

### **LEADER IN INFECTION CONTROL SOLUTIONS**

Addressing the need for safer, faster and eco-friendly high level disinfection of ultrasound probes

Michael Kavanagh, CEO and President ASX Spotlight Conference - London March 6<sup>th</sup> 2014

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### **Company Overview**

- Improving the safety of patients, clinics and their staff
- Proprietary automated system for low temperature, high level disinfection
- First product, trophon<sup>®</sup> EPR for high level disinfection of ultra sound probes
- Approved for sale by: US FDA, TGA(AU), CE mark notified body (TUV Rheinland), Health Canada, Medsafe (NZ) & South Korean FDA
- 110 Staff across Australia, US, UK, Germany & France
- GE Healthcare exclusive distributor in North America
- Toshiba and GEHC UK distributors
   nanosonics



### Key Corporate Data

Share price*	\$0.80
Shares on issue	263.1 million
Market capitalisation*	\$210 million
Cash (31 Dec 2013)	\$21.7 million
Share register breakdown	Founders and Related Parties 22.2% Institutions 33.1% Private 40.6% Corporate 4.1%

\* Close of trade: 20 February 2014

## 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>3</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).



### maging procedure HAIs



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Imaging procedure HAIs – a critical subset of HAIs that are not often discussed.

- $\checkmark~0.9$  9% of barrier sheaths and condoms leak.1,
- A meta-analysis has shown that 12.9% of transducers are contaminated with pathogenic bacteria following routine disinfection.<sup>2</sup>
- ✓ HPV, a known cause of cervical cancer, has been found on up to 7.5% of transvaginal ultrasound transducers following routine disinfection.<sup>3</sup>
- ✓ A fatal case of hepatitis B and non-fatal case of hepatitis C have been attributed to improper ultrasound transducer disinfection.<sup>4,5</sup>
- Ultrasound transducer handles are not routinely disinfected and can harbour pathogens including MRSA.<sup>6</sup>

- 1. Vickery et al, J Inf Pub Health 2013; in press
- 2. Leroy, S. J Hosp Infect 2013 83(2): 99-106.
- 3. Ma S et al. Emerg Med J. 2013 30(6):472-5
- 4. Ferhi K, et al. Case Rep Urol, 2013: p. 797248.

- 5. Medicines and Healthcare products Regulatory Agency (UK), Medical Device Alert
- Ref: MDA/2012/037
- 6. McNally G, Ngu A, ISUOG world congress, Sydney, 2013



## 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 sterlised.<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.

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



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

### **Current HLD methods – time for change**

Disinfection processes unchanged in 20+ years

Existing methods have many shortfalls







### The old methods: soak, spray or wipe

- Chemical spills, vapour control present OH&S risks
- High risk of cross contamination
- Wipes and spray not approved by the FDA for HLD





### ssues with current practice

- Efficacy: Pathogens have been found to remain on ultrasound transducers following disinfection with routine wipe and soaking methods.<sup>1-3</sup>
- Inefficiency: Many disinfection methods cannot be performed at the bedside, meaning devices must be transported to a central sterilisation facility.
- ✓ OHS: PPE must be worn and many disinfectants are highly toxic. Regular use of glutaraldehyde can increase risk of spontaneous abortion in pregnant healthcare workers.<sup>2</sup>
- Environmental impact: Toxic chemicals like glutaraldehyde must be disposed of as chemical waste.
- Material compatibility: An alert has been issued in the UK, asking all users of disinfectant wipes to review material compatibility following the degradation of plastic on devices.<sup>1</sup>



 Leroy, S. J Hosp Infect 2013 83(2): 99-106.
 Ma S et al. Emerg Med J. 2013 30(6):472-5
 McNally G, Ngu A, ISUOG world congress, Sydney, 2013 4. Lawson, C.C., et al. Am J Obstet Gynecol, 2012. 206(4): p. 327 e1-8.

5. Medicines and Healthcare products Regulatory Agency (UK), Medical Device Alert Ref: MDA/2013/019



## A new solution required ...

The CEO of a group of imaging clinics in Canada captures the issue perfectly:

"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 Keshavjee, CEO, Radiology Consultants Associated

Any solution needs to mitigate risks to patients, staff and the environment by having the following attributes:

- Proven efficacy
- Automation
- Easy method compliance
- Process controls

- Straightforward validation
- Cost effectiveness
- Non-toxic to patients and staff
- Avoid production of toxic waste products



## trophon<sup>®</sup> EPR

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 intra-cavity probes

## trophon<sup>®</sup> EPR



# 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

nanosonics

- 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.



### The trophon EPR has gained regulatory approval from:

- VUS FDA ✓ TGA (AU) ✓ CE mark notified body (TÜV ✓ Medsafe (NZ) **Rheinland**)
- ✓ Health Canada

- ✓ MFDS (South Korea)
- ✓ HAS (Singapore)

MDCO (Hong Kong) ✓ Roszdravnadzor (Russia)



### **Attractive Revenue Model**

Multiple revenue streams: Up-front sales plus consumables, accessories and service contracts



Each unit sale results in robust annuity type revenue streams moving forward



## Nanosonics: Financial Results for H1 F14

	H1 F14 \$million	H1 F13 \$million	% Change
USA	7.994	3.034	<b>1</b> 63%
Aus/NZ*	1.094	1.213	↓ 10%
Europe +ROW	.592	.173	<b>1</b> 242%
Total Sales Revenue	9.68	4.42	<b>†</b> 119%
Operating Expenses	10.3	9.4	<b>↑</b> 10%
Operating Loss	3.482	6.027	<b>↓</b> 42%

\* Due to order timing





Cash Balance at Dec 31 \$21.65 million

### **North America**





# **38 of the top 50 Hospitals as of Jan 2014**





## 1286 USA locations as of Jan 2014



nano sonics

locations may have multiple units installed

### **United Kingdom**



- Number of key hospitals adopting trophon EPR
- Health Boards reviews nearing completion
- 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> <li>Reusable transoesophageal, echocardiography, transvaginal and transrectal ultrasound probes (transducers).</li> <li>All models.</li> </ul>	<ul> <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> </ul>	• 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.
All manufacturers	<ul> <li>The MHRA is issuing this alert to advise users to appropriately decontaminate all types of reusable ultrasound probes</li> </ul>	Ensure that staff who decontaminate medical devices are appropriately trained and fully aware of their responsibilities.

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

Device	Problem	Action	
Detergent and disinfection wipes used on reusable medical devices with plastic surfaces	• Detergent and disinfection wipes can damage plastic surfaces of medical devices if they are not compatible with the surface material.	<ul> <li>Ensure detergent and disinfectant wipes are compatible with the device.</li> <li>Always follow the device manufacturer's decontamination instructions.</li> </ul>	
All manufacturers	<ul> <li>Damaged surfaces may compromise the ability to decontaminate medical devices adequately and / or may interfere with device function</li> </ul>	<ul> <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.



Bwrdd Iechyd Hywel Dda Health Board

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



### **Recent market survey**

Survey conducted amongst 70 Superintendent Sonographers:

0%

Are you aware of the need to High Level Disinfect TV and TR probes?

Were you aware of this need 1 year ago?

Are you actively looking at solutions to High Level Disinfect TV and TR probes?



No



## Whittington Hospital

In light of the serious cost pressures facing UK NHS Trust Hospitals there is a recognition of the potential issues which may result from inappropriate U/S probe care Trophon approved by Whittington Hospital

#### 4. Cost Pressures

4.1. It has been agreed by the Executive Committee that only cost pressures which are absolutely unavoidable will be agreed, in these instances Executive team approval and Chief Executive sign off is required. In 2013/14 unavoidable cost pressures which total £191k have been approved, the equivalent value for 2014/15 being a saving of £359k. This is further illustrated in the following figure:

#### FIGURE 10: Unavoidable Cost Pressures Approved in 2013/14

Division / Service	Description	2013/14 Cost Pressure £000's	2014/15 Cost Pressure £000's
Corporate - E&F	Purchase of Trophon Decontamination Units		

## 10 trophon EPR units delivered January 2014!





### **Fundamentals for the business continue to strengthen**

- Growing awareness of the Healthcare Acquired Infection risk associated with Imaging
- Regulation / Guidelines Trends towards stricter controls (HLD) and Automation.
- Risk mitigation growing in importance under Accountable Healthcare models
- Clinical evidence for trophon® 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



