



# LEADER IN INFECTION CONTROL SOLUTIONS

*Improving the safety of patients, clinics, their staff  
and the environment*

Michael Kavanagh, CEO and President

Canaccord Genuity 34<sup>th</sup> Annual Growth Conference  
Boston, August 2014

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# Corporate 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

Johns Hopkins Photo Credit: American Nurse Project. Does not imply endorsement

# Company Overview

- Proprietary automated system for low temperature, high level disinfection
- First product, **trophon<sup>®</sup> EPR**, for high level disinfection of ultrasound probes
- Approved for sale by: US FDA, TGA(AU), CE mark notified body (TUV Rheinland), Health Canada, Medsafe (NZ) & South Korean FDA, Japan PMDA
- 110 Staff across Australia, US, UK, Germany & France
- GE Healthcare exclusive distributor in North America
- Toshiba and GEHC - UK distributors
- Miele Professional – distributor in Germany

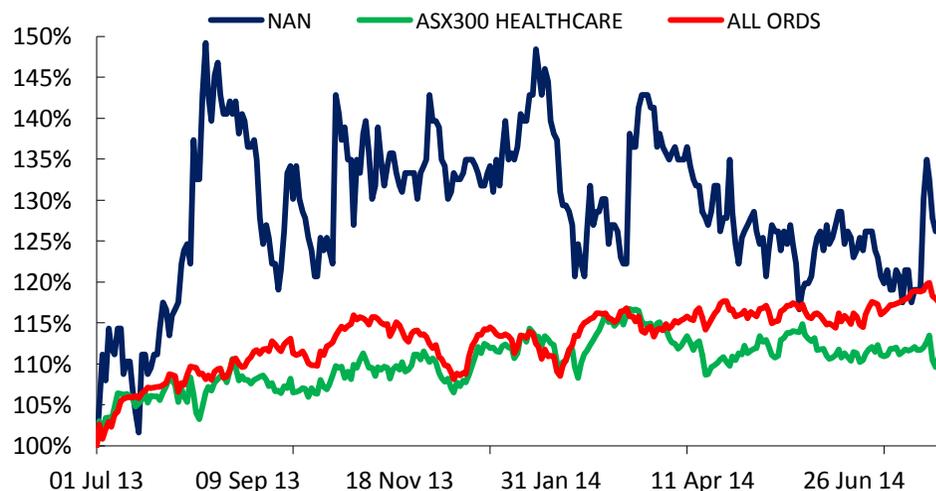


# Company Overview

## Key Corporate Data

Share price*	\$0.82
Shares on issue	264.2 million
Market capitalisation*	\$216 million
Liquidity (30 day avg)	223,000 shares
Cash (31 Mar 2014)	\$21.2 million
Share register breakdown	Founders/Related Parties 22% Institutions 33% Private 41% Corporate 4%

\* Close of trade: 7 Aug 2014



# Executive Team



**Michael Kavanagh**  
CEO and President,  
Managing Director

- Non Executive Director from July 2012
- Commenced as CEO and President effective October 2013
- Over 25 years' experience in healthcare marketing
- Previously Senior Vice President of Global Marketing for Cochlear for more than 10 years



**Ron Weinberger**  
President Technology  
Development &  
Commercialisation

- Joined the company in August 2004 . Currently President of Technology Development/Commercialisation
- Co-inventor of several key Nanosonics' inventions which underpin the company's technology platform
- Has a PhD in medical research and over two decades experience in biotechnology



**McGregor Grant**  
CFO and Company  
Secretary

- Joined Nanosonics in April 2011
- 15 years' experience in senior roles in medical device and healthcare industries in Australia and the US
- Previously worked for Coopers & Lybrand in Australia and Europe



**Gerard Putt**  
Head of Manufacturing

- Joined Nanosonics full time in April 2011 after 18 months on the Nanosonics advisory board
- Over 12 years' experience in the Medical Device industry as a leader of development, engineering and production teams at ResMed



**Michael Potas**  
Head of RD&D

- Joined Nanosonics in August 2006
- More than 16 years' experience in the development and commercialisation of new products and technologies
- Instrumental in the research, design & development of the Trophon<sup>®</sup> EPR



**Vincent Wang**  
Head of Global Services

- Over 11 years' experience in in global medical device markets
- Previously worked for Sonova Hearing Healthcare Group and as Regional Technical Service and Repair Manager for Cochlear



**Ruth Cremin**  
Head of Quality and  
Regulatory

- Joined Nanosonics in June 2011 and has extensive regulatory affairs experience
- Previously Senior Regulatory Affairs Specialist at Cochlear for the Asia Pacific Region, and also regulatory and quality roles at Pfizer and Bio-Medical Research



**Kirste Courtney**  
Human Resources  
Manager

- Joined Nanosonics in 2008
- Has extensive human resources experiences having worked in variety of industry sectors including chartered accounting, media, logistics and banking

# Board of Directors



**Maurie Stang**  
Non-Executive  
Chairman

- Appointed Non-Executive Chairman March 2007, Director since 2000
- Entrepreneur with over 20 years of experience in building and managing companies in the healthcare and biotechnology sector
- Currently Non-Executive Chairman of Aeris Environmental Ltd. Owns 28.7M shares (10.9%) of Nanasonics



**Michael Kavanagh**  
CEO and President,  
Managing Director

- Joined Nanasonics as CEO and President effective October 2013
- Over 25 years' experience in healthcare marketing
- Previously Senior Vice President of Global Marketing for Cochlear for more than 10 years



**Richard England**  
Non-Executive Director

- Chartered Accountant with over 30 years experience in accounting and financial services
- Previously was Chairman of Gropep, and Director of ITL Ltd
- Outside of the life sciences, Mr England is Chairman of Ruralco Holdings and Chandler Macleod and a director of Macquarie Atlas Roads.



**David Fisher**  
Non-Executive Director

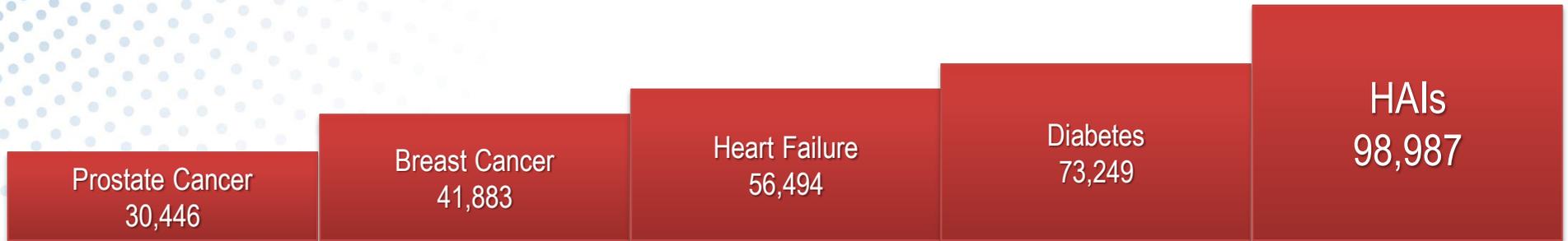
- Over 25 years' experience in the biotechnology and healthcare industry in Australia and overseas
- Founding partner of Brandon Capital Partners, a leading venture capital firm which specialises in investments in the Life Sciences sector
- Previously CEO of Peptech, which was acquired by US-based Cephalon, and Pharmacia, which is now part of Pfizer



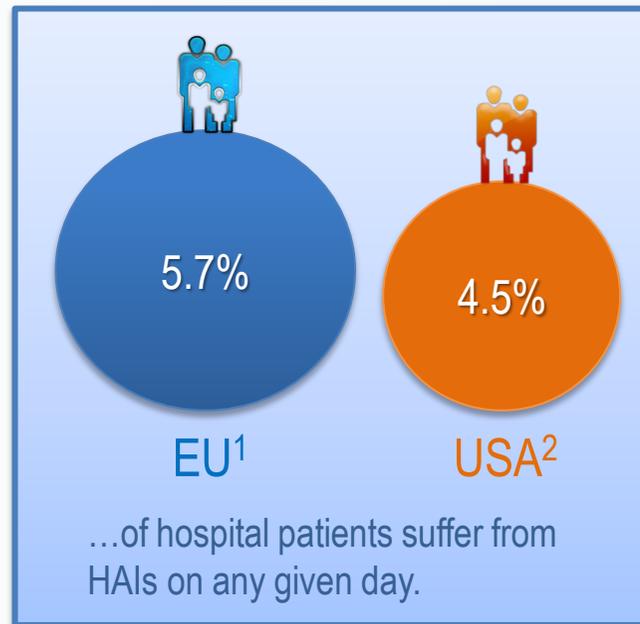
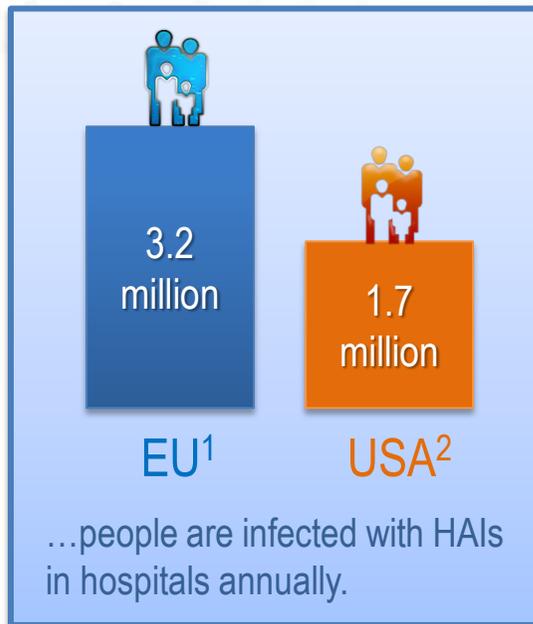
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Executive Director

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- Has a PhD in medical research and over two decades experience in biotechnology

# Healthcare Acquired Infections (HAIs)



HAIs kill more people in the US each year than **Breast Cancer** and **Prostate Cancer** combined.<sup>1,2</sup>



- ✓ Up to 70% of HAIs are preventable using existing infection prevention practices.<sup>3</sup>
- ✓ The financial benefit of using these prevention practices is estimated to be \$25.0 billion to \$31.5 billion in medical cost savings in the US alone.<sup>4</sup>

1. Klevens et al, Public Health Reports (2007)
2. Kochanek et al, National Vital Statistics Reports CDC 53:(5) (2004)
3. European Centre for Disease Prevention and Control. Stockholm: ECDC (2013)
4. Scott RD. Atlanta: Centers for Disease Control and Prevention (2009).



# The Need for Disinfection in Ultrasound

- ✓ Ultrasound transducers must be reprocessed between patients to prevent cross-infection
- ✓ Any transducer that contacts broken skin, mucous membranes or sterile body cavities should be high level disinfected or sterilised<sup>1</sup>
- ✓ Heat sensitive transducer construction materials mean that sterilisation is generally not practical; high level disinfection (HLD) is carried out instead
- ✓ Despite this knowledge, problems in ultrasound disinfection persist



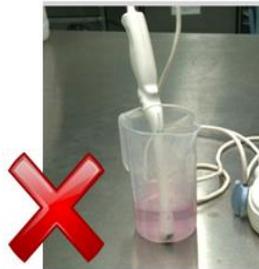
HLD – “the complete elimination of all microorganisms in or on an instrument, except for small numbers of bacterial spores”.<sup>1</sup>

1. Rutala W., Weber DJ., 2008, Centers of Disease Control and Prevention

# Traditional HLD Methods

Disinfection processes unchanged in **20+ years**

Existing methods have many shortfalls



## The traditional methods: soak, spray or wipe

- Chemical spills and vapour control present OH&S risks
- Probes often must be transported to a central sterilisation facility
- Pathogens may remain - increased risk of cross contamination
- Wipes and sprays not approved by the FDA for HLD
- Toxic chemicals must be disposed of as chemical waste



# Automation and Trends Towards Stricter Reprocessing Controls

- FDA mandates and multiple guidelines state that semi-critical ultrasound probes must undergo sterilization or high level disinfection (HLD)
- A number of international bodies recommend automated reprocessing over manual methods <sup>1-3</sup>
- The American Institute of Ultrasound in Medicine (AIUM) guidelines recommend “hydrogen peroxide nanodroplet emulsion” (trophon EPR’s technology) for effective high level disinfection without toxicity

1. Rutala W., Weber DJ., 2008, Centers of Disease Control and Prevention
2. Recommendation of the commission for hospital hygiene and infection Prevention at the Robert Koch Institute (RKI), Federal Health Gazette Health Research – Health Protection, 2001 44:1115–1126
3. Department of Health, Estates & Facilities Division, HTM01-01 2007



## Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Probes Between Patients

Approved 4/2/2014

The purpose of this document is to provide guidance regarding the cleaning and preparation of external and internal ultrasound probes. Some manufacturers use the term “transducers” or “imaging arrays.”

Medical instruments fall into different categories with respect to their potential for pathogen transmission. The most critical instruments are those that are intended to penetrate skin or mucous membranes. These require sterilization. Less critical instruments (often called “semicritical” instruments) that simply come into contact with mucous membranes, such as fiber-optic endoscopes, require high-level disinfection rather than sterilization. “Noncritical” devices come into contact with intact skin but not mucous membranes.

**External probes** that only come into contact with clean, intact skin are considered noncritical devices and require cleaning after every use as described below.

All **internal probes** should be covered with a single-use barrier. If condoms are used as barriers, they should be nonlubricated and nonmedicated. Although internal ultrasound probes are routinely protected by single-use disposable probe covers, leakage rates of 0.9% to 2% for condoms and 8% to 81% for commercial probe covers have been observed in recent studies (Rutala and Weber, 2011). These probes are therefore classified as semicritical devices.

*Note:* Practitioners should be aware that condoms have been shown to be less prone to leakage than commercial probe covers and have a 6-fold enhanced acceptable quality level (AQL) when compared to standard examination gloves. They have an AQL equal to that of surgical gloves. Users should be aware of latex sensitivity issues and have non-latex-containing barriers available.

For maximum safety, one should therefore perform **high-level disinfection** of the probe between each use and use a probe cover or condom as an aid to keep the probe clean. *For the purpose of this document, “internal probes” refer to all vaginal, rectal, and transesophageal probes, as well as intraoperative probes and all probes that are in contact with bodily fluids/blood or have a remote chance to be in contact with dry/cracked skin and body fluids, including blood.*

### Definitions

All cleaning, disinfection, and sterilization represent a statistical reduction in the number of microbes present on a surface rather than their complete elimination. Meticulous cleaning of the instrument is the key to an initial reduction of the microbial/organic load by at least 99%. This cleaning is followed by a disinfecting procedure to ensure a high degree of protection from infectious disease transmission, even if a disposable barrier covers the instrument during use.

According to the Centers for Disease Control and Prevention (CDC) “Guideline for Disinfection and Sterilization in Healthcare Facilities” (2008):

“Cleaning is the removal of visible soil (eg, organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic material that remains on the surfaces of instruments interfere with the effectiveness of these processes.”



# Compliance with Guidelines

- **TJC Quick Safety 2014** identified Infection Control as one of the top five non-compliant TJC requirements<sup>1</sup>
- In addition<sup>1</sup>
  - Of 13 immediate threat to life (ITL) discoveries from surveys conducted in 2013, seven were directly related to improperly sterilized or high level disinfected equipment
  - Breaches in equipment sterilization and high level disinfection processes can result in outbreaks of HIV, and hepatitis B and C, as well as the transmission of bacterial infecting agents
- The Joint Commission (TJC) reports that **36% of accredited hospitals surveyed in 2011 were noncompliant** with its standards to reduce the risk of infection associated with medical equipment, devices and supplies<sup>2</sup>



1. The Joint Commission Quick Safety May 2014
2. ECRI Institute's Top 10 Health Technology Hazards Report for 2013

# It's Time for a New Solution



“Here we are, with a new \$150K ultrasound machine and \$15K probes to go with it that we’re cleaning with 1960s glutaraldehyde soaking technology.”

*Feisal Keshaviee, CEO, Radiology Consultants Associated, Canada*

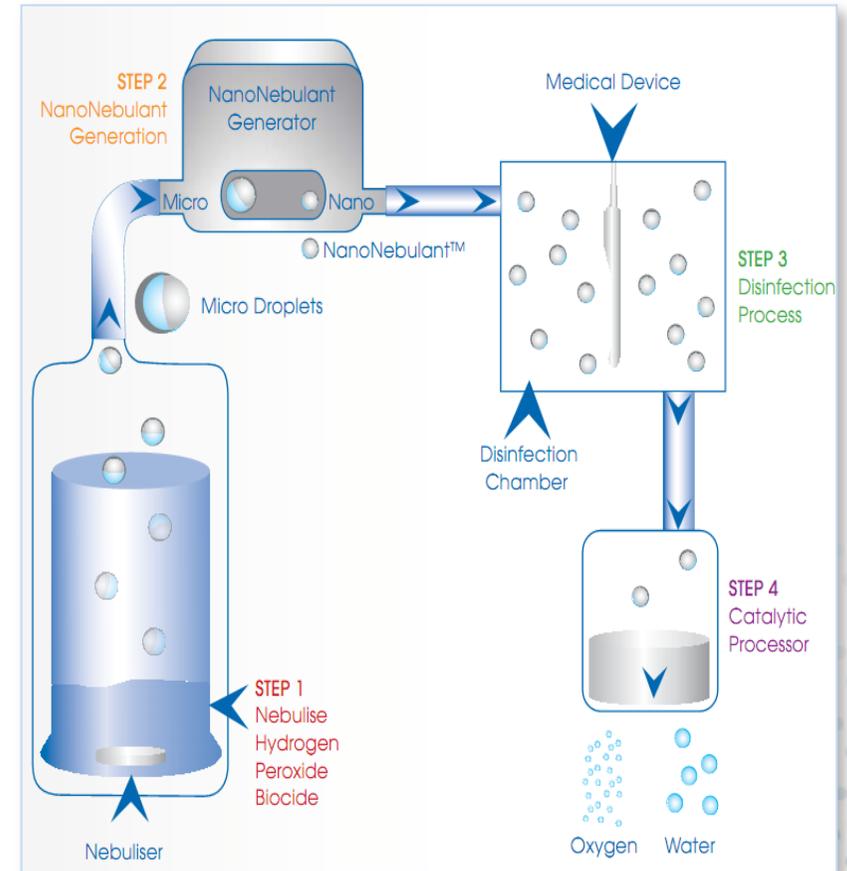
First fully automated system for disinfection of ultrasound probes  
- **compatible with all major ultrasound probes.**



Offers a safer, quicker,  
quality assured method of  
disinfecting ultrasound  
probes

# Our Technology – Nano-Nebulisation for Low Temperature Disinfection

- ✓ High frequency sonic vibration turns disinfecting liquid into nano-sized droplets
- ✓ “Nano” droplets disperse like a gas
  - Covers entire surface of object being disinfected
- ✓ NanoNebulant is a strong oxidising agent
  - Lethal to bacteria, viruses and fungi
- ✓ NanoNebulant evaporates
  - Surface of disinfected object left dry and ready to use
- ✓ Non-toxic by-products
  - Water and oxygen
- ✓ 14 Patents families most to 2025



# The Case for trophon EPR - Efficacy

- ✓ A peer-reviewed publication reported on 59 different efficacy experiments at four different testing locations in Europe and Australia. Successful tests against 21 species of bacteria, fungi and viruses demonstrated the HLD efficacy of trophon EPR using multiple international standards.<sup>1</sup>
- ✓ Clinical data has also demonstrated trophon EPR efficacy in disinfecting transducer handles.<sup>2</sup>
- ✓ trophon EPR efficacy has been independently validated by German testing company SMP GmbH.



1. Vickery et al., Evaluation of an automated high-level disinfection technology for ultrasound transducers. J Infect Public Health. 2013 Dec.
2. McNally, G., et al., Reducing infection risk from ultrasound transducer handles, in ISUOG World Congress. 2013: Sydney, Australia.

# trophon<sup>®</sup> EPR

-  **Fast:** Fast automated high level disinfection
-  **Helps protect:** Fully enclosed system limits exposure to harmful chemicals
-  **Consistent:** Quality assured consistency
-  **Probe friendly:** Probe friendly process. Compatible with more than 600 probe models
-  **Environmentally Friendly:** Harmless oxygen and water by-products.  
More than 70% recyclable components
-  **Cost Efficient:** Integrates into HLD process at point of care and improves workflows
-  **Effective:** Clinically validated trophon EPR disinfects both probe shaft AND handle
-  **Traceability:** Best practice documentation solution

# Fast 7 Minute Cycle

Preclean

trophon® EPR

Wipe/Print Label



7 minute  
Automated  
HLD cycle



PPE Preclean Test/Log



5 to 20 minutes  
Soak in solution

Vented Soak Station



PPE Rinse Rinse Rinse Wipe Log

# Compatible With More Than 600 Probe Models

- ✓ More than 600 probes approved to date by leading manufacturers
- ✓ Nanosonics performs extensive testing on new probes
- ✓ Probe is returned to OEM for inspection, quality verification and approval

“We’re now trying to ‘trophon’ every transducer after use, not just endocavitary.”

*Robert De Jong Jr., The Johns Hopkins Hospital*



# Large and Accessible Market

## ✓ Addressable install base: ~120,000 trophon EPR units

- ~40,000 units in North America
- Equivalent sized markets in Europe and RoW

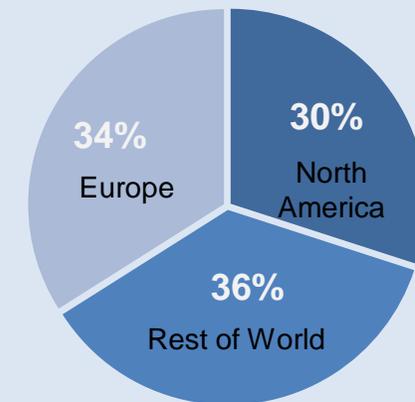
## ✓ NAN revenue potential >\$300 million p.a.\*

- Installed Base 120,000 units
- 5 year replacement cycle
- 4 disinfections cycles / trophon EPR / day

## ✓ Main targeted uses:

- Obstetrics and gynaecology
- Other HLD mandated procedures including:
  - Urology
  - Surgical / anesthesia
  - Emergency

Distribution of ultrasound machines



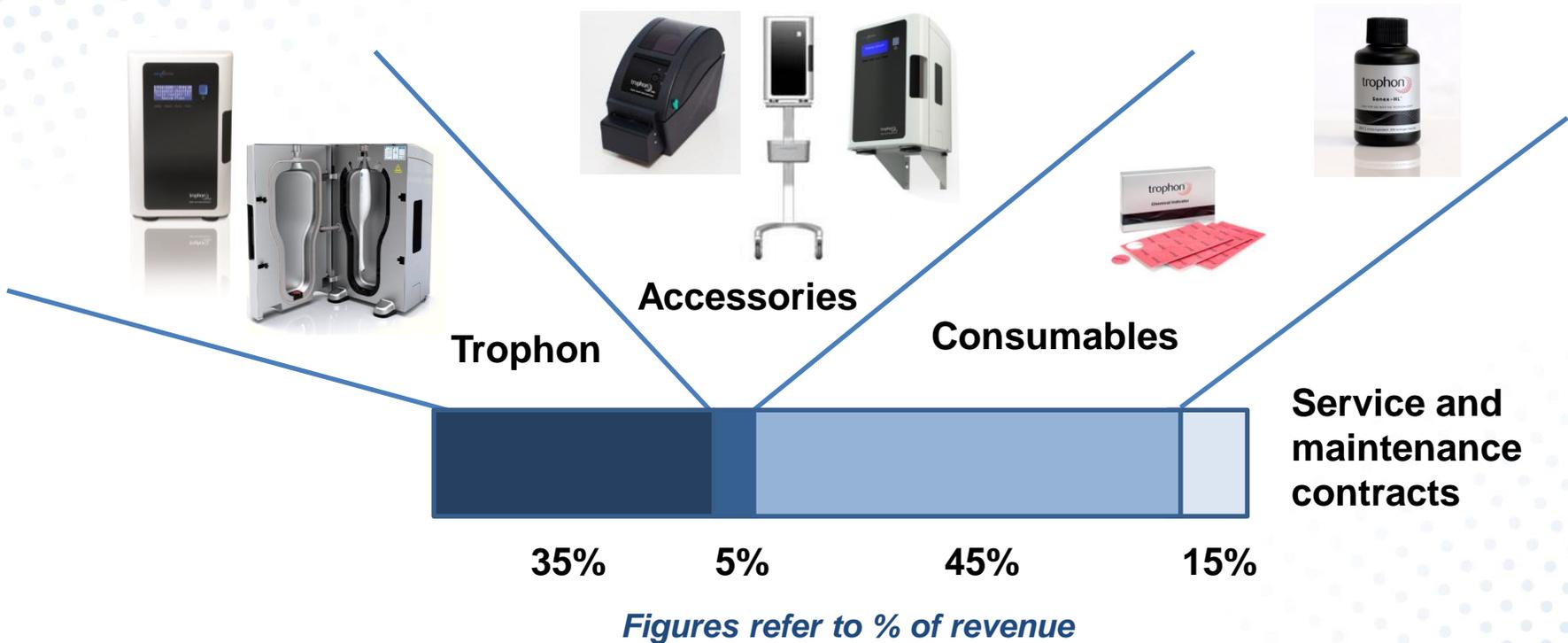
- ✓ > 500,000 ultrasound consoles
- ✓ > 600 million procedures p.a.
- ✓ Ultrasound market growing >8% CAGR

\* Revenue from sales of trophon EPR only including consumables and accessories

# Attractive Revenue Model

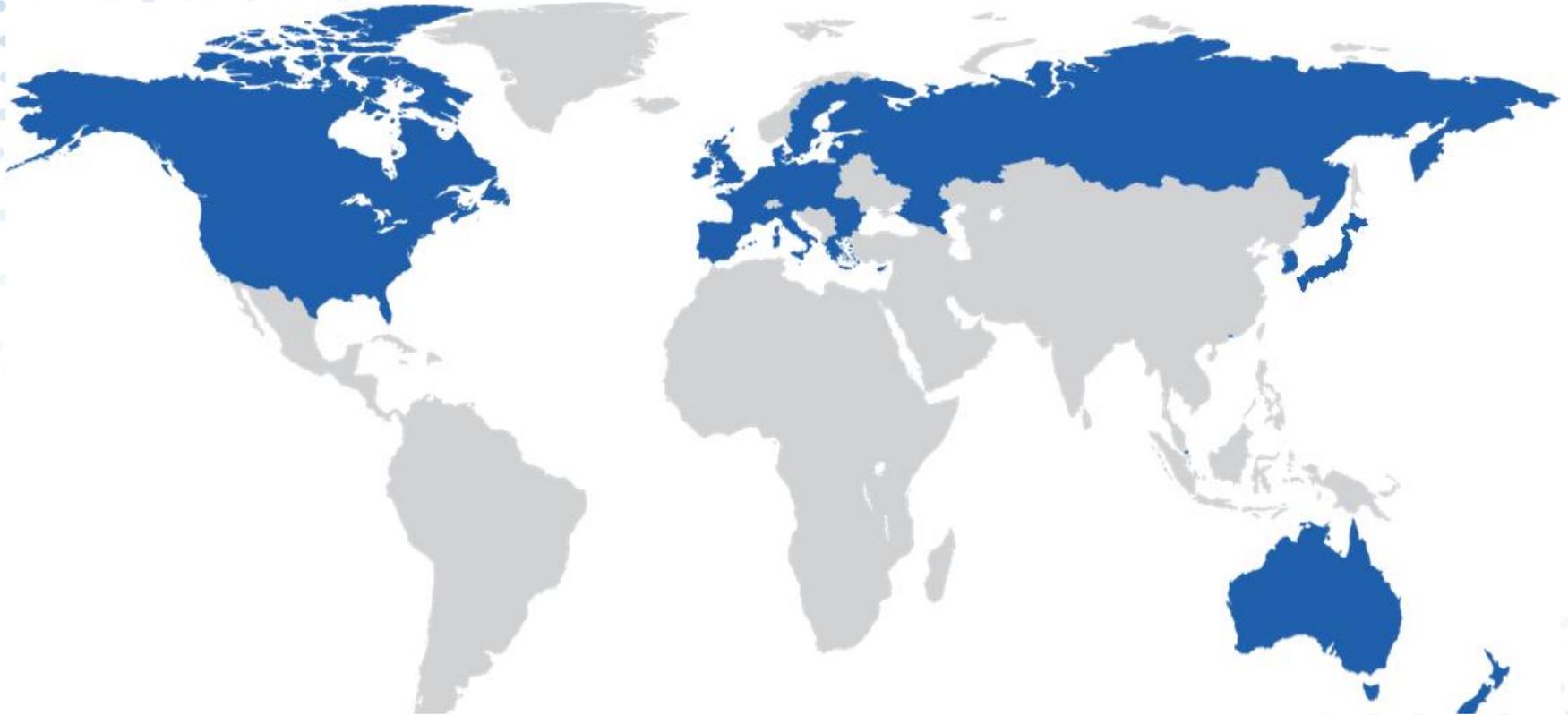
*Multiple revenue streams:*

*Up-front sales plus consumables, accessories and service contracts*



**Each unit sale results in robust annuity type revenue stream**

# Regulatory Approval Across all Major Markets



- ✓ US FDA
- ✓ CE mark notified body (TÜV Rheinland)
- ✓ Health Canada
- ✓ TGA (AU)
- ✓ Medsafe (NZ)
- ✓ MFDS (South Korea)
- ✓ HAS (Singapore)
- ✓ MDCO (Hong Kong)
- ✓ Roszdravnadzor (Russia)
- ✓ PMDA (Japan)

# Financial Results for FY14

	FY13 \$million	FY14 \$million	% Change
<b>Total Sales Revenue</b>	<b>14.899</b>	<b>21.492</b>	<b>44%</b>
<b>Cash Balance at 30 June</b>	<b>24.1</b>	<b>21.2*</b>	<b>-12%</b>

\* Additional cash receipts of \$3.0 million were received in July relating to sales in the fourth quarter.



# North America



**Ron Bacskai**  
President & CEO,  
Nanosonics Inc.



**Keith Koby**  
Vice President Sales



**John Corbett**  
Program Manager



**Kevin Markham**  
Southeast Regional  
Sales Manager



**Donna Fiorentino**  
Northeast Regional Sales  
Manager



**Norm Rich**  
Western Regional  
Sales Manager



**Tom O'Neill**  
North Central Regional  
Sales Manager



**Ray Beams**  
South Central  
Regional Sales Manager

# Exclusive Distribution Agreement with GE Healthcare in North America

“GE Healthcare is pleased to be offering this new technology in ultrasound probe reprocessing which is effective, efficient and environmentally friendly. Through our investments in highly innovative technologies and as the exclusive distributor of trophon® EPR in North America, GE Ultrasound is further demonstrating our commitment to providing solutions to our customers in order to improve patient care and clinical workflow.”



GE Healthcare

## **Anders Wold, President and CEO of GE Ultrasound**

"Nanosonics is a great example of our goal at GE Ventures which is to partner with innovative organisations to scale great ideas that drive growth for those partners and GE"

## **Noah Lewis, Managing Director and Operating Leader, GE Ventures**



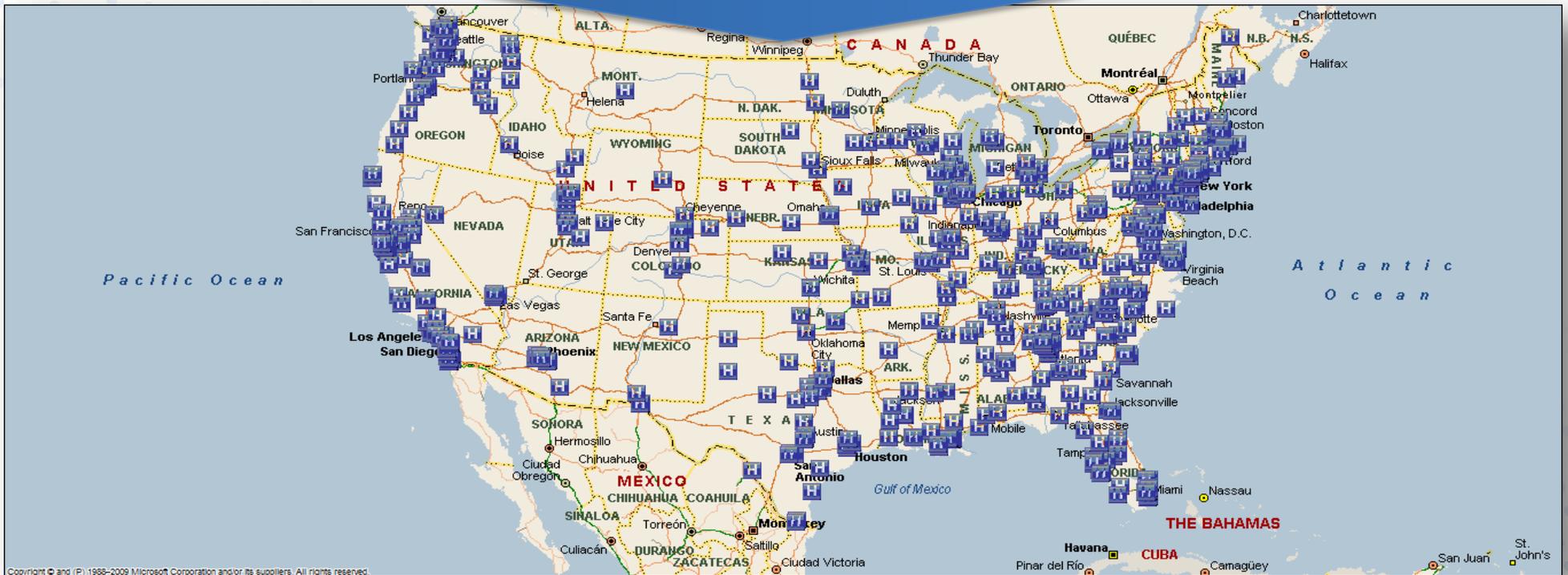
GE VENTURES

# 40 of the Top 50 Hospitals as of August 2014



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# USA Order Locations >1000 USA Locations



**Note: locations may have multiple units installed**

# “...complete and safer protection for our patients and staff ”

“The trophon EPR has been the biggest thing to hit ultrasound since color Doppler.

“trophon was an answered prayer! It has solved so many high level disinfection (HLD) issues while offering more complete and safer protection for our patients and staff – in half the time.



*Robert De Jong Jr., RDMS, RDCS, RVT, Radiology Technical Manager, Ultrasound, The Johns Hopkins Hospital, Baltimore, US*



# United Kingdom



**Bryn Tudor-Owen**  
Country Manager

- ✓ Toshiba & GE as distributors
- ✓ Nanosonics also selling direct
- ✓ Number of key hospitals adopting trophon EPR
- ✓ Awareness activities progressing



# Medicines & Healthcare products Regulatory Agency



**Government agency with responsibilities for standards of safety, quality & performance**

**Medical Device Alert Ref: MDA/2012/037 Issued: 28 June 2012**

Device	Problem	Action
<ul style="list-style-type: none"> <li>• Reusable transoesophageal, echocardiography, transvaginal and transrectal ultrasound probes (transducers).</li> <li>• All models.</li> <li>• All manufacturers</li> </ul>	<ul style="list-style-type: none"> <li>• The MHRA is aware of an incident where the death of a patient from hepatitis B infection may have been associated with a failure to appropriately decontaminate a transoesophageal echocardiography probe between each patient use.</li> <li>• The MHRA is issuing this alert to advise users to appropriately decontaminate all types of reusable ultrasound probes</li> </ul>	<ul style="list-style-type: none"> <li>• Review, and if necessary update, local procedures for all ultrasound probes that are used within body cavities to ensure that they are decontaminated appropriately between each patient use, in accordance with the manufacturer's instructions.</li> <li>• Ensure that staff who decontaminate medical devices are appropriately trained and fully aware of their responsibilities.</li> </ul>

**Medical Device Alert Ref: MDA/2013/019 Issued: 27 March 2013**

Device	Problem	Action
<ul style="list-style-type: none"> <li>• Detergent and disinfection wipes used on reusable medical devices with plastic surfaces</li> <li>• All manufacturers</li> </ul>	<ul style="list-style-type: none"> <li>• Detergent and disinfection wipes can damage plastic surfaces of medical devices if they are not compatible with the surface material.</li> <li>• Damaged surfaces may compromise the ability to decontaminate medical devices adequately and / or may interfere with device function</li> </ul>	<ul style="list-style-type: none"> <li>• Ensure detergent and disinfectant wipes are compatible with the device.</li> <li>• Always follow the device manufacturer's decontamination instructions.</li> <li>• Look for signs of damage to the medical device and follow local reporting procedures as appropriate.</li> <li>• If the manufacturer's decontamination instructions are inadequate, report this fact to the MHRA and the manufacturer.</li> </ul>

# Health Boards Review Nearing Completion



Health Facilities Scotland



## News

### Ultrasound Probe Decontamination - National Survey Launched

4th October 2012

In August HFS launched a national survey of current decontamination practice of reusable transrectal (TRU), transvaginal (TVU) and transoesophageal echocardiography (TOE) ultrasound probes/transducers.



GIG  
CYMRU  
NHS  
WALES

Bwrdd Iechyd  
Hywel Dda  
Health Board

Full review of TV and TR  
reprocessing services in  
order to establish clear  
National Recommendations  
underway

# Delivers “significant cost savings”

“It has also had a positive impact on patient confidence as they know the probe has been automatically reprocessed rather than manually cleaned.

“While there is an additional cost required to implement the trophon EPR, versus the alternative HLD wipe system we looked at, there are very significant cost savings year on year.”

*Ann Allen, Clinical Lead Sonographer, King’s Mill Hospital, UK*



# Germany



**Ralf Schmaehling**  
Country Manager

- ✓ Miele Professional German Distributor
- ✓ Nanosonics also selling direct
- ✓ Number of key hospitals adopting trophon EPR
- ✓ Awareness activities progressing



# France

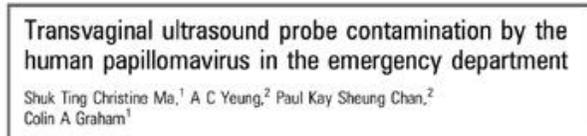
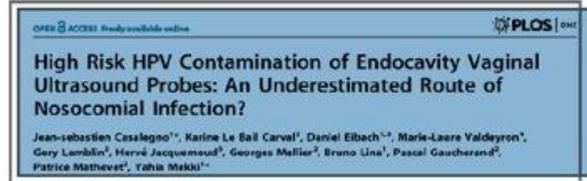
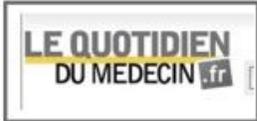


**Julien Laronze**  
Country Manager

- ✓ GE Healthcare as French Distributor
- ✓ Nanosonics also selling direct
- ✓ Awareness activities progressing



# “A real risk of transmission”<sup>1</sup>



Poor infection control practices in France may cause up to **30,000 people** to develop an infection from intracavity ultrasound procedures.

Of the four million yearly intracavity examinations the following transmissions could occur:<sup>1</sup>

- 63 HIV cases
- 1,624 hepatitis B cases
- 239 hepatitis C cases
- 14,840 HPV cases
- 14,920 herpes cases.

<sup>1</sup> Dr Sandrine Leroy (CHU Nîmes and Montpellier, service Biostatistics, Clinical Epidemiology, Public Health), *in press* study.

# Summary

- Growing awareness of the Healthcare Acquired Infection (HAI) risk associated with Imaging
- Regulation / Guidelines – Trends towards stricter controls for high level disinfection (HLD) and automation.
- Risk mitigation growing in importance under Accountable Healthcare models
- Clinical evidence for trophon<sup>®</sup> EPR mounting
- Growing recognition and adoption as we implement global expansion strategy
- Current toxic HLD solutions progressively being rejected by customers and regulators
- Trend towards Point of Care adoption

**Thank you**