nanosonics

Infection Prevention. For Life.

INVESTOR PRESENTATION
2024 FULL YEAR RESULTS

Michael Kavanagh
CEO and President

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CFO

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Our mission

We improve the safety of patients, clinics, their staff and the environment by transforming the way infection prevention practices are understood and conducted and introducing innovative technologies that deliver improved standards of care.

Our aspiration and strategy

Transform medical device reprocessing for improved patient safety and better health outcomes

VALUE CREATION

By establishing new standards of care and category leadership

- Leading ultrasound reprocessing
- Transforming endoscope reprocessing
- R&D, strategic partnerships and M&A

Growing, optimising and protecting our customer base

- International expansion
- Customer value expansion
- Excellence in customer experience

Operational excellence will deliver value for all stakeholders

- R&D and bioscience innovation
- Medical and clinical affairs impact
- Asset allocation and operational efficiencies
- Manufacturing and supply chain scalability and continuity

ORGANISATIONAL FOUNDATIONS

Strong organisational foundations will underpin our achievements

- Excellent talent
- Digital and data transformation
- Quality
- Sustainability

Contents

Key highlights

Michael Kavanagh
CEO and President

"The effects of inflation on hospital capital budget availability were felt during the year in particular in the first half. Despite ongoing capital budget challenges, a significant turnaround in the second half was experienced, with a considerable upswing in unit sales.

We remain confident in the underlying growth opportunity of the Company's ultrasound reprocessing business as well as the broader growth opportunity through the investments being made in both product and geographical expansion."

Revenue
- Total revenue: $170.0 million, up 2% on prior period (0% in constant currency[1])
- H2 revenue: $90.4 million, up 14% on FY24 H1

Global installed base
- Up 2,340 units to 34,790 units globally, a 7% increase in the last 12 months

trophon®2 upgrades
- 1,510 units, down 17% compared to prior period
- H2 upgrades: 890 units, up 44% on FY24 H1

Gross profit margin
- For the year: 77.9%
- H2: 76.3% down 3.4 pts on the 79.7% in FY24 H1 due to the one-off production reduction

Operating expenses
- $125.6 million, up 10% on prior period
- Includes investments in product expansion (CORIS), geographical expansion, and over $1 million for new ERP system

Operating profit before tax
- $13.0 million compared to $21.6 million in prior period reflecting lower units sales and ongoing investment in growth strategy

Free cash flow and cash
- Free cash flow of $20.4 million, with cash and cash equivalents of $129.6 million at 30 June with no debt

CORIS® progress
- Positive progress with FDA de novo regulatory application submitted and currently under review.

1. Constant currency removes the impact of foreign exchange rate movements to facilitate comparability of operational performance. This is done by converting the current year sales of entities that use currencies other than Australian dollars at the average rates that were applicable in the prior year. The average exchange rate used for the Company's major foreign currency (USD) for the half year was 0.66 (2023:0.67).

FY24 Financial highlights

	TOTAL REVENUE	CAPITAL REVENUE	CONSUMABLES AND SERVICE REVENUE	GROSS PROFIT MARGIN	OPERATING EXPENSES	CONSOLIDATED PROFIT BEFORE TAX
FY24 VS FY23	**$170.0M**	**$48.2M**	**$121.8M**	**77.9%**	**$125.6M**	**$13.0M**
	▲ 2% (0% CC[1])	▼ 11%	▲ 9%	▼ 0.8 pts	▲ 10%	▼ 40%
FY24 H2 VS H1						
H1	$79.6M	$21.9M	$57.7M	79.7%	$60.8M	$4.9M
H2	$90.4M ▲ 14%	$26.3M ▲ 20%	$64.1M ▲ 11%	76.3% ▼ 3.4 pts	$64.8M ▲ 7%	$8.1M ▲ 65%

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FY24 Global units highlights

FY24 VS FY23

	GLOBAL INSTALLED BASE	NEW INSTALLED BASE	UPGRADES	TOTAL UNITS
	34,790 units	2,340 units	1,510 units	3,850 units
	▲ 7%	▼ 10%	▼ 17%	▼ 13%

FY24 H2 VS H1

	GLOBAL INSTALLED BASE	NEW INSTALLED BASE	UPGRADES	TOTAL UNITS
H1	33,550 units	1,100 units	620 units	1,720 units
H2	34,790 units ▲ 4%	1,240 units ▲ 13%	890 units ▲ 44%	2,130 units ▲ 24%

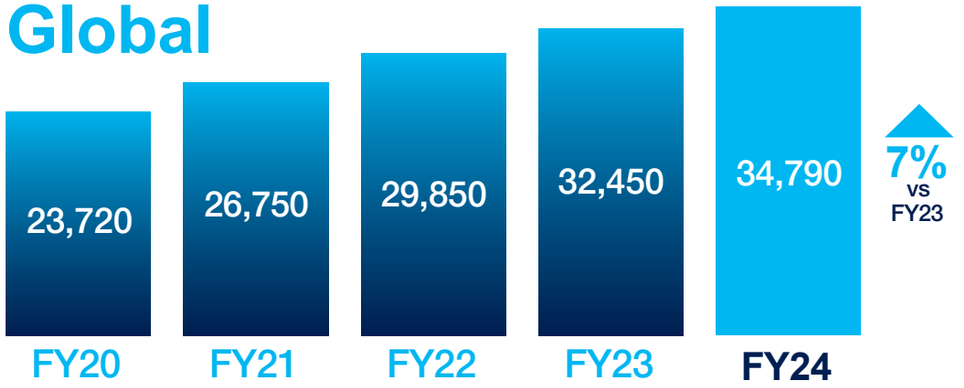
Installed base and upgrades

Total installed base

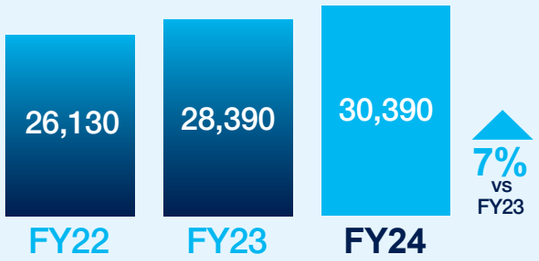
7% growth in total installed base in FY24.

- Total Installed base grew 2,340 units in the year.
- 34,790 units now in operation, protecting approximately 27 million patients annually.

Global

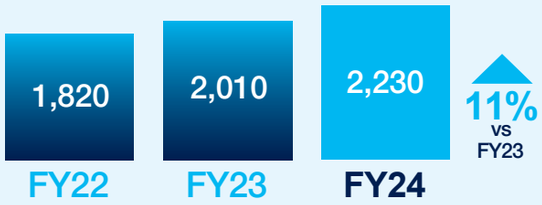


North America



Installed base grew by 7% in North America with 2,000 new units installed. 30,390 units represents approximately 50% of the estimated total addressable market.

Europe and Middle East



Installed base grew by 11% in Europe and Middle East with 220 new trophon units installed. The Company continues to invest in its growth plans in the region.

Asia Pacific

Installed base grew by 6% in Asia Pacific with 120 new trophon units installed, further consolidating the market leading position for trophon in Australia and New Zealand.

Graphs are not to scale and therefore not comparable.

New installed base growth

2,340 new IB installed

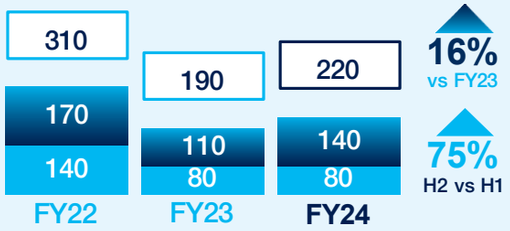
- Sales in a growing pipeline delayed due to hospital capital budget constraints, especially in H1.
- New IB down 10% over PCP with H2 recovering leading to 13% growth in H2 over H1.

Global

North America

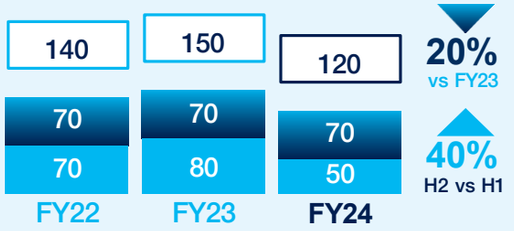
2,000 new installed base units were added in North America, where the total installed base has now reached 30,390 units representing approximately 50% of the total addressable market.

Europe and Middle East



220 new installed base units were added in Europe and Middle East up 16% compared with prior corresponding period.

Asia Pacific



120 new installed base units were added in Asia Pacific, consolidating our market leading position in Australia and New Zealand. In Japan, we continue our work towards the development of national based guidelines similar to those in other international markets.

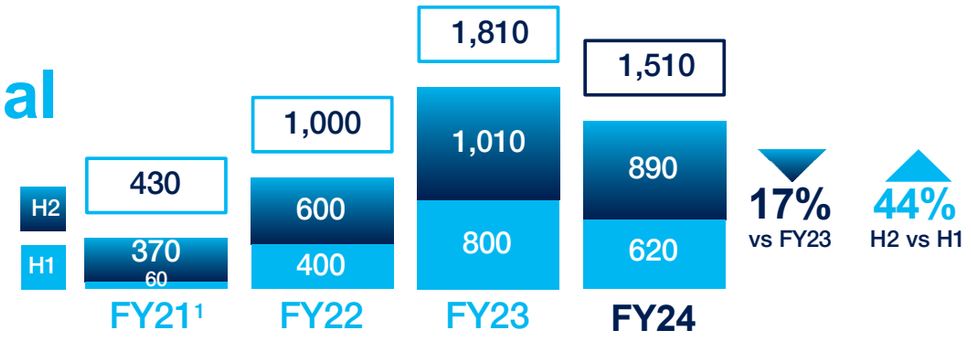
Graphs are not to scale and therefore not comparable.

Upgrades

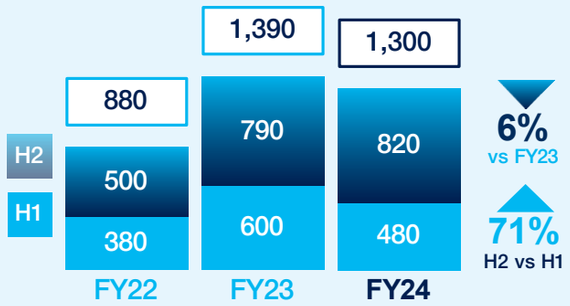
1,510 upgrade units installed

- Upgrade volumes down 17% vs FY23. This was particularly marked in H1 as customers extended use of existing trophon EPR devices due to capital budget constraints.
- Upgrade pipeline continued to grow throughout the year with strong recovery in H2 up 44% compared to H1.
- North America upgrades up 71% in H2 over H1, strongest half to date.

Global

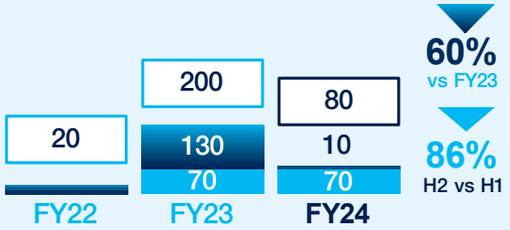


North America



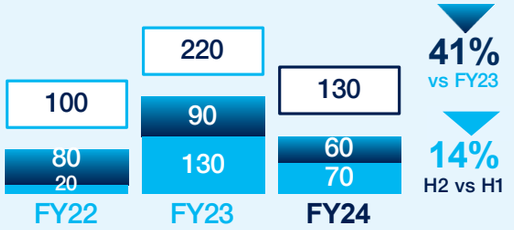
1,300 trophon units were upgraded in North America. The upgrade opportunity in North America remains strong with approximately 30% of the current installed base over 7 years of age.

Europe and Middle East



Less opportunities for upgrade in Europe and Middle East based on size of current installed base with high percentage of original trophon EPR devices upgraded.

Asia Pacific



Less opportunities for upgrade in Asia Pacific based on size of current installed base with high percentage of original trophon EPR devices upgraded.

1. Upgrades commenced in FY21.

Graphs are not to scale and therefore not comparable.

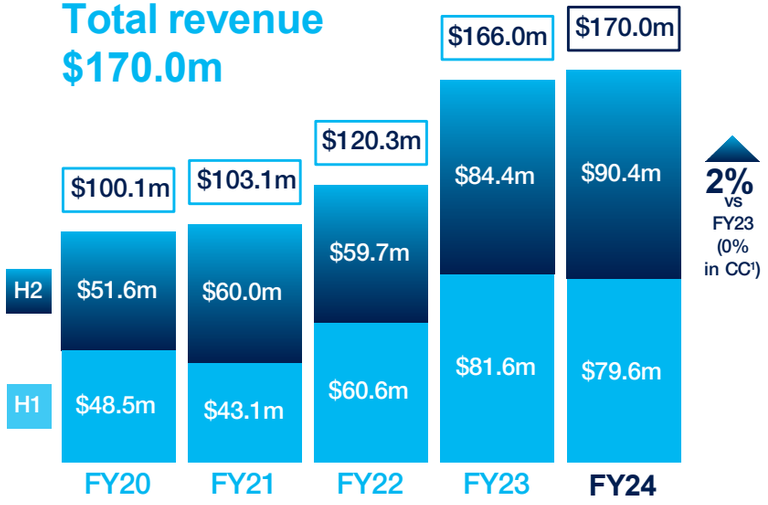
FY24 financial results

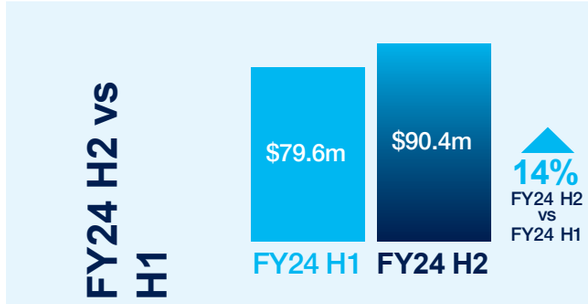
Global revenue of $170 million

A significant turnaround in the second half

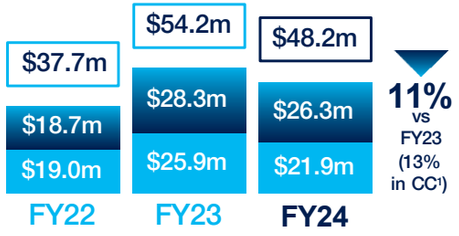
- Overall revenue grew 2% to $170.0 million.
- Recurring revenue from consumables and service up 9% vs PCP.
- Capital revenue down 11% on PCP.
- Significant turnaround in the second half despite ongoing capital budget challenges, with total revenue up 14% in H2, capital revenue up 20% and recurring revenue up 11%.

Total revenue $170.0m

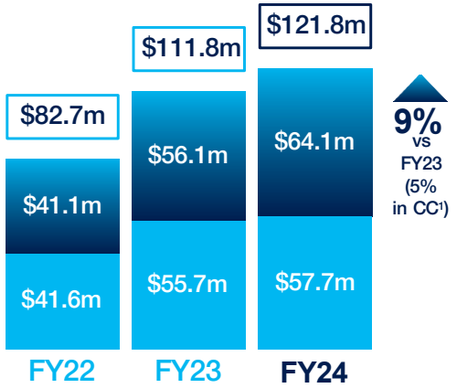


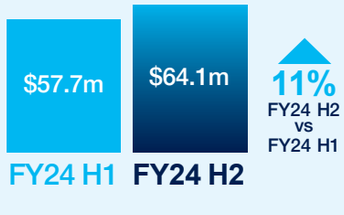


Capital revenue $48.2m



Consumables/service revenue $121.8m





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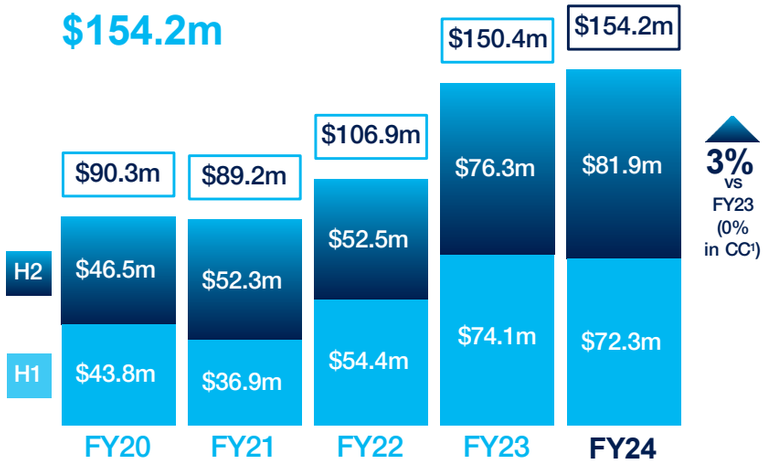
Graphs are not to scale and therefore not comparable.

North America

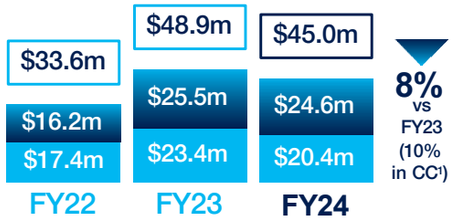
Significant turnaround in H2 with considerable upswing in unit sales

- Total revenue up 3% to $154.2 million.
- Capital revenue of $45.0 million, down 8% vs PCP, driven by capital budget constraints in particular in H1, with significant improvements in H2, up 21% over H1.
- Recurring revenue from consumables and service of $109.2 million, up 8% vs PCP.

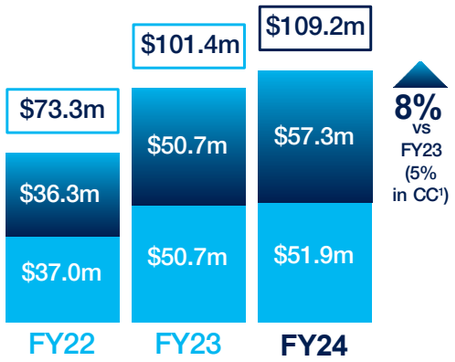
FY24 Total revenue $154.2m



Capital revenue $45.0m



Consumables/service revenue $109.2m



FY24 H2 vs H1

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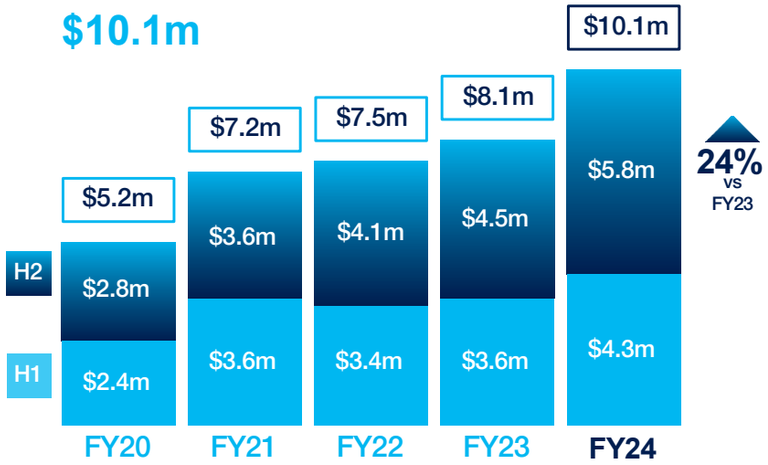
Graphs are not to scale and therefore not comparable.

Europe and Middle East

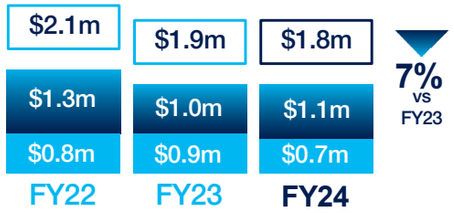
Growth in new IB and recurring revenue

- Total revenue in Europe and Middle East up 24% to $10.1 million.
- Growth driven by a 33% increase in recurring consumable and service revenue.
- New IB grew 16% in the year however Capital revenue down 7% with many new IB and upgrades placed under MES program.

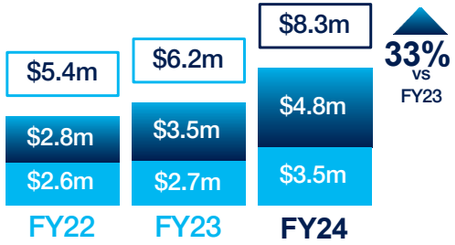
FY24 Total revenue $10.1m



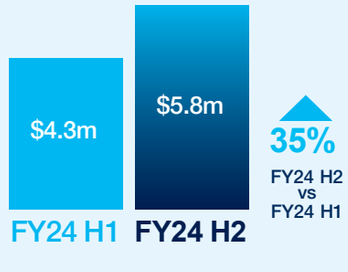
Capital revenue $1.8m



Consumables/service revenue $8.3m



FY24 H2 vs H1



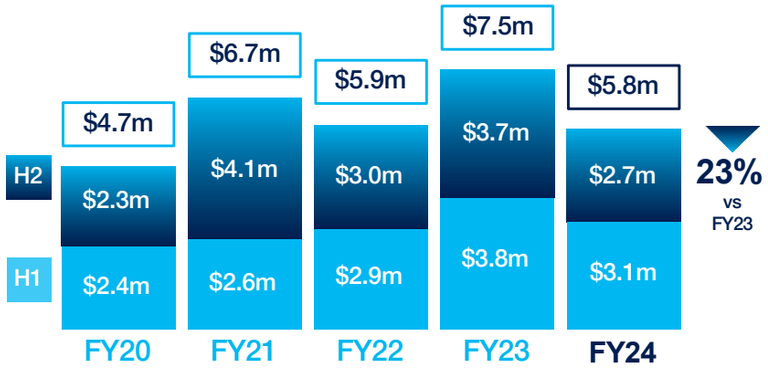
Graphs are not to scale and therefore not comparable.

Asia Pacific

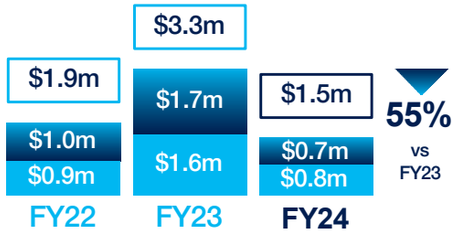
Capital revenue reduced with high upgrade penetration in ANZ

- Total revenue of $5.8 million down 23% vs PCP.
- While new IB up 6%, capital revenue down 55% for year to $1.5 million due to lower upgrade sales with high percentage of trophon EPR units already upgraded.

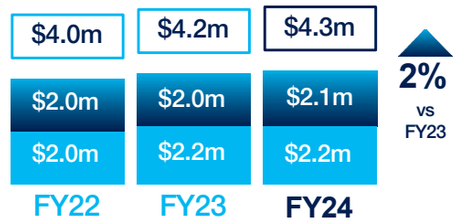
FY24 Total revenue $5.8m



Capital revenue $1.5m



Consumables/service revenue $4.3m



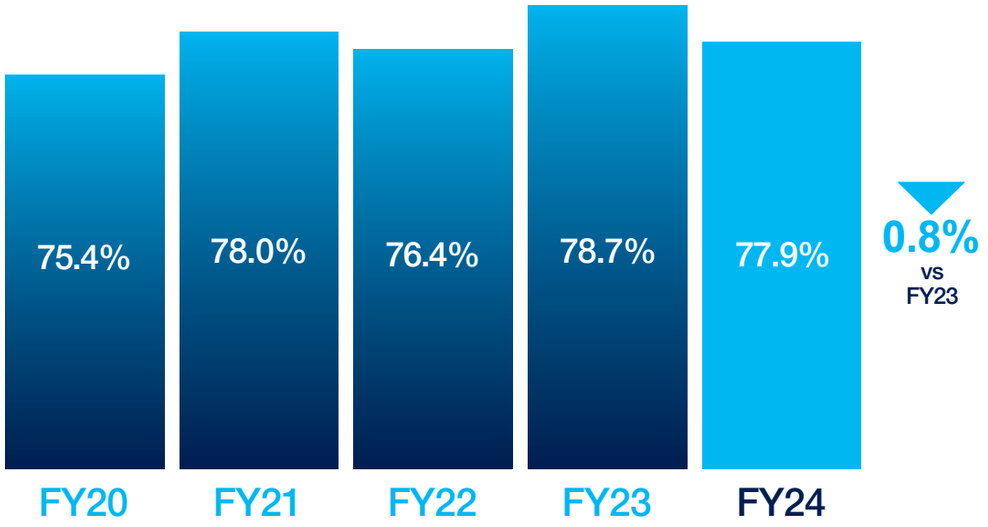
FY24 H2 vs H1

Graphs are not to scale and therefore not comparable.

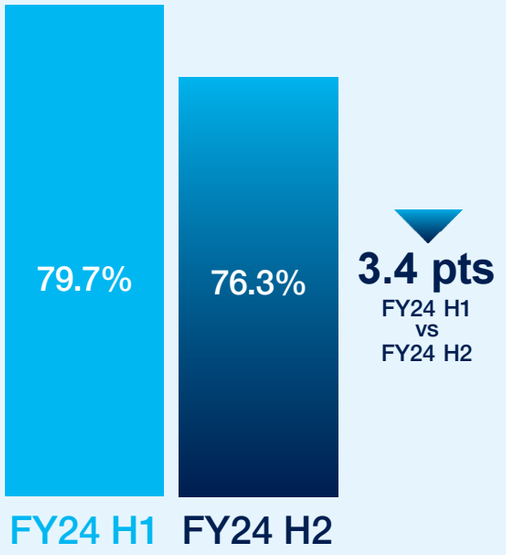
Gross profit margin

One-off H2 impact on gross margin with planned lower production

FY24 gross profit margin rate 77.9%



Gross profit margin rate H2 vs H1



Gross profit margin was **77.9% for the year, down 0.8 percentage points** from 78.7% in the prior period.

Lower second half margin of 76.3% due to:

- One-off production slowdown to lower working capital and return inventory to desired levels.
- Product mix with more trophon units sold in H2 over H1.

Graphs are not to scale and therefore not comparable.

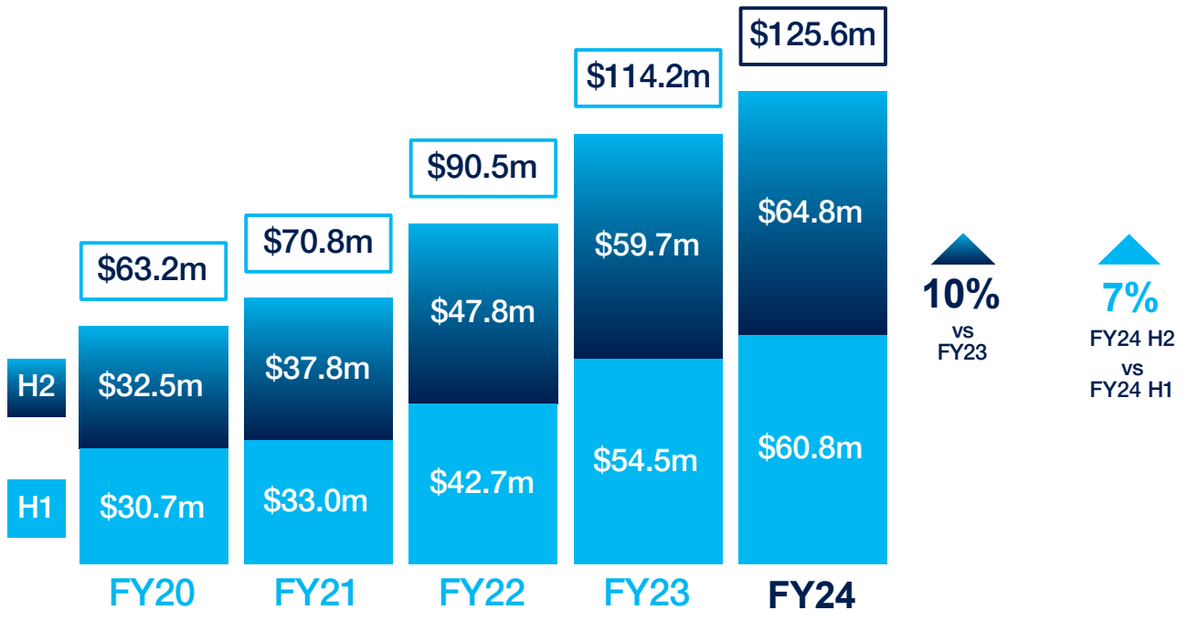
Operating expenses

Continued investment in significant infection prevention market opportunity

Operating expenses of $125.6m, up 10% on PCP compared to initial 17% – 22% projected in original FY24 outlook statement.

Operating expenses include investments in:

- Ongoing growth in established markets plus market preparation for introduction of CORIS.
- Geographical expansion and market development.
- Research and development.
- Infrastructure, capability and capacity growth.



Graphs are not to scale and therefore not comparable.

Global operating expenses

Investing in significant infection prevention market opportunity

Investment in established markets drives and funds the operations of the business today
(40% FY23)

Drives growth in established markets

- Continue to grow new installed base
- Convert significant installed base upgrade opportunity.
- Grow consumables, ecosystem & service.
- Deliver exceptional customer experience.

Investment in developing markets underpins growth for the future
(6% FY23)

Expands geographical presence in developing markets

- Target Europe and the Middle East, and Japan to become material contributors to the global trophon business.
- Strengthen market fundamentals for high level disinfection.
- Expand local infrastructure to support growth momentum.

Investment in R&D to maintain growth today and for the future
(26% FY23)

During the year the Company invested $32.8m in R&D, up 11% vs FY23

- Investment made in the core areas of ultrasound reprocessing, endoscope reprocessing, compliance and traceability, and new innovation research.
- Through our R&D investments, the Company has developed unique strengths building depth in its capabilities and capacity.

Investment in infrastructure and capability for today and the future
(28% FY23)

Drives scalable operation, HQ and support capacity and capability

- Scalable manufacturing capacity to support ongoing growth in global demand and new product introductions.
- Transform our digital capability with investments in enterprise-wide digital tools and platforms. During the year, over $1m was incurred relating to the new ERP implementation which commenced in FY24.

Graphs are not to scale and therefore not comparable.

Profit and loss summary

Key highlights

- Revenue of $170 million, up 2% on PCP.
- Gross profit margin of 77.9% compared with 78.7% in PCP.
- Operating expenses of $125.6 million, up 10% on PCP. This includes investment in the new ERP system which commenced in FY24 and further investment into CORIS R&D and pre-commercialisation costs.
- Other income for the year of $1.7 million mainly attributable to the NSW Jobs Plus program.
- Net finance income of $3.9 million reflects higher interest earned on higher cash balance during the year.
- Operating profit before tax of $13 million compared with $21.6 million in PCP.

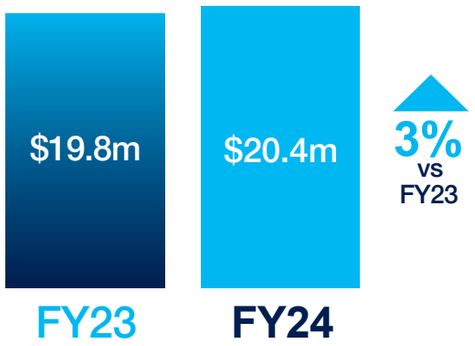
$ millions	FY24	FY23	Change %	
Capital revenue	48.2	54.2	▼	-11%
Consumable/service revenue	121.8	111.8	▲	9%
Total revenue	**170.0**	**166.0**	▲	**2%**
Gross profit	**132.4**	**130.6**	▲	**1%**
%	77.9%	78.7%		
Operating expenses				
Selling and general	65.8	60.9	▲	8%
Administration	27.0	23.7	▲	14%
Research and development	32.8	29.5	▲	11%
Total operating expenses	**125.6**	**114.2**	▲	**10%**
Other income	1.7	1.3	▲	31%
Fx gains – net	0.5	1.8	▼	-72%
Earnings before interest and tax	**9.1**	**19.6**	▼	**-54%**
Finance income – net	3.9	2.0	▲	95%
Operating income before income tax	**13.0**	**21.6**	▼	**-40%**
Income tax benefit/(expense)	(0.0)	(1.7)	▼	-100%
Profit after income tax	**13.0**	**19.9**	▼	**-35%**

Cash reserves

Cash and cash equivalents grew to $129.6m at 30 June 2024, with strong free cash flow of $20.4m

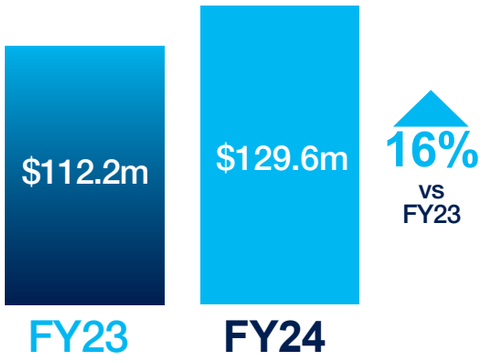
This provides a strong foundation for continued investment for growth, as well as potential M&A opportunities to expand the Company's product portfolio. The Company has no debt and continues to regularly review its capital management strategy.

Free cash flow ($m)



- Free cash flow of $20.4 million was up 3% on PCP.
- Driven by an increase in service contracts with customers paying up-front for multi-year service as well as a reduction in working capital.

Cash and cash equivalents ($m)



- Cash and cash equivalents at 30 June 2024 of $129.6 million, up 16% compared with $112.2 million at 30 June 2023.

Graphs are not to scale and therefore not comparable.

Trophon business, unaudited P&L[1]

The ultrasound reprocessing business continues to generate strong profitability and high returns with unaudited profit before tax of $40.4m[1].

$ millions	FY24	FY23	Change %
Capital revenue	48.2	54.2	▼ -11%
Consumable/service revenue	121.8	111.8	▲ 9%
Total revenue	**170.0**	**166.0**	▲ 2%
Gross profit	**132.4**	**130.6**	▲ 1%
%	77.9%	78.7%	
Operating expenses			
Selling, general and administration	86.4	80.7	▲ 7%
Research and development	11.8	11.0	▲ 7%
Total operating expenses	**98.2**	**91.7**	▲ 7%
Other income	1.7	1.3	▲ 31%
Other gains – net	0.5	1.8	▼ -72%
Earnings before interest and tax	36.5	42.1	▼ -13%
Finance income – net	3.9	2.0	▲ 95%
Profit before income tax	**40.4**	**44.0**	▼ -8%

- Profit before tax (excluding CORIS investments) was approximately $40.4 million,[1] equating to 24% of sales.
- Return includes one-off costs for a new ERP implementation, due for completion in FY25.
- Investments continue in emerging markets for trophon, not yet significantly contributing to revenue.
- Investments continue in the ultrasound reprocessing technology road map.

1. The pro forma profit and loss statement is unaudited and reflects total Company results less operating costs associated with new product development and commercialisation. Operating costs reflect unaudited management allocation estimates where resources are shared between trophon and new product development and commercialisation. The pro forma profit and loss statement also includes income received from the Jobs Plus Program. The pro forma P&L was subject to an agreed upon procedure by the Company's statutory auditor.

FY25 business outlook

Business outlook for FY25

The Company is optimistic about the potential for growth in the trophon ultrasound reprocessing sector and its wider strategic objectives for expansion, particularly regarding the prospects with CORIS following regulatory approval.

8% - 12%[1] revenue growth

- Growing capital revenue with increased unit volumes over FY24.
- Increasing consumables and service revenue aligned with growth in installed base and service contract coverage.

77% - 79%[1] gross margin

- With a planned return to higher production volumes in FY25 and with anticipated increase in unit volume sales, gross margin is expected to return to 77-79%.

6% - 10%[1] operating expenses growth

- Includes ongoing investment in CORIS commercialisation readiness, R&D and geographical expansion.
- One-off expenses associated with the introduction of a new ERP.
- Expecting positive operating leverage in trophon only business.

All guidance is subject to uncertainty in relation to the impact of inflation on hospital budgetary pressures and healthcare costs in general.

1. The FY25 outlook assumes a USD/AUD rate of 0.67.

trophon opportunity

Ultrasound used in many hospital departments

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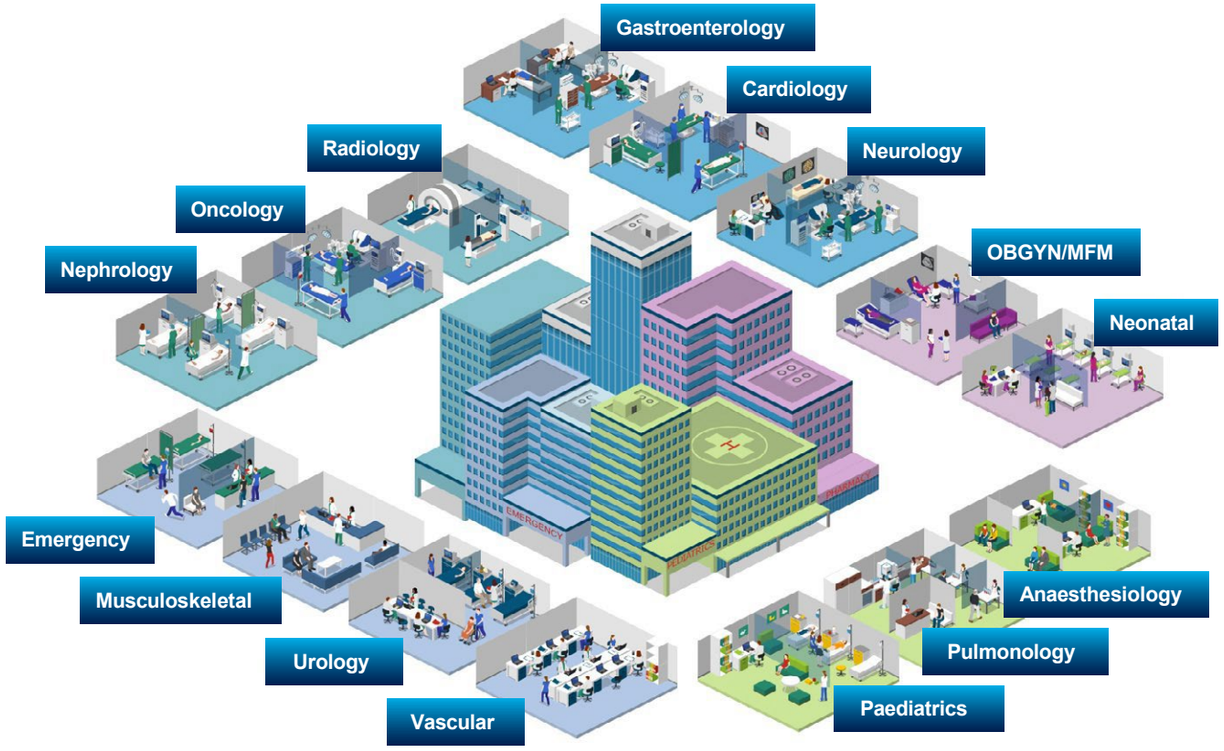
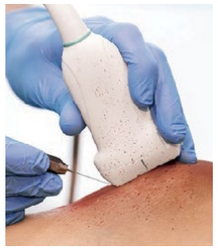
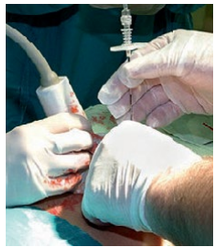
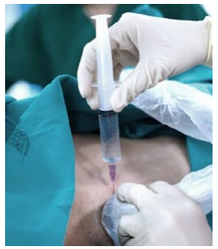
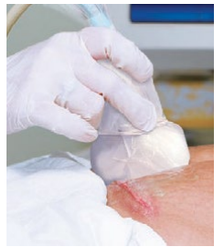
There are over 150 procedures that use ultrasound probes across many hospital departments that risk contact with mucous membranes, non-intact skin and/or sterile tissue[1]



ENDOCAVITARY

- Abdominal Duplex Vascular (complete & limited, transvaginal)
- Pregnancy scan
- Chorionic Villus Sampling
- Transrectal scan
- Transrectal prostate biopsy

UG[2] BIOPSY

- Biopsy of liver
- Biopsy of pancreas
- Biopsy of pleural fluid
- Biopsy of pulmonary lesions
- Biopsy of salivary gland
- Biopsy of sclerosing mesenteritis

INTRAOPERATIVE

- Intraoperative neurosurgical procedures
- Intraoperative UG tracer injection
- UG implantation of iodine seeds
- UG percutaneous renal transplant biopsy
- UG transthoracic punctures

NERVE BLOCKS

- UG cervical nerve root block
- UG ankle block
- UG femoral nerve block
- UG ophthalmic regional anesthesia
- UG percutaneous peripheral nerve stimulation

WOUNDS

- UG burn patient assessment
- UG Focused Assessment with Sonography in Trauma (FAST)
- UG focused diagnostic echocardiography (e.g., cardiac resuscitation in presence of trauma).

and many more

1. Nanosonics analysis, SDMS guidelines, market reports.

trophon growth and value opportunity

In addition to growing the installed base, we strive to deliver continuous value over the lifetime of trophon devices by driving improved compliance with HLD standards.

GROWTH DRIVERS

Installed base growth

Significant opportunity to grow installed base across all regions as fundamentals for adoption increase. Each new installed base unit delivers exceptional customer value while generating annuity revenue over that period.

Usage per trophon

With >150 ultrasound procedures across numerous hospital departments requiring HLD, there is an opportunity to drive increased compliance and usage across the existing and future installed base.

Service

Increasing service contract coverage with new installed base and upgrades.

Capital upgrades

Upgrading the installed base offers existing customers new features and benefits. This creates opportunity for additional capital revenue, as well as extending recurring revenue from consumables and opportunity for growth in service revenue.

Upgrade value and potential

Significant upgrade potential delivering value to customers and Nanosonics

- In addition to best in class efficacy, the latest trophon2 brings significant benefits to customers in terms of usability, traceability and digitisation.
- Upgrades represent significant capital revenue opportunity as well as significant service contract recurring revenue opportunity through direct sales channel in North America.

Significant global opportunity

A GLOBAL INSTALLED BASE OPPORTUNITY OF 140,000[1] UNITS

market penetration

- Significant global growth opportunity.
- Increasing number of international guidelines requiring high level disinfection (HLD) supporting growing international demand.
- Nanosonics expanding its footprint geographically both direct and through distribution.

NORTH AMERICA

Installed Base Opportunity
60,000[1] UNITS

Market Penetration

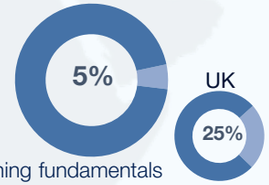
Strong Fundamentals

- Fundamentals for adoption strong with requirements for HLD in place.
- trophon device established as standard of care with 50% market penetration.
- trophon installed base of 30,390 units and already in approximately 70% of all hospitals using ultrasound, including majority of luminary hospitals.
- Nanosonics has established a direct infrastructure to access remaining opportunity within existing hospitals through expansion into all ultrasound-using departments, introduction into new hospitals and large private physician centres.
- Appointed new channel partners specialised in private physician office market.

EUROPE AND MIDDLE EAST

Installed Base Opportunity
40,000[2] UNITS

Market Penetration



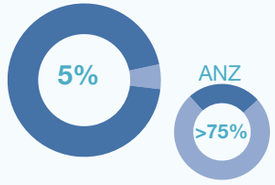
Strengthening Fundamentals

- Expanded geographical reach, strengthening fundamentals for adoption and growing awareness.
- Manual wipe HLD solution holds the largest share in Europe. Ongoing opportunity to move them to automation via trophon.
- Trophon established on NHS Framework UK, HSE in Ireland and now on UGAP public purchasing in France.
- Established partnership with Ecolab France, as a trophon distribution partner in France and select Middle East countries and Turkey. Ecolab France, is a market leader in infection prevention with strong footprint in hospital and in private healthcare.
- In UK and Ireland, the Company has now partnered with Ecolab to distribute their Soluscope TEE ultrasound disinfection solution to strengthen position in the market and enhance our ability to meet the diverse needs of our customers.

ASIA PACIFIC

Installed Base Opportunity
40,000[2] UNITS

Market Penetration



Strengthening Fundamentals and Expanding Markets

- Sales mainly in ANZ where trophon is standard of care and market penetration is >75%.
- The Company continues to invest in its expansion plans in the Asia Pacific region with primary focus on Japan. Progress is being made on the development of national based guidelines similar to those in other international markets.

1. Nanosonics analysis last updated in 2021 based on updated ultrasound information commissioned by Nanosonics and an estimated trophon to ultrasound attachment rate.
2. Based on Nanosonics' estimate from around 2011. While current data is not readily available for the Asia Pacific and Europe and Middle East regions, the Company considers that the ultrasound market has grown in these regions since the initial estimate of the Installed Base Opportunity was made.

Ongoing NA market opportunity

Approximately 270,000 ultrasound devices in use in North America across….

5,700 relevant hospitals with departments using ultrasound[1]

Large (~250)
(>501 beds)

Medium (~750)
(251-500 beds)

Small (4,700)
(<250 beds)

Together with approximately 12,000 relevant private physician centres[1]

trophon TAM
NORTH AMERICA[2]
60,000 units

trophon devices established as standard of care with **50% market penetration**

Remaining 30,000 TAM

Hospital market ~ 20,000
Private physician market ~ 10,000

1. Nanosonics analyses of North America hospitals and procedures data conducted in 2024
2. Nanosonics analysis last updated in 2021 based on ultrasound information commissioned by Nanosonics.

North America New IB growth strategy

Go deep into existing hospitals, go wide into private physician centres

1. Access all 5,700 relevant hospitals and all departments using ultrasound[1] (20,000 units opportunity[1])

Large (~250)
(>501 beds)

Medium (~750)
(251-500 beds)

Small (4,700)
(<250 beds)

- **Continue to access new hospitals**
  trophon devices currently exist in approximately 70% of all hospitals.
- **Access all relevant departments within current hospitals**
  Approximately 60% of current new installed base sales are into existing hospitals which have trophon devices.

2. Access large private physician centres (10,000 units opportunity[1])

- **New channel partners specialised in private physician office market appointed**

1. Nanosonics analysis last updated in 2021 based on ultrasound information commissioned by Nanosonics.

Access all relevant hospital departments

Case Studies

1. Case study: Small hospital From 2 to 13 units

First sales

A small regional hospital on the Gulf Coast with 200 beds originally purchased 2 trophon devices in 2017.

Compliance requirements drives further adoption

As additional guidance from the FDA and the joint commission came out regarding reprocessing surface probes, the hospital's Infection Preventionists reviewed requirements.

Nanosonics site assessment, education and training leads to a further 3 devices for outpatient clinics followed by 8 devices for 4 further departments (Cardiology, PICC, Anesthesia and wound care unit) over next 3 years.

2. Case study: Large hospital From 30 to 100 units

First sales

Original 30 devices purchased between 2014 and 2017 for HLD of endocavitary probes.

Compliance requirements drives further adoption

As additional guidance and requirements were documented, the facility worked with Nanosonics to determine requirements across the different departments, in particular procedures using surface probes in semi-critical procedures.

Assessment results in a further 60 new units plus 30 upgrades. Facility now has total of 100 devices with ongoing growth opportunity as facility expands.

Transforming endoscope reprocessing

CORIS

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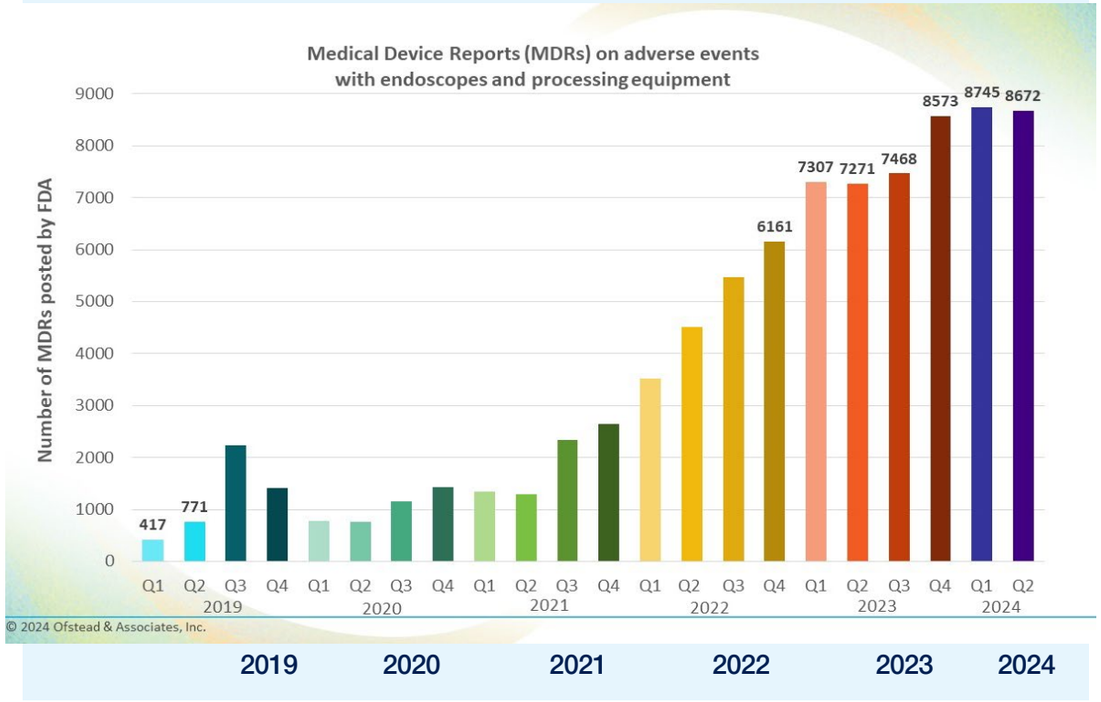
Contaminated endoscopes - a known potential source of infection

Adverse events continue to grow and reprocessing failures and infections have been reported across all major endoscope types[1]



Numerous outbreaks caused by multi-drug resistant organisms continue to occur, with significant impact to healthcare facilities and patients

- 5 multidrug-resistant organisms (MDRO) outbreaks with 1,527 patients exposed and 23 currently confirmed infections have been reported in the peer-reviewed literature YTD in 2024 in the USA.[2-6]
- Some patients became carriers and did not show active signs of infection for up to 320 days after the endoscopic procedure.[2]
- Authors noted published outbreaks greatly underestimate the true rate of exposure and infection[2-4] and biofilm was implicated in several outbreaks.[3-5]
- One outbreak investigation alone in the US involved 77 healthcare professionals to manage.[7]

References: 1. Analysis of FDA MAUDE database by Ofstead and Associates https://www.linkedin.com/posts/ofstead-%26-associates-inc%2E_during-q2-our-team-discovered-8672-endoscope-related-activity-7216858486154964992-dtHg 2. Suleyman, G. et al. Infect Control Hosp Epidemiol. (2024) doi:10.1017/ice.2024.36. 3. Cimen, C. et al. Antimicrob. Resist. Infect. Control 13, 31 (2024). 4. van der Ploeg, K. et al. J. Hosp. Infect. 147, 56–62 (2024). 5. Yang A. et al. Infect Control Hosp Epidemiol. Apr 2:1-6. (2024) 6. Codman et al. Am J Infect Control.2024;52 7. Gubler et al. Am J Infect Control. 2024:52.

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Despite strong standards, manual cleaning remains a problem

Often manual cleaning isn't performed correctly[1]

TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing

Observed Activity	Steps Completed (%) (n = 69)
Leak test performed in clear water	77
Disassemble endoscope completely	100
Immerse endoscope completely in detergent	99
Immerse components completely in detergent	99
Flush endoscope with detergent	99
Rinse endoscope with water	96
Purge endoscope with air	84
Load and complete automated cycle for high-level disinfection	100
Flush endoscope with alcohol	86
Use forced air to dry endoscope	45
Wipe down external surfaces before hanging to dry	90

Manual cleaning is physically demanding[2]

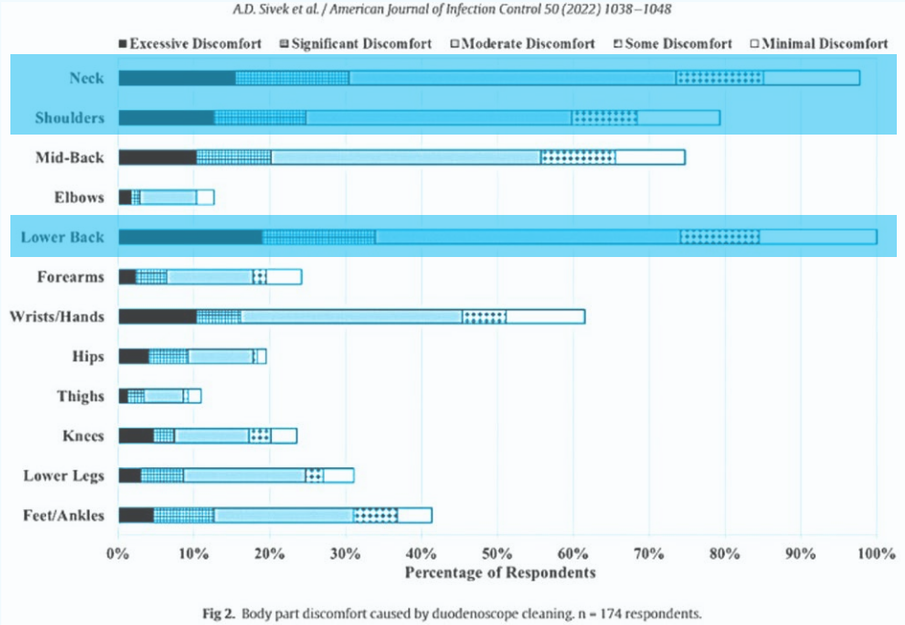

Fig 2. Body part discomfort caused by duodenoscope cleaning. n = 174 respondents.

Manual cleaning poses problems for hospitals and clinics[3,4]

- The ability to maintain the repeatability of individual staff actions is limited.
- Staff are exposed to hazardous materials during the manual cleaning process.
- Job dissatisfaction amongst reprocessing staff leads to higher turnover increasing cost and exacerbating training and repeatability issues.

1. Ofstead, C. L., Wetzler, H. P., Snyder, A. K. & Horton, R. A. Endoscope Reprocessing Methods. Gastroenterol Nurs 33, 304–311 (2010).
2. Sivek, A. D. et al. Healthcare worker feedback on duodenoscope reprocessing workflow and ergonomics. Am J Infect Control 50, 1038–1048 (2022).
3. Lukejohn W. et al. Multisociety guideline on reprocessing flexible GI endoscopes and accessories. American Society for Gastrointestinal Endoscopy (2020)
4. Kenters, N. et al. Worldwide practices on flexible endoscope reprocessing. Antimicrobial Resistance & Infection Control, 153 (2018).

CORIS

CORIS aims to deliver safer endoscopes to patients through superior cleaning

Designed to deliver better cleaning outcomes

Combining a unique mode of action with the CORIS QUANTUM cleaning agent that can remove even the toughest biofilm from all channels, even the smallest ones that cannot be brushed.

Automating the cleaning process

Removing the risk of human error in the cleaning process to provide reliable cleaning outcomes every time.

Improving the safety of reprocessing staff

Removing the manual actions that cause fatigue and injury via its Smart Drain technology, reducing the risk of splashes and aerosolisation of contaminants.

Increasing the efficiency of the facility

Automating traceability tasks and releasing staff from hands-on reprocessing activities to perform other duties.

CORIS

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CORIS delivers cleaning results far exceeding manual cleaning

Available online at www.sciencedirect.com

Journal of Hospital Infection

journal homepage: www.elsevier.com/locate/jhin

Comparison of two endoscope channel cleaning approaches to remove cyclic build-up biofilm

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[d] School of Psychological Sciences, Faculty of Medicine, Health & Human Sciences, Macquarie University, Sydney, Australia
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ARTICLE INFO

Article history:
Received 25 February 2024
Accepted 25 May 2024
Available online 1 June 2024

Keywords:
Biofilm
Endoscope
Manual cleaning
Outbreak
Infection
Contamination

SUMMARY

Introduction: Biofilm contributes significantly to bacterial persistence in endoscope channels. Enhanced cleaning methods capable of removing biofilm from all endoscope channels are required to decrease infection risk to patients. This head-to-head study compared cyclic build-up biofilm removal of an automated endoscope channel cleaner (AECC) with standard manual cleaning according to instructions for use (IFU) in polytetrafluorethylene channels.

Methods: Cyclic build-up biofilm was grown in 1.4-mm (representing air/water and auxiliary channels) and 3.7-mm (representing suction/ biopsy channels) inner diameter polytetrafluorethylene channels. All channels were tested for residual total organic carbon, protein, and viable bacteria. Internationally recognized ISO 15883-5:2021 alert levels were used as cleaning benchmarks for protein (3 μg/cm²) and total organic carbon (6 μg/cm²).

Results: The automated cleaner significantly outperformed manual cleaning for all markers assessed (protein, total organic carbon, viable bacteria) in 1.4-mm and 3.7-mm channels representing air/water/auxiliary and suction/biopsy channels, respectively. Manual cleaning failed to remove biofilm from the air/water and auxiliary channels. According to the IFU, these channels are not brushed, suggesting a potential root cause for a portion of the numerous endoscopy-associated infections reported in the literature.

Conclusion: AECC shows potential to deliver enhanced cleaning over current practice to all endoscope channels and may thereby address infection risk.

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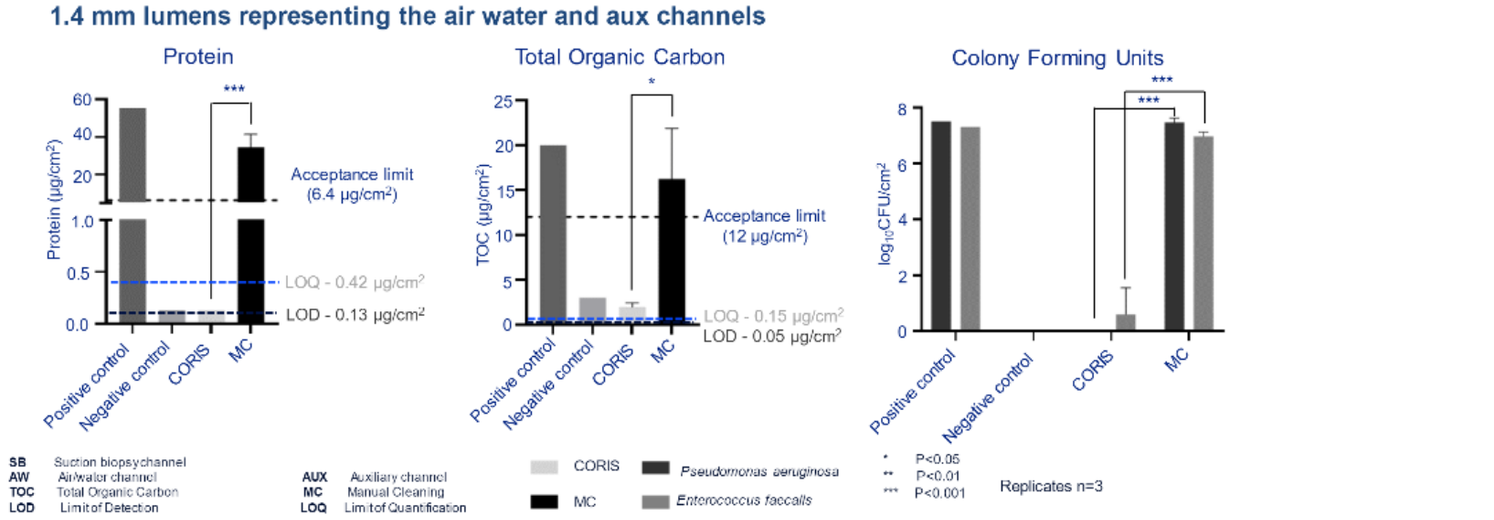
[i] These authors contributed equally to this work.

https://doi.org/10.1016/j.jhin.2024.05.014
0195-6701/

Key findings

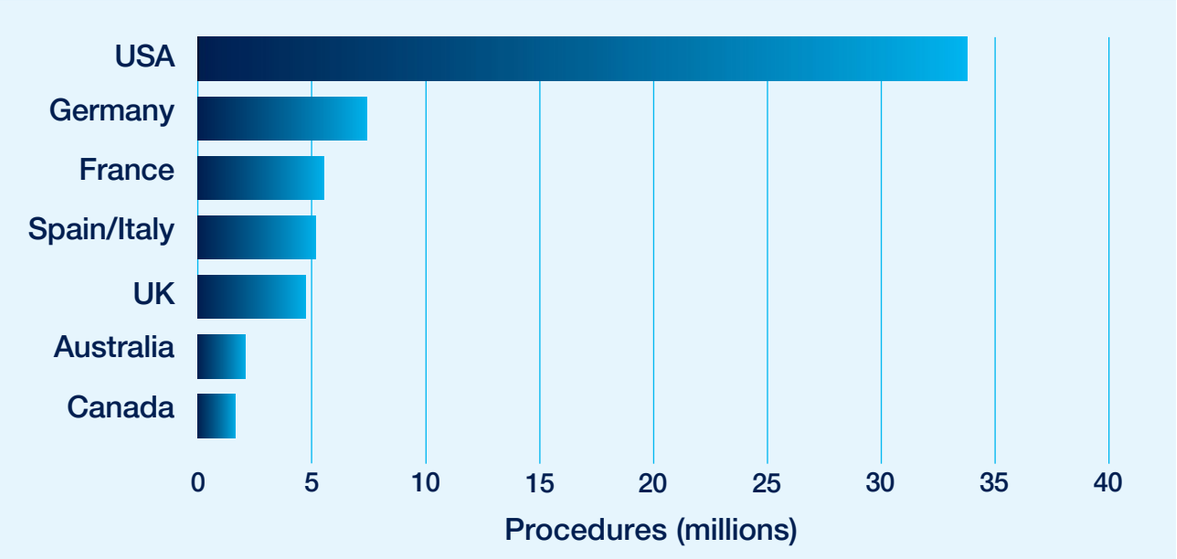
- CORIS significantly outperformed manual cleaning in all channels across all markers including protein, total organic carbon and viable bacteria.
- 1.4-mm and 3.7-mm channels were tested, representing air/water/auxiliary and suction/biopsy channels respectively.
- Manual cleaning failed to remove biofilm from the air/water and auxiliary channels.



Large global opportunity for CORIS

More than 60 million flexible procedures annually across major markets

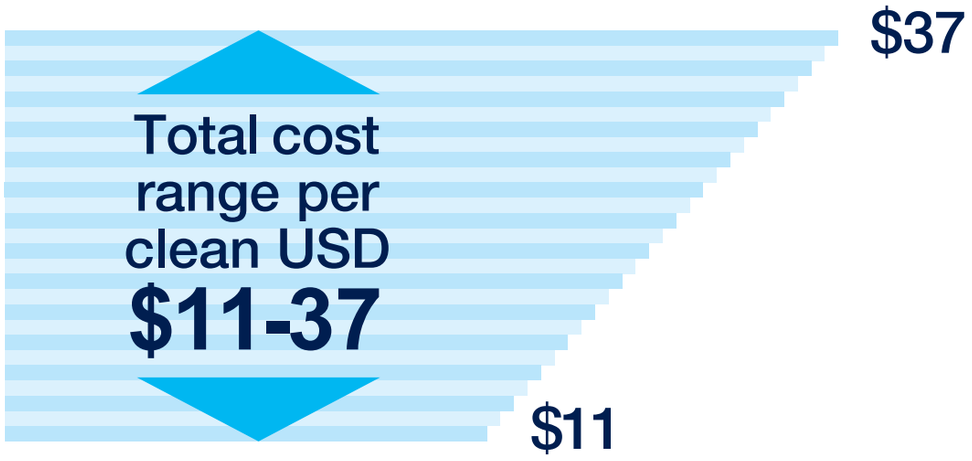
Endoscopy, 60 million annual procedures[1]



- Projected procedure growth rate of 6% p.a.[1]
- The USA is the largest contributor to procedure volume.
- 75% of the total are upper and lower gastro-intestinal (GI) procedures.
- Colonoscopes and gastroscopes are most-commonly used.

Manual cleaning costs[2]

EXAMPLE: Total cost to manually clean **a single GI endoscope**[2]



Current cost of manual cleaning of endoscopes is estimated to be between USD $11-$37.

References: 1 Frost & Sullivan, Endoscope Reprocessing Systems and Software Solutions Market Assessment (US, W. Europe, Australia), 2018. 2. Ofstead, C.L., Quick, M.R., Eiland, J.E. and Adams, S.J., 2017. A glimpse at the true cost of reprocessing endoscopes. International Association of Healthcare Central Service Material Management.

Global standards for reprocessing

Endoscope reprocessing standards established globally

There is a large variety of endoscopes for complex clinical procedures

Endoscopes require cleaning and disinfection (reprocessing) after every use with strong fundamentals and standards for reprocessing

Colonoscopy
Colon

Gastroscopy
Stomach interior

Duodenoscopy
Pancreas and bile ducts

Enteroscopy
Small intestine

Endoscopic ultrasound
Digestive tract and other organs

Bronchoscopy
Lungs and air passages

Urology
Urinary tract

ENT
Nasal and sinus passages

Gynaecology
Obstetrical and infertility conditions

CORIS - the pathway to market[1]

United States Food and Drug Administration **(FDA)**

De Novo Regulatory Pathway

As CORIS is a completely novel technology platform, Nanosonics is pursuing the FDA's De Novo regulatory pathway in the United States. Approval via this pathway would establish CORIS as a completely new category for endoscope cleaning technology.

CORIS currently under FDA review

- CORIS was submitted for De Novo approval at the end of April 2024 and is now proceeding through the FDA's De Novo review process.
- Upon approval, 510K submissions planned to cover all flexible endoscopes.

1. All research and new product development programs involve inherent risks and uncertainties which can impact commercialisation timelines.

Progressing our Sustainability Journey

Caring for all our stakeholders

Nanosonics cares for our customers and their patients, our partners, our people, the planet and the community

- Trophon currently protects approximately 27 million patients each year and growing from the risk of cross-contamination associated with ultrasound procedures
- We deliver this in an environmentally friendly way – trophon technology produces only environmentally friendly oxygen and water as by-products.
- Whilst our emissions profile is modest, we have taken active steps to play our part by measuring and where possible reducing our emissions.

Our FY25 targets

Caring for our customers and their patients

- Continue growth in the number of patients protected against the risk of cross-contamination through the use of our trophon technology
- Zero material adverse events/ recalls
- Maintain all relevant regulatory approvals globally
- Receive QMS certification for 100% of Nanosonics' sites

Caring for our partners

- Conduct multiple onsite modern slavery audits with tier one suppliers.
- Conduct further remediation activities with key suppliers (note: no suppliers were classified as 'high risk')
- Investigate modern slavery risks associated with all new suppliers associated with CORIS
- Seek to maintain 100% compliance on all training modules associated with the Code of Conduct and Ethics

Caring for our planet

- Use 100% renewable energy source for Australian business operations by end of FY25
- Identify opportunities for reducing scope 3 emissions, in particular through our manufacturing and supply chain strategy.
- Meet the APCO annual reporting requirements by increasing the review of our packaging from 20% to 40% against the Sustainable Packaging Guidelines

Caring for our people

- Achieve FY25 diversity, equity and inclusion objectives set out in the Report
- Maintain or exceed employee engagement at or above FY24 level of 71%
- Achieve below NSW Safe Work Industry target for safety incidents (LTIFR)

Caring for our communities

- Exceed 10% of total workforce training in Mental Health First Aid to maintain recognition of Skilled Mental Health First Aid Workplace
- Identify further opportunities to advance the commitments expressed in our RAP statement, in particular, employment or internship opportunities

APPENDIX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trophon2
nanosonics

Leading ultrasound reprocessing

trophon technology is the world's leading HLD solution

Safer for patients, staff and the environment – that's the power of nebulised hydrogen peroxide	• trophon is the only automated HLD solution for ultrasound probes that uses hydrogen peroxide chemistry - deadly for organisms but safe for staff and the environment. • US FDA recently recognised hydrogen peroxide as an established category A sterilization method based on its 'long history of safety and effectiveness'.[1]
Designed to HLD probe surfaces in the real world	• Ultrasound probes vary in design and topology, containing grooves, notches or bends. Only trophon uses a nebulised mist, capable of reaching all accessible surfaces of ultrasound probes. • trophon technology is the only point-of-care automated high-level disinfection technology for ultrasound probes that passes the demanding 'penicylinder test' required by the FDA. • Multiple peer-reviewed studies have been published showing the efficacy of trophon devices in laboratory and clinical settings.[2-5]
Standards-compliant traceability	• Confident capture of traceability information for customers to demonstrate compliance to global and national standards. • Meets the needs of a rapidly evolving cybersecurity landscape.
Endorsed by more OEMs and clinicians	• Compatible with more than 1,300 different probes. • The most endorsed OEM product for probe compatibility.

The trophon® family includes the trophon® EPR and trophon®2 devices which share the same core technology of 'sonically-activated' hydrogen peroxide.

1. https://www.fda.gov/news-events/press-announcements/fda-facilitates-broader-adoption-vaporized-hydrogen-peroxide-medical-device-sterilization
2. Vickery, K., et al. (2014). J Infect Public Health; 3. Becker, B., et al. (2017). GMS Hygiene and Infection Control 12; 4. Ryndock, E., et al. (2016). J Med Virol; Buescher, D. L., et al. (2016). Ultrasound Obstet Gynecol; 5. Ngu, A., et al. (2015). Infect Control Hosp Epidemiol.

Income tax

$ millions	30-Jun-24	30-Jun-23
Income tax expense / (benefit)	0.0	1.7

Components of Net Deferred Tax Asset	30-Jun-24	30-Jun-23
Tax losses	0.5	0.5
R&D tax credits	1.3	-
All other timing differences	14.9	14.0
Total	**16.7**	**14.5**

Value of carried forward losses & R&D credits	Gross	Tax Benefit	Effective rate %
Losses recognised	2.0	0.5	26.2%
R&D credits carried forward	2.8	1.3	45.8%
Total losses and R&D credits recognised	**4.8**	**1.8**	**37.5%**
Losses not recognised	8.9	2.9	32.5%
Total	**13.7**	**4.7**	**34.3%**

Effective income tax for the period was 0.1%

Deferred tax asset consists of:

- $0.5m tax losses relate to the recognised portion of losses for UK and Canada
- $1.3m R&D tax credits not utilised.
- $14.9m all other timing differences

Assessment of probability of recovery (and therefore recognition of related benefit) of unrecognised losses is made on an on-going basis. Currently we have $8.9m unrecognised losses