.53%
Aktia Assets Management	2.21%
Martin Olausson	2.16%
Andra AP-fonden	2.14%
Total	48.17%

** Shares held through companies*

Consolidated income statement

kSEK	2023-01-01	2022-01-01	2022-01-01
	2023-03-31	2022-03-31	2022-12-31
Net sales	6,824	3,127	14,340
Capitalized development work	172	1,139	2,413
Other operating income	48	464	1,036
Total operating income	7,045	4,729	17,790
Cost of goods sold	-2,684	-1,570	-5,489
Other external expenses	-2,675	-3,234	-12,550
Personnel costs	-1,777	-1,989	-9,906
Depreciation/Amortization	-13	-12	-53
Total operating costs	-7,149	-6,805	-27,998
OPERATING RESULT	-104	-2,076	-10,208
Net financial items	517	526	1,450
Result from financial items	413	-1,549	-8,758
PROFIT OR LOSS BEFORE TAX	413	-1,549	-8,758
PROFIT OR LOSS FOR THE PERIOD	413	-1,549	-8,758

Consolidated balance sheet

kSEK	2023-03-31	2022-03-31	2022-12-31
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development cost	12,526	11,079	12,354
Tangible assets			
Technical equipment and tools	352	359	365
Financial assets			
Shares in subsidiaries	-	7	-
Total fixed assets	12,878	11,444	12,719
Current assets			
Inventory	1,117	774	1,531
Accounts receivable	6,381	4,298	4,934
Other short-term receivables	852	447	326
Prepayment and accrued income	362	327	641
Short-term deposits	-	10,604	6,909
Cash and cash equivalents	10,429	9,868	3,672
Total current assets	19,140	26,317	18,013
TOTAL ASSETS	32,018	37,761	30,731

kSEK	2023-03-31	2022-03-31	2022-12-31
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1,404	1,404	1,404
Restricted reserve	598	598	598
Development fund	12,586	11,139	-12,414
Non-restricted equity			
Retained earnings	12,757	23,850	46,319
Profit or loss for the period	413	-1,549	-8,758
Total equity	27,758	35,442	27,149
Liabilities			
Short-term liabilities			
Accounts payable	2,503	1,332	981
Other short-term liabilities	263	246	465
Accruals and deferred income	1,495	741	2,136
Total liabilities	4,260	2,319	3,582
TOTAL EQUITY AND LIABILITIES	32,018	37,761	30,731

Consolidated cash flow

	2023-01-01 2023-03-31	2022-01-01 2022-03-31	2022-01-01 2022-12-31
kSEK			
Cash flow from operating activities	20	-3,326	-9,783
Cash flow from investment activities	6,737	10,782	10,868
Cash flow from financing activities	-	-2,572	-2,395
Cash flow for the period	6,757	4,885	-1,311

Consolidated changes in equity

kSEK	Share capital	Other paid-in capital	Retained earnings	Total equity
Opening balance January 1, 2022	1,404	123,631	-87,543	37,492
Result for the period			-8,758	-8,758
Warrant issuance			252	252
Exchange rate differences and other adjustments			-1,837	-1,837
Closing balance December 31, 2022	1,404	123,631	-97,886	27,149

kSEK	Share capital	Other paid-in capital	Retained earnings	Total equity
Opening balance January 1, 2022	1,404	123,631	-87,543	37,492
Result for the period			-1,549	-1,549
Exchange rate differences and other adjustments			-501	-501
Closing balance March 31, 2022	1,404	123,631	-89,593	35,442

kSEK	Share capital	Other paid-in capital	Retained earnings	Total equity
Opening balance January 1, 2023	1,404	123,631	-97,886	27,149
Result for the period			413	413
Warrant issuance				0
Exchange rate differences and other adjustments			196	196
Closing balance March 31, 2023	1,404	123,631	-97,277	27,758

Parent company's income statement

kSEK	2023-01-01 2023-03-31	2022-01-01 2022-03-31	2022-01-01 2022-12-31
Net sales	4,687	2,330	10,516
Capitalized development work	172	1,139	2,413
Other operating income	48	464	369
Total operating income	4,907	3,933	13,298
Cost of goods sold	-2,684	-1,692	-5,489
Other external expenses	-2,107	-2,458	-8,834
Personnel costs	-1,247	-1,546	-7,591
Depreciation/Amortization	-1,209	-1,209	-4,840
Total operating costs	-7,247	-6,904	-26,753
OPERATING RESULT	-2 340	-2,971	-13,455
Net financial items	517	526	1,450
Result from financial items	-1,823	-2,445	-12,005
PROFIT OR LOSS BEFORE TAX	-1,823	-2,445	-12,005
PROFIT OR LOSS FOR THE PERIOD	-1,823	-2,445	-12,005

Parent company's balance sheet

kSEK	2023-03-31	2022-03-31	2022-12-31
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development cost	12,526	11,079	12,354
Patent	20,484	25,270	21,680
Tangible assets			
Technical equipment and tools	352	359	365
Financial assets			
Shares in subsidiaries	7	7	7
Receivables from group companies	9,202	15,598	12,346
Total fixed assets	42,570	52 312	46 751
Current assets			
Inventory	629	729	689
Advances to suppliers	488	-	789
Accounts receivable	0	112	150
Receivables from group companies	14,862	2,210	10,320
Other short-term receivables	798	447	326
Prepayment and accrued income	362	327	641
Short-term deposits	-	10,604	6,909
Cash and cash equivalents	6,356	8,527	220
Total current assets	23,495	22,955	20,044
TOTAL ASSETS	66,065	75,267	66,795

kSEK	2023-03-31	2022-03-31	2022-12-31
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	1,404	1,404	1,404
Restricted reserve	598	598	598
Development fund	12,586	11,139	12,414
Non-restricted equity			
Retained earnings	49,191	62,391	61,368
Profit or loss for the period	-1,823	-2,445	-12,005
Total equity	61,957	73,088	63,780
Liabilities			
Short-term liabilities			
Accounts payable	2,441	1,192	688
Other short-term liabilities	270	246	465
Accruals and deferred income	1,397	741	1,862
Total liabilities	4,108	2,180	3,015
TOTAL EQUITY AND LIABILITIES	66,065	75,267	66,795

Notes

Note 1 Accounting principles

These interim financial statements have been prepared in accordance with the Swedish Annual Accounts Act as well as the Swedish Accounting Standards Board BFNAR 2012:1 annual report and consolidated (K3). The accounting policies are the same as the previous year. For further information, please refer to the Annual Report for 2022, page 27.

Note 2 Key ratios and financial metrics

Definitions of the key ratios and financial metrics used in the Group's financial reporting:

Graphs of net sales

Redsense has chosen to report graphs of the net sales on a rolling 12-month basis as corporate management also follows the development over time on a rolling 12-month basis and believes that this provides supplementary information to the calendar-based interim data otherwise given in the report.

Operating profit/loss, operating margin, EBIT and EBIT margin

In this report Redsense uses the result measure EBIT, Earnings Before Interest and Taxes, as an alternative term for operating profit. EBIT margin is thus an alternative term for operating margin, calculated as operating profit divided by net sales. Operating profit is calculated as net sales decreased by costs of goods sold and operating costs.

Gross profit

Net sales less cost of goods sold.

Investments

Acquisition of property, plant and equipment, intangible assets and financial assets during the period.

Earnings per share

Net profit for the period divided by the average number of shares during the period.

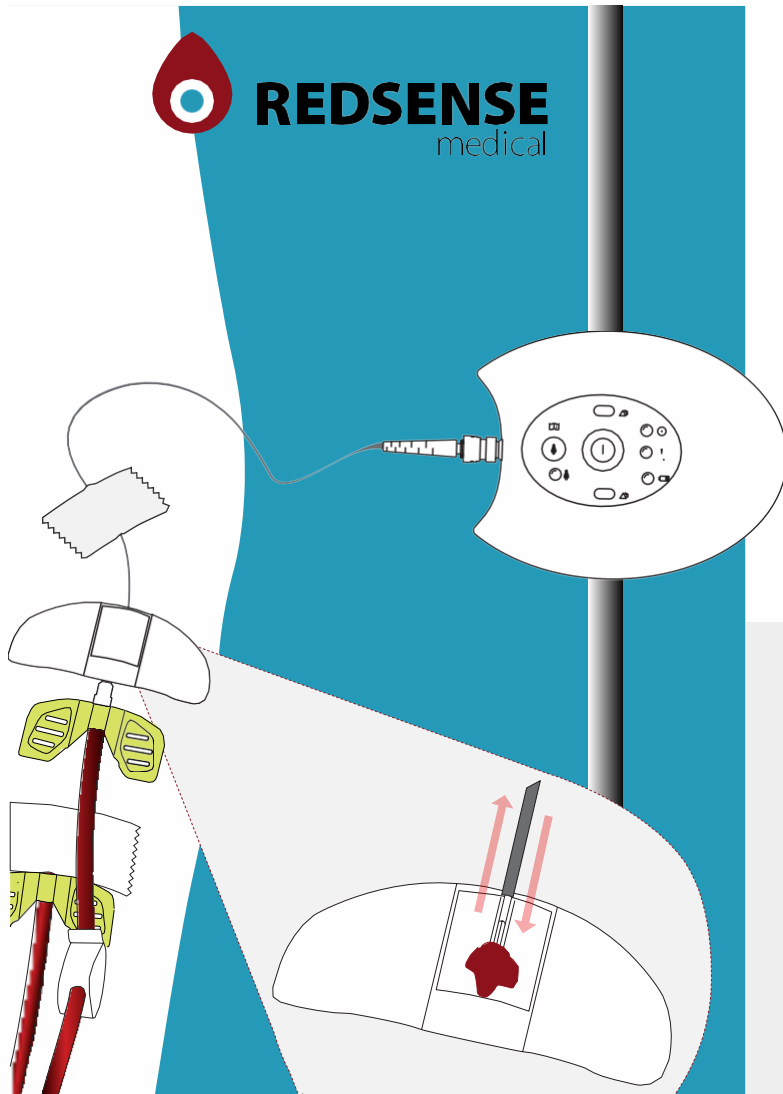
Solidity

Equity divided by total assets.

Note 3 Pledged assets and contingent liabilities

Pledged assets amounted to MSEK 1.5 as per March 31, 2023. There are no contingent liabilities in the group.

This is Redsense Medical



Saving lives

Redsense Medical AB is born-global medical device innovator established in Sweden in 2006. Redsense's mission is to improve the safety and quality of life for dialysis patients worldwide. The group has its main market in the United States and additional operations in Europe and Canada.

Early, reliable warning – without false alarms

Redsense promotes patient safety through highly cost-efficient fiber-optic monitoring of the blood access site during hemodialysis. The Redsense System immediately detects Venous Needle Dislodgement (VND) – a potentially life-threatening complication that causes 21 avoidable deaths per week worldwide. In essence, the Redsense alarm provides patients, nurses, and caregivers an extra pair of eyes; always alert, focused on one thing only, never looking away.

- During **hemodialysis**, blood is pumped from the patient at a rate of up to 500 ml/min per minute to be cleaned in a **dialyzer** outside the body.
- With Redsense, a fiber-optic **sensor layer** integrated in a disposable patch is attached to the access where the blood is returned to the body via the venous needle.
- **Red light** is carried back and forth to the sensor from an **alarm unit**. If blood is absorbed in the patch, the device observes a reduced level of red light in the return signal, indicating that the venous needle have dislodged, resulting in bleeding.

Key to at-home safety

Redsense products are used in both clinics and at home, daily and nocturnally. Today, the majority of treatments are performed in clinical settings, but home treatment is gaining popularity thanks to lower cost, increased convenience for the patient, improvements in technology and political initiative. This is where Redsense's solution adds safety.

A standard element of dialysis care

The number of patients undergoing hemodialysis several times per week due to chronic kidney disease is approaching 3.8 million, worldwide. The projected growth rate is six percent annually, driven by ageing population and other factors. Every hemodialysis treatment carries the risk of VND. In the last years more than 1 million treatments have been conducted with the Redsense System worldwide.

- A **visual and audible alarm** is triggered. This alerts the attention of the nursing staff, so that they can clamp the bloodline and **stop the dialysis machine's pump** and prevent further blood loss from the patient.
- Redsense can be **integrated** with dialysis machines implementing a certain standard. In such cases, the alarm unit can stop the machine's blood pump **without human intervention**.
- **Redsense Clamp** is a novel accessory product, currently in clinical validation, which equips the Redsense System with the ability to **automatically**, as prompted by the alarm unit, **clamp the bloodline** to prevent bleeding and stop the blood pump.



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