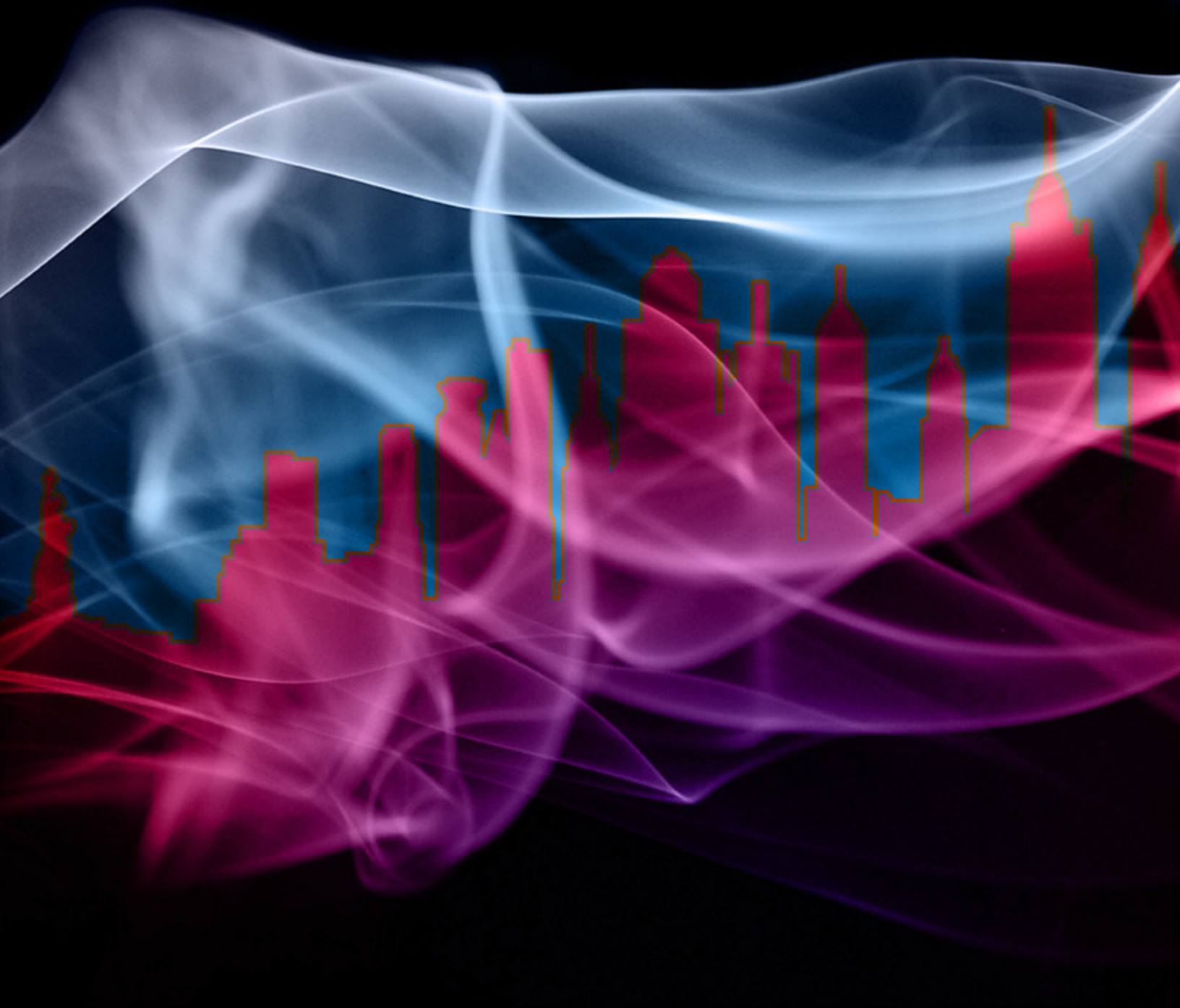




MSP *Industry Alert*TM

VI6N1 | Professional Information Transforming North American Healthcare MarketsTM

2014 PostGraduate Assembly in Anesthesiology





VI6N1 Feature Articles

[03]

Introduction

In this issue we cover the changing monitoring market and how the vendors are responding, we continue to explore Obamacare's impact on the U.S.

[06]

2014 PostGraduate Assembly in Anesthesiology

What would an anesthesia conference be without the anesthesia workstations, monitors, and sedation devices? Interestingly, the established anesthesia workstation vendors were emphasizing different aspects of their enhanced machines. In addition, there were many improvements in the latest monitors and a few stand out anesthesia sedation devices.

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Masimo Shows Monitoring System Point-of-Care 'Root'

No shrinking market woes here! From the humble beginnings as a better vendor of pulse oximetry, Masimo has grown and acquired respiratory and brain monitoring technologies and developed a wireless network for communications, and now has a bedside "Root." Masimo has also developed a centralized display (central stations), making it by all definitions a full-fledged patient monitoring company, rather than simply an OEM supplier of pulse oximetry and respiratory monitoring circuit boards to other patient monitoring, defibrillator and vital signs companies.

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Vendor Short Takes

Class 1 Recall On Nellcor Ventilator System; Helping Aco's Overcome Their Challenges: Remote Patient Monitoring; Masimo Announces FDA 510(K) Clearance of Radius-7™ -- First Rainbow® Set® Noninvasive Wearable, Wireless Monitor for Root®; Meaningful Use Penalties Start January 1st; New Brain Study Confirms Anesthesia Risk in Elderly; New Study Reveals How Quickly Viruses Contaminate Buildings; Noninvasive Assay Monitored Treatment Response in Patients with Metastatic Prostate Cancer; Texas Ebola Hospital Losing Medicare Reimbursements Next Year; and Verizon Wireless Introduces Sure Response -- all announced.

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Time is Short -- What Will the Shemitah of 2014/2015 and Yovel of 2015/2016 Bring?

The year of Shemitah is here, followed by a year of Yovel. With the current mind set of America, what will that mean for our country's future? Is there any hope?



Introduction

First, a warm Merry Christmas or Happy Hanukkah to all our readers; and very best wishes for 2015. The current year has been a time of high hopes and great disillusionment for many Americans, as the results fell way short of the exaggerated rhetoric. Hopefully, the November elections and harsh dose of Obamacare reality will awaken American to how it continues to be duped by liberal politicians.

Obamacare Stumbles Into 2015

Obamacare continues to negatively impact both U.S. healthcare and the broader economy, with large rate increases just announced. The long-term sustainability of the entire program is on shaky grounds, while an intellectual snob, leftist architect of the program like Jonathan Gruber (shown below), brags that the entire program was simply a “deceptive” and only “passed because Americans were stupid.” Gruber offered only mock humility, and did not recount his remarks when called to testify before Congress about his comments.

It is nearly impossible to separate how the VA is today (after years of government management incompetence and lack of concern for patients) with how Obamacare will be five years from now -- if it still exists by then, since it will be administered by government



Jonathan Gruber before Congress
Photo credit: AP Photo.

bureaucrats who have the same lack of regard for the patients financed by the government.

New Products Amid Vendor Mergers in Healthcare

Because of the changes in the North American medical equipment markets, many companies are being affected.

Nihon Kohden (NK) is refocusing on other world markets; meanwhile smaller companies like Sotera are focusing on taking the places of NK and Welch Allyn.

Sotera has enormous VC investment yet almost no sales, so the future of that company and its management team is uncertain unless sales grow substantially in 2015. A major roll-out site is Intermountain Healthcare, who is also a major investor in the company.

New Products Change Market Landscape

Because of the changes in the North American monitoring markets, many companies are being affected.

Welch Allyn seems to be throwing in the towel and looking to exit the patient monitoring market. What impact that may ultimately have on Zoll Medical, who OEM's monitoring components from Welch Allyn is unknown. It may open the door for Zoe Medical, Andover, MA (or some other vendor) to replace the Welch Allyn components;

Medtronic on the other hand, has decided that getting in is appropriate, and acquiring Covidien might be just the ticket.

Masimo is also upping the ante, by introducing new products that make it clear their role has changed from OEM oximetry supplier, to full-fledged patient monitoring company. The introduction of the 'Root' bedside display and control product makes that clear. (See article on Masimo Root).

Nihon Kohden is refocusing on other world markets, but as it does, smaller companies like Sotera are focusing on taking its market share, Welch Allyn's and Nihon Kohden.

Fall was the time for the ASA and PGA meetings, and we have a lot of coverage on that meeting in this issue.

Industry Alert Takes on New Role

Long time readers of Industry Alert have noticed some changes over time in the publication, but the changes in MSP are perhaps less apparent. MSP is expanding its role as a healthcare business intelligence vendor, with the addition of its Triad Dataspace™ Technology, which we have been writing about in recent issues. In determining how best to serve both our readers who are healthcare providers and those who are medical and information system device manufacturers, we have decided to open up the healthcare technology library to Industry Alert readers in 2015.

Starting next month, subscriptions to the MSP healthcare technology library will be \$995 per year. Subscribers will get 3-4 issues of Industry Alert, which will simply be a synopsis of NEW CONTENT that MSP is pushing into the repository. All subscribers will have full access to the entire repository, including the entire series of IA publications we have produced. This will be an Internet-based access available

to readers online. The printed copies will be sent as each new IA issue is released. This provides a dual format, printed and online access for one price. Subscriptions will be renewable yearly at the \$995 per year price. The entire content will be electronically indexed, allowing keyword searches of the PDF content that the library contains. This will make it simpler and faster for our readers who serve on technology committees to find content they have seen perhaps in a previous issue, without having to root through printed copies or remember in which issue the topic was covered. This is simply the next evolution in making as much market intelligence available to our diverse readerships as possible. We hope you like the expanded access to Industry Alert's content. More on this change in the next issue.

National Policy Affecting Healthcare

We continue showcasing how Obamacare is affecting U.S. healthcare, and individual Americans. It is nearly impossible to separate how the VA is today (after years of government management incompetence and lack of concern for patients) and how Obamacare will be five years from now, since it will be run by the same bureaucrats who have the same lack of regard for the patients who care is being financed by the government, and are just as untouchable and unaccountable.

Supreme Court Rebukes Obama -- But He is Unphased

Since the last issue the Supreme Court has ruled in three different cases that Obama has exceeded Presidential authority on forcing organizations to pay for abortion coverage, on police being able to search mobile phones, and on unilateral appointments by Obama made when the Senate was in session. Of course, Obama has little concern for the rulings of the Supreme Court, and in fact two new cases are working their way up to that court about the constitutionality of his Amnesty executive actions.

Voters Rebuke Obama But He is Unphased

Not only this the Supreme Court rebuke Obama, but so did American voters by a substantial margin. Nonetheless, Obama has not gotten the message, but many other Democrats have, and have begun to distance themselves further from this increasingly unpopular President.

John Banner Confuses Law Suits with Impeachment Proceedings

Banner's lawsuit seems absurd, as it's unlikely you can successfully sue a sitting President -- but you can impeach one. Banner should at least pursue a course that has some potential to succeed because his current course makes Republicans seem stupid, Banner needs to go and so does Obama. Neither seems to pass the "in touch with the people," reality test for elected officials. Why should the Congress consider impeachment? Well the IRS abuses coming to light are a good reason.

IRS Scandal Just Fabricated

The President is still saying that the IRS scandal is trumped up and phoney, dismissing e-mails that were "lost" as insignificant, making him seem totally out of touch with reality. The characterization by Obama that people who oppose him overstepping Constitutional limits, as some people "just don't like me," is really amazing.

IRS Scandal - 1,000 Americans' Records Accessed by White House

This is another example of promising transparency and delivering cover-up for criminal acts. It is the one consistent thread of Obama's entire administration over the last 6 years, and gives Jonathan Gruber a strong foundation for claiming that Americans are just plain stupid to believe Obama.

The statement by Obama that people who oppose him overstepping Constitutional limits as, "Some people just don't like me," is amazing. Now it comes to light that there were thousands of

e-mails between IRS and the White House, a fact that emerged from a FOIA inquiry. Apparently the lost emails have now been found, and the White House has illegally obtained IRS records on over 1,000 Americans. This exceeds the IRS abuse of the Nixon administration that led to his impeachment.

Banner Should Sue Himself for Ineffectiveness

On the other hand, Banner's lawsuit is absolutely absurd. You can't sue a sitting President, but you can impeach one. Banner should at least pursue a course that has some potential to succeed and legal standing. Not doing so make him and Republicans seem stupid. Banner needs to go to. Perhaps there should be an "in touch with reality," test for people who run for high office? All you would have to do is compare politicians' public statements with reality. Hillary's "I was/am poor" statement is ridiculous. Apparently no political candidate can speak the truth, they say anything to pander to voters.

MSP Economic Forecast on Track

GDP has been adjusted downward by many economists. The latest data shows the U.S. economy contracted significantly more than previously estimated in the first quarter of this year.

Come Jan. 28, 2015 the Fed is likely to turn down or off the printing presses, and the U.S. economy is poised for another fall, including the Housing market, which will further destroy the nation's shrinking middle class.

Obamacare Premiums Up in 2015

Remember all the promises of lower insurance rates under Obamacare? It was stated by Obama that this would be the result of the passage of the ACA. Well, the 2014 premiums were 41% higher than the private policies the federal government canceled and replace with less coverage, higher out-of-pocket expenses and an overall worse insurance program. Now the 2015 premiums are being announced and they have gone up again.

What should be easy to track has been complicated by government deception. "There are literally no comparisons to current rates. That is, [the Department of Health and Human Services] has chosen to dodge the question of whose rates are going up, and how much. Instead they try to distract with a comparison to a hypothetical number that has nothing to do with the actual experience of real people." —Douglas Holtz-Eakin, President, American Action Forum.

Consider the wisdom of President Obama, who said, "My guiding principle is, and always has been, that consumers do better when there is choice and competition. That's how the market works. Unfortunately, in 34 states, 75 percent of the insurance market is controlled by five or fewer companies. In Alabama, almost 90 percent is controlled by just one company. And without competition, the price of insurance goes up and quality

goes down." -President Barack Obama, September 9, 2009

How right he is. The ACA has stifled competition, the rates have gone up and in many cases the quality has only stayed the same or in some cases gotten worse. Look at the VA hospitals for example.

The 2014 rates were terrible for many families. Here is the experience of one three person family in Vista, CA. who previously had a policy in 2013, which was canceled by the government and replaced with Obamacare in 2014.

Under the ACA this CA family is mandated to spend \$8,657 per year in premiums and to self-insure almost three times that amount in out-of-pocket risk that they had to before ACA under their private policies that the ACA cancelled. The biggest problem for the family is having to incur the out-of-pocket deductible gap that is almost doubled (compared to their

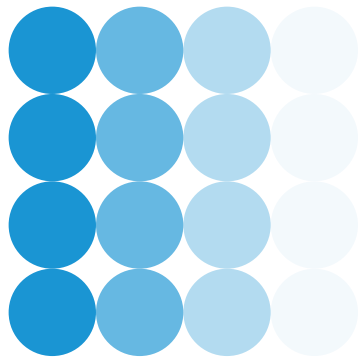
pre-ACA policy) before insurance coverage starts paying at all. The gap between 100% patient-paid costs (the deductible) and 100% insurance paid costs (above the out-of-pocket maximum) was substantially increased. As the policyholder commented,

"I can afford to pay for Obamacare, I just can't afford to go to the doctor."

In simple terms, the family's health insurance has been involuntarily converted from a family health plan to a type of very expensive, catastrophic coverage, with the family left to pay more of their actual expenses incurred and no alternative but to accept the ACA policy or have no insurance. The new ACA-compliant insurance covers nothing in the first \$8,000 that are considered the average family's per person maximum yearly need for a family of average health. It only covers the family if the insured person has found a way to finance the deductible. Middle-class wage earners may find a way to pay for out-of-pocket expenses, but those at or below the poverty level will not.

This particular family earns less than \$75,000, has a mortgage and struggles every month to make ends meet. Their income is too high for an ACA-subsidy; but it wouldn't matter even if the family were subsidized, because any significant health "event" would bankrupt them before the ACA ever starts paying a dime. Further, actual large pool catastrophic healthcare policies (such as California Choice) cost less than \$200 per month for an equivalent out of pocket maximum, so the federal program at \$8,657 in premiums is exorbitantly expensive by comparison because the total burden of subsidizing the "poor", illegal aliens and other undocumented persons who receive care at emergency departments, has been completely placed on this middle-class family under Obamacare and provides no benefit to the family itself, contrary to what politicians repeatedly said about costs. In 2015 the premiums are increasing again! Δ

Monthly Premium	2013 Pre-ACA	2014 ACA	% change
Total per month	\$ 411	\$ 721.49	43%
Primary	\$ 292	\$ 452.65	
Spouse/Child	\$ 119	\$ 268.84	
Individual and Family Expenditure Limits	2013 Pre-ACA	2014 ACA	% change
Individual deductible	\$ 3,000.00	\$ 5,000.00	40%
Family deductible	\$ 6,000.00	\$ 10,000.00	40%
Out-of-pocket maximum			
Individual	\$ 6,000.00	\$ 6,350.00	6%
Family	\$ 12,000.00	\$ 12,700.00	6%
Patient Out of Pocket For Care	2013 Pre-ACA	2014 ACA	% change
Inpatient Hospital Care (After Deductible)	20%	30%	33%
2014 per day observation stay (\$12K)	\$ 2,400.00	\$ 3,600.00	33%
Emergency Room (After Deductible)	\$ 200.00	30%	
AHRQ estimate of ER visit cost (\$1318)	\$ 200.00	\$ 395.40	49%
X-Rays, Lab Tests, MRI, CAT Scan	20%	30%	33%
Drugs			
Generic	\$ 10.00	\$ 19.00	47%
Brand	\$ 35.00	\$ 50.00	30%
Coverage Risk Comparison	2013 Pre-ACA	2014 ACA	% change
Expenditure Before Insurance Coverage	\$ 10,931.40	\$ 18,657.88	41%
Maximum Total Cost Per Year	\$ 16,931.40	\$ 21,357.88	21%
Payments	\$ 4,931.40	\$ 8,657.88	43%
Deductible	\$ 6,000.00	\$ 10,000.00	40%
Out of Pocket Care Maximum	\$ 12,000.00	\$ 12,700.00	6%



2014 PostGraduate Assembly in Anesthesiology

An Editorial by Arthur Gasch - Publisher

Article Content Summary

- PGA Conference Overview
- Revolutionary Medical Devices AirSPACE & SuperNOVA
- Nihon Kohden BSM-1700
- Zoll X Series Monitor/Defibrillator
- Casmed FORE-SIGHT ELITE
- Mennen VitaLogik 6000
- Respiratory Motion ExSpiron 1Xi
- Mindray A7
- Siemens ACUSON Freestyle
- GE Universal Viewer for Centricity™ PACS and PACS-IW
- Johnson & Johnson Sedasys System



PGA Conference Overview

Although we were not able to make it to this year's American Society of Anesthesiologists Conference, held in New Orleans in October, due to a scheduling conflict, we were able to attend and anxious to see what the 68th Annual PostGraduate Assembly in Anesthesiology in New York City had to offer.

What would an anesthesiology conference be without the latest and greatest anesthesia workstations? For a small percentage of vendors, it was a recap of products shown at the ASA, while for other vendors, it was an opportunity to showcase their new, higher-end products. Among the vendors with the most market share, GE, Drager, Mindray and Spacelabs showed the newest systems. Prominent by their absence was both Philips and Maquet.

Interestingly, the established anesthesia workstation vendors were emphasizing different aspects of their machines and how they made

each more productive. Also notably different were the variations in price for these workstations. Mindray was the market leader in value, offering the least expensive solutions. This may account for the rapid displacement of established vendors in this market.

There were many products that stood out at the PGA. One company in particular caught our eye - Revolutionary Medical Devices.

Revolutionary Medical Devices AirSPACE & SuperNOVA

Revolutionary Medical Devices, Inc. (or RMD) was showing two products created for better airway management of a patient during intubation. Dr. Michael Pedro, CTO of Revolutionary Medical Devices, Inc. and co-inventor of the AirSPACE management system and the SuperNOVA™, a nasal oxygenating and ventilating apparatus was there and his technology created a real stir. Even vendors from other companies were taking prospects to the RMD booth to see it.



Left image: RMD AirSPACE™ (Air Sniffing Position And Chin Elevation). Right image: RMD SuperNOVA™ nasal oxygenating and ventilating apparatus.

The first product is called AirSPACE™ (Air Sniffing Position And Chin Elevation). It's an airway management device designed to provide a custom-fit sniffing position or head-up position (ear-to-sternal notch) for every patient. Placing the patient in a sniffing position is accomplished with independent vertical neck and head position adjustments. The ramp's length adjusts to fit the patient's torso, and can be raised during the operation if an emergency intubation must be performed. The AirSPACE™ airway management device allows the provider to adjust the head and neck angles while intubating the patient in order to provide an improved glottic view. The AirSPACE™ airway management device also comes with disposable covers, which are designed to protect the device from fluids and allows for fast cleanup after the operation.

Benefits include: Custom fit positioning in <60 seconds; Enables a variety of airway management positioning; Head-tilt chin lift; Sniffing position; HELP position; Head neutral; Adjusts the glottic view in real time; Minimizes lifting and moving patients; Designed to support patients up to 500 lb.; Attaches to most operating tables; 4" cushions with welded seams; Maximize comfort; and Minimize pressure. The cushion that goes on the table allows imaging to be done with no interference; but the buzz was about the new mask that allows intubation without blocking off the airway.

The second product is called the SuperNOVA™ and is a nasal oxygenating and ventilating apparatus designed to provide improved patient outcomes through clinically driven

airway management. It is a break through in intubation of patients, something that every anesthesiologist must do all the time. This product improves safety during this important procedure, and was the buzz of the entire conference. Other new medical devices were also shown.

Nihon Kohden BSM-1700

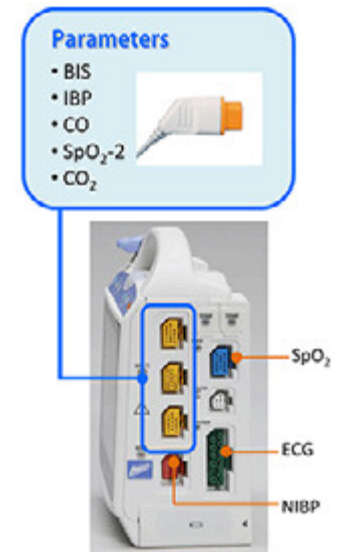
NK introduced the new model BSM-1700 Series featuring a Life Scope PT -- a smart transport monitor that attaches to their larger bedside monitor allowing one action removal for patient transport. It takes the place of the Input Module in any NK 6000 Series monitor and like all NK monitors, comes with a 5 year warranty and an aggressive purchase price.



Nihon Kohden BSM-1700

The Life Scope has a large, easy to see 5.7-inch touchscreen display that operates in both standard and transport mode. It's lightweight and easy to carry and its handle hooks onto a bedrail without needing any bed-rail adapter. It

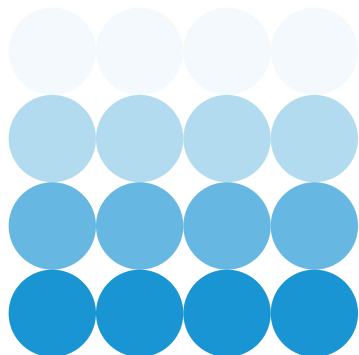
has a 5 hour battery life is scheduled to add wireless telemetry transmission in the next release, so that patient vital signs and waveforms can be send back to a central monitor through an attached transmitter, if it is within range. Either way, the Life Scope PT shows comprehensive review data including full disclosure that are typically found only in a central monitor. It saves 24 hours of trend data and alarm history as well as 24 hours of 5 full disclosure waveforms during transport.



Flexible Parameters with MULTI Connectors 3 MULTI connectors allow monitoring of advanced parameters such as BIS, IBP, CO, SpO2-2, and CO2 in addition to the basic parameters of ECG/Resp, SpO2, dual temperature and NIBP.

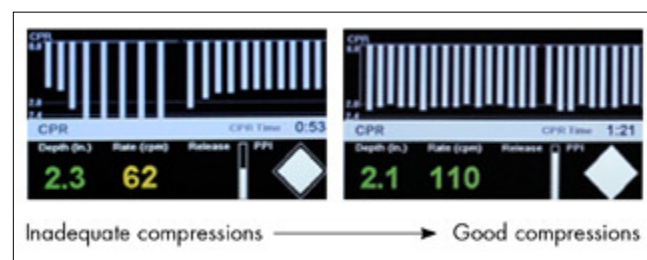
Flexible Usage Life Scope PT can be used as a standalone bedside monitor or as an input unit for a BSM-6000 series bedside monitor. After connecting the Life Scope PT transport

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Zoll X Series Monitor/Defibrillator



Numerical displays of compression depth and rate as well as a release indicator for full recoil

monitor to another bedside monitor on the network, the data in the Life Scope PT is automatically transferred to the bedside monitor and central monitor. All patient information, including trend and waveforms, is automatically transferred to create one seamless patient record.

Zoll X Series Monitor/Defibrillator

The ZOLL X Series® Monitor/Defibrillator (shown above) is a small, portable monitor, but has an integrated defibrillator as well. It's designed to be compact with no compromise in display size, capability, or performance, the X Series provides lots of options. At less than 12 pounds (6 kilograms), the X Series® is about half the size and half the weight of competitive full-featured monitor/defibrillators and is designed to be used with patients of all ages, including neonates.

It offers advanced monitoring capabilities such as: NIBP; pulse oximetry; capnography; three invasive pressures; two temperature channels; and is the first monitor/defibrillator with integrated WiFi and Bluetooth - standard. Also, the monitoring and ECG work off the same electrodes, saving accessory costs and accelerating the ability to shock the heart in the event of fibrillation or cardiac standstill. It's also less expensive to transport with one, integrated monitor-defibrillator device, than to monitor on one device and have to also lug along a separate defibrillator.

The X series has numerical displays of compression depth and rate (shown above right) and a release indicator that shows you when to release for full recoil, helping the clinicians performing CPR to provide consistently effective compressions and timing, and are released quickly enough to allow for full ventricular filling. Studies have documented that the more effective the CRP is, the higher likelihood of rapidly converting the patient and achieving a successful outcome.

The X Series also has the ability to simultaneously display multiple waveforms, including four physiological waveforms or all 12 ECG leads on-screen.

Casmed FORE-SIGHT ELITE

Casmed showed their FORE-SIGHT ELITE tissue oximeter which is the first and only FDA cleared tissue oximeter featuring 5 wavelengths of near-infrared light for greater accuracy and enhanced tissue recognition.

- Enhanced FORE-SIGHT algorithm improves accuracy to unprecedented levels (3.05 % Arms)1
- Eliminates the need for pre-induction baseline reading
- Detects otherwise unnoticed cerebral desaturation events
- Wide range of connectivity options with VGA output, Philips IntelliBridge, and EMR Systems



Casmed Fore-Sight Elite

Mennen VitaLogik 6000

Mennen was a surprise to see at the conference - Welcome back to the U.S. monitoring markets. Even though they are not a significant competitor in the US market they have made their mark in Israel and some other countries.



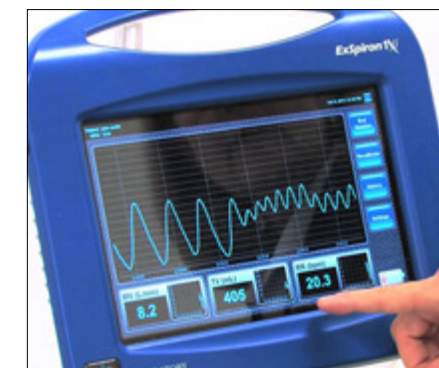
The VitaLogik™ 6000 is a pre-configured multi-parameter patient monitor with a 15" flat screen display, supported by an internal battery for uninterrupted vital signs' monitoring. The VitaLogik™ 6000 has an extensive storage capability of full disclosure, charts, trends and events, in addition to the saved data of up to 10 discharged patients. Features Include:

- ECG, Respiration, SpO2, NIBP, Temperature, and 2 (optional 4) Invasive blood pressure channels and thermo-dilution cardiac output
- Optional Built-in recorder
- Optional Touch screen
- Optional Microstream EtCO2.
- Line operated with 3 hours (optional 6 hours) battery backup
- Data transfer to central station and printer via wired or wireless (optional) Local Area Network

Respiratory Motion ExSpiron 1Xi

They make a novel non-invasive minute ventilation and respiratory rate monitor which helps prevent respiratory

depression. The ExSpiron™ system passes a small amount of electrical current across several vectors through the lung, and exploits the large conductivity difference between air and tissue, which gives it the ability to accurately quantify the amount of air moving in and out of the lung in real time. This would be useful for COPD patients, for example since only a small percentage of smokers get lung cancer, but 100% of them get emphysema.



Other companies have tried to do what the ExSpiron does, but this is the first company we are aware of with FDA clearance.

The ExSpiron™ system is portable and can be easily carried between patient bedsides. It can also be attached to an IV pole with its quick-fastening back clamp. Features include:

- A monitor with an easy to use graphical user interface (GUI) clearly displaying ventilatory parameters.
- A durable Patient Cable

- A disposable Patient Padset

Siemens ACUSON Freestyle

Siemens' Acuson Freestyle ultrasound system (shown below) features wireless transducers, eliminating the impediment of cables in ultrasound imaging. To enable this technology, the system brings to the market a large number of innovations, including acoustics, system architecture, radio design, miniaturization, and image processing. The development of wireless ultrasound is in line with the objectives of the Healthcare Sector's global initiative Agenda 2013, specifically in the areas of innovation and accessibility. The Acuson Freestyle system will expand ultrasound's use in interventional and therapeutic applications, where the technology provides numerous workflow and image quality advantages.

Wireless ultrasound transducers help deliver procedural efficiency with cable-free scanning, easy sterile field management, and single user operation.

Integrated Transducer Controls With integrated controls for real-time operation, this advanced technology allows an improved range of scanning motion, as well as single operational use on procedures that previously required additional personnel.

Optimized Infection Control Each of the ACUSON Freestyle transducers is fully submersible for high level disinfection, and since they are wireless,



Siemens ACUSON Freestyle monitor

cable sterility is eliminated from your workflow.

Streamlined, Cable-free Workflow Increase your freedom of motion with wireless connectivity up to three meters from the console. With an out-of-range probe alert system built in, you can better achieve on-the-go, point-of-care imaging without misplaced transducers.

Key Transducer Options Choose from three available transducers—L13-5 linear, L8-3 linear, and C5-2 curvilinear array—to help meet your patients' needs.

Meet your imaging needs at the point of care with advanced technologies for automatic, uniform focusing, enhanced procedural guidance, and exam efficiency.

Pixelformer™ Image Processing Architecture The ACUSON Freestyle system features computational focusing, which delivers uniform clarity without manual focal-zone adjustment, providing a clear picture of patient anatomy with excellent detail resolution and image clarity.

Enhanced Needle Visualization This system uses an optimized viewing angle to ensure you get the most crystalline view of the needle in-plane or out-of-plane for enhanced procedural confidence.

Expanded Image Display Choose from three image size options, including an expanded clinical-imaging display for enhanced procedural operation.

The ACUSON Freestyle uses innovative technologies that strive to improve safety and quality of care through wireless communication.

Ultra-Wideband Radio Transmit data at rates up to 10x faster than a 4G smartphone with 7.8 GHz ultra-wideband radio (UWB) to help produce exceptional, cable-free point-of-care imaging in real time.

Wireless Networking Designed for wireless enterprise networks,

enterprise authentication helps ensure a safer, more reliable connection to securely send and store patient exam data to your facility's file archiving system.

Bluetooth® Radio Bluetooth technology enables the system and transducer to communicate clearly and seamlessly for reliable, uninterrupted scanning.

Practical Design The ACUSON Freestyle ultrasound system features a compact console design with rechargeable battery functionality and rapid boot-up for increased mobility, more streamlined operation, and enhanced exam efficiency.

ACUSON Freestyle Mobile Link App Wirelessly connect your Windows® tablet and ACUSON Freestyle system with the mobile link app. Designed for efficiency, the app allows you to securely access studies to view images and clips—and even input patient work list data—for a more streamlined, flexible workflow experience wherever you work.

Spacelabs ARKON

This “evolutionary” anesthesia delivery system expands to enable a wide-angle view of the clinical setting, so the clinician can face the patient. Plus, it offers additional clinical advancements, including:

- Centrally located clinical controls for ease-of-use
- A touchscreen display with intelligent navigation
- Intuitive and highly customizable user interface
- Signature lighting to emphasize active controls
- A rotating breathing circuit for bringing anesthesia delivery closer to the patient
- A full range of ventilation modes

Using innovative concepts in industrial design, ARKON offers a variety of features that help to manage



Spacelabs ARKON anesthesia workstation

overall workflow in the operating room, including:

- Natural storage areas for equipment and paperwork
- An expandable work surface
- A system status computer that communicates, the state of the battery back up, inlet gas pressure, gas scavenging and machine check out
- Seven electrical outlets distributed where they are needed
- Built-in USB and Ethernet ports
- Alternate height work surfaces
- A convenient drop down shelf
- A pull out keyboard tray
- Built-in lighting

Built From a Clinical Perspective ARKON is the result of years of research and interviews with clinicians from across the globe. We also observed a full range of anesthesia delivery systems in use and studied the latest findings in the field of ergonomics.

Dräger Perseus A500

Design Today, an anesthesia machine has to do more than put people to sleep – it has to be a place to work.

Everything you need to provide the best possible care should be reflected in the workstation's design. It should be flexible to ensure the best possible fit to your individual workflow requirements. No long reaches, no searching through menus, no fumbling for accessories, and no shortage of space for storage or documentation. Setup, self-checks, and routine maintenance should be fast and simple. You can experience all this and more with the Perseus A500.

Resources The Perseus A500 anesthesia workstation provides you with state-of-the-art ventilation therapy and hemodynamic monitoring as well as an operating concept that lets you manage resources quickly and effectively.

After all, time is one of your most precious resources. It should also include technology that facilitates the administration of low-flow and minimal-flow anesthesia to help reduce the consumption of costly volatile anesthetic agents.

Accessibility What you need, at your fingertips. That's what accessibility means, whether its access to patient data, laboratory findings, diagnostics, or imaging – in short, the complete set of relevant clinical information. No more waiting for essential prerequisites to be brought to the operating room before you can begin with induction.

Hygiene Nosocomial infections are a significant source of morbidity and mortality. The Perseus A500 features optimized hygiene concepts including enhanced cable management and a surface structure that is easy to clean. Both of which help to prevent microbial contamination of your anesthesia machine – and your patients.

Outcome The Perseus A500 helps you influence patient outcomes by providing you with rapid access to the right information, which lets you make the right choices in a timely fashion. Whether routine or ICU patient cases,

across all patient categories. With reliable, effective technology that supports your therapeutic process, the Perseus A500 is a strong link in the outcome chain. Features include:

- Mobile patient monitoring that travels with the patient for continuous surveillance
- Various mounting spots and rails for customized placement of monitoring, IT Hardware, IV pumps, and additional shelves
- Color touch screens with our standardized user interface for reduced training measures and human errors
- Additional LCD system control field for display of gas and power status as well as airway pressure, individual gas flows, and time
- Improved workplace illumination for better legibility and operation in dark environments
- Large working surface for completing paperwork easily and for organizing materials
- Hooks and brackets for hose and cable guidance and drawers and shelves for optimal storage of important material



Dräger Perseus A500 anesthesia workstation

- Perseus® A500 workstation can include the Infinity® Acute Care System monitoring solution, Infinity® C700 for IT, Innovian® Anesthesia, and more

- High-performance breathing system and ventilator optimized for minimal flow and ICU quality ventilation.

Mindray A7

Although the A7 does not yet have FDA clearance, so Mindray was showing as a “work in progress.” The A7 utilizes an electronic gas mixer which sets and delivers fresh gas efficiently, whatever the flow rate. Combined with a fresh gas optimizer, the clinician is able to deliver safe, continuous low flow anesthesia to all patients, improving the overall anesthetic experience and contributing to cost saving for the hospital.



The A-Series user interface simplifies workflow, enabling clinicians to direct their attention to patient. The intuitive 15” full color touch screen facilitates informed decision making based on clearly displayed graphic and numerical data.

The A7 Anesthesia Workstation offers a full range of ventilation modes that fully meet your routine and specialized demands at all stages of the anesthetic procedure. The integrated multi-gas module supports comprehensive breath-by-breath analysis of inspired and expired gases and anesthetic agent.

Total Information Integration The iChart-OR system integrates

monitoring, anesthesia delivery and care process information management. It can also connect with the server, making it possible to share the clinical data directly from the point of care. When approved for the U.S. market it will become the instant low-cost price leader among U.S. vendors of higher-end anesthesia workstations.

GE Universal Viewer for Centricity™ PACS and PACS-IW

With the introduction of Universal Viewer for Centricity™ PACS and PACS-IW, GE Healthcare delivers a powerful unified workspace for radiologists and clinicians. Universal Viewer brings together intelligent tools, enhanced usability and access, advanced visualization and breast imaging to help optimize productivity. Unlike disparate PACS and 3-D systems, Universal Viewer helps to increase efficiency by simplifying information access with a single image repository across 2-D and 3-D studies, enabling holistic oncology and other specialty work flows, with easy access to prior exams.

Centricity PACS offers a proven, scalable imaging IT platform designed to optimize radiologist productivity, enhance physician satisfaction, and interoperate with existing departmental (RIS, dictation) and enterprise (electronic medical records [EMR], VNA) systems. This PACS solution meets the needs of today’s healthcare institutions with innovations like single DB Rad/Card, RIS/PACS, native mammography workflow, advanced visualization, web-based clients, EMR integration, DR/BC and high



availability, and most recently, mobile access on an Apple or Android enabled device.

Universal Viewer optimizes radiologist work-flow efficiency through the use of advanced study layouts; multiple presentation states; advanced, intelligent hanging protocols with variable-sized, asymmetrical windows and “copies” of windows; 2-D stack-based reading tools; and an integrated view of 3-D reconstructions.

Within a few mouse clicks, a referrer accesses the same software and clinical tools as radiologists: report and diagnosis, key images, and scanned documents, as well as access to the patient study and set of viewing tools. The overall user interface is highly customizable to meet explicit needs and preferences of the users.

Universal Viewer is a unified web-based viewer that focuses on improving productivity and enhancing patient care by delivering standard as well as many innovative applications and technologies.

Universal Viewer is a next-generation viewer that requires less exam setup. Its smart reading protocols give users the option to apply case-based reasoning techniques, including machine learning algorithms, image analytics, and text mining for automating exam setup. It places the visionary radiologist at the forefront of technology.

Centricity PACS provides radiologists with: clinical tools to increase productivity and reduce report turnaround; real-time work lists to help

balance case load; and real-time exam statuses that prioritize urgent cases.

Johnson & Johnson SEDASYS System

Sedasys is a machine made by Johnson & Johnson (J&J) to automate the sedation of certain adults who are 18 years or older and undergoing a colon-cancer screening. Patients who are eligible for the machine are healthy or have one well-controlled medical condition.



In the United States, the current standard of care for procedural sedation provided to healthy patients undergoing colonoscopy and esophagogastroduodenoscopy (EGD) includes benzodiazepines and opioids delivered by gastroenterologist/nurse teams. In recent years, there has been an increase in anesthesia professionals providing propofol sedation, also known as MAC (monitored anesthesia care), for these procedures. Up until this point, there has not been an on-label option for the Gastroenterologist/Nurse team to deliver propofol.

With the SEDASYS® System, a new option for sedation delivery is available for trained physician-led teams to safely and effectively deliver on-label

minimal-to-moderate sedation with propofol for colonoscopy and EGD.

Core Components of the SEDASYS® System The SEDASYS® System features innovative technology that monitors 5 patient parameters and delivers personalized sedation based on those parameters. It is designed to continuously monitor the patient in the pre-procedure area, procedure room, and post-procedure area.

Bedside Monitoring Unit (BMU) The BMU monitors the patient’s oxygen saturation, blood pressure, and heart rate. It is connected to the patient in the pre-procedure area and stays with the patient through recovery, providing continuous automated monitoring throughout the procedure.

When the patient enters the procedure room, the BMU is connected to the Procedure Room Unit to combine physiological monitoring with drug delivery.

The user interface on the PRU displays comprehensive physiological and responsiveness monitoring data.

- **Capnometer** - Displays capnogram, respiratory rate, and end-tidal CO₂ (EtCO₂).
- **Pulse Oximeter** - Displays the plethysmogram and oxygen saturation (% SpO₂). The Capnometer and Pulse Oximeter work in tandem to detect indicators of oversedation, such as low respiratory rate, apnea, and low oxygen saturation.
- **Electrocardiogram** - Displays the electrocardiogram and heart rate.
- **Non-Invasive Blood Pressure** - Displays last-measured systolic and diastolic blood pressure.
- **Automated Responsiveness Monitor (ARM)** - Exclusive to the SEDASYS® System, the ARM helps assess the level of sedation by measuring patient responsiveness through auditory and tactile stimuli. This field displays a trend graph of the patient’s responsiveness and the patient’s current response time.

There are components for both single patient use as well as multiple patient use.

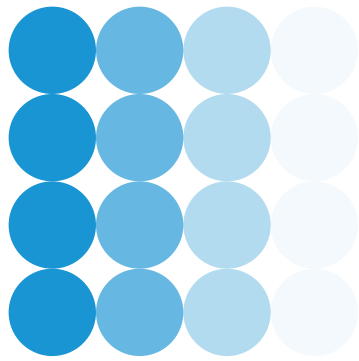
Procedure Room Unit (PRU) The PRU serves as the physician-led team’s primary interface with the SEDASYS® System and is designed to stay in the procedure room.

The SEDASYS® System uses a proprietary drug delivery/dosing algorithm and intravenous infusion pump, which are also part of the PRU.

The PRU’s monitor displays all of the patient’s physiological parameters on a single, intuitive touchscreen user interface. Through it, clinicians can quickly and easily assess the status of the patient and adjust propofol dosing if desired. The PRU also provides respiratory rate monitoring, responsive oxygen delivery and, when connected to the BMU, provides automated responsive monitoring.

Cart The Cart provides a stable mounting surface for the PRU, facilitating easy movement of the PRU within or between procedure rooms. The Cart also provides convenient storage for the disposable Single-patient-use Components of the System that will be used during a day of endoscopy procedures.

Market Adoption Use of the machine could potentially cut spending on the colon-cancer screenings. J&J hopes the potential savings will appeal to hospitals and clinics and drive machine sales. Anesthesiologists typically charge \$600 to \$2,000 for their involvement. Sedasys would cost about \$150 a procedure. Reimbursement would vary, but insurers are expected to pick up the tab. On the other hand, it has a large footprint, which speaks to the previous generation of technology embodied in it. In order for real market penetration, some downsizing and cost reduction will be required, once the FDA blesses it. Δ



Masimo Shows Monitoring System Point-of-Care 'Root'

By Karen Esposito and Arthur Gasch

Article Content Summary

- Monitoring Market Conditions
- Impact of a Shrinking Market
- Competitive Responses
- Iris Connectivity Gateway
- Root Interoperability
- ISA Capnography MOC-9 Module
- MOC-9: OEM Platform for Expanded Measurements
- Masimo Rainbow™
- Patient SafetyNet™
- About Masimo



Masimo's Root with Radical-7 Oximeter docked

From the humble beginnings as a better pulse oximetry vendor, Masimo has acquired respiratory and brain monitoring technologies and developed a wireless network for communications and now has become a full-fledged monitoring company thanks to its bedside "Root" and "Iris" products.

Masimo's new Root™ is a point-of-care 10" visualization and control platform (shown above) that allows its Radical-7, and the SedLine® brain function monitoring with the Masimo Open Connect™ (MOC-9™) module to "dock" and track consciousness levels for patients under general anesthesia or sedation. The point of care is important, because it may not be at the bedside. It certainly isn't when used in surgery, whether in the hospital OR, or a FASC OR, during a disaster at the disaster site, or in a military MASH

unit, where Masimo may well displace Welch Allyn, who is withdrawing from the market, and hold off Mindray who is trying to emerge.

Masimo has developed a centralized display (central stations), making it by all definitions a full-fledged patient monitoring company, rather than simply an OEM supplier of pulse oximetry and respiratory monitoring circuit boards to other patient monitoring, defibrillator and vital signs companies. That puts it in direct competition with Philips, GE, Spacelabs, Draeger, and dozens of other vendors in the general ward at least. So while other small monitoring companies like Fukuda Denshi, Sotera, and Welch Allyn are struggling or looking to exit the monitoring market altogether, Masimo is growing as a mainstream monitoring supplier. Normally

this would position Masimo squarely in competition with its own OEMs oximetry and cerebral function customers, but the Masimo twist is that they have an open API, so that smaller monitoring vendors can leverage the Masimo products as privately labeled middleware of sorts. It's a clever strategy for a major OEM vendor.

Of course Root directly competes with Covidien (formerly Nellcor and Aspect Medical and soon to become known as Medtronic if the merger is approved). But the real question is what impact will it have on GE Healthcare, Philips, Draeger, and Spacelabs who are all Masimo OEMs. They are unlikely to be interested in using Masimo's open API products in their own product lines? The merger of Covidien with Medtronic, opens the door for the acquisition of Masimo by GE, who already holds a small position in their stock or maybe Spacelabs. Alternatively, Masimo would solve a problem for Cerner or Epic, or any EHR vendors that needs a vital signs front end to its EHR products.

Monitoring Market Conditions

On the monitoring front, Welch Allyn has dramatically downsized staff at their Beaverton, OR facility and are telling some clients with large installed bases of Propaq monitors, that there will be no new monitoring products. We did verify that many staff there are being laid off or transferred.

Masimo is a viable alternative to companies with weak market positions. Sotera is also seeking a place in the market. Meanwhile, due to Obamacare and market shrinkage, the volume of hospitals is becoming smaller, causing the market size to decrease further. Companies with smaller market shares are also offering lower prices, and that may divert unit sales away from market leaders like Philips and GE. The two big competitors are always in everyone's rifle sights, but have proven hard to pick off over the years. We expect however that they will have a smaller unit market share in 2015 and 2016.



Masimo Patient SafetyNet monitoring system

Impact of a Shrinking Market This shrinking market change cuts both ways. On the one hand, it means fewer total units will be sold to fewer hospitals. On the other, it means the price at which they are sold will definitely favor Masimo, NK, Mindray and others who sell inexpensive products. One could argue that monitors are to some degree becoming commodity products.

Competitive Responses Any of our major Masimo OEMs is not beyond developing its own oximetry technology, but that has proven impossible so far without violating Masimo's SET patents. That is why the most likely strategy would be acquisition of Masimo. Of the large competitors, we think GE would be the most likely candidate. The cost however would be very high. Like the acquisition of Ohmeda, it would be a clever way for GE to enhance revenues in what otherwise is a weak overall market.

Iris™ Connectivity Gateway to Root

Despite medical technology advances, the lack of device communication and integration creates risks to patient safety in hospitals around the world. Without device interoperability, critical patient information can go unnoticed -- leaving busy clinicians in the dark and unaware of patients who are in danger.

Existing approaches to device interoperability could require separate hardware, software, and/or network infrastructure, which cluttered the patient room, increased complexity, burdened IT management, and increased costs -- until now. Enter Masimo's Iris™ -- a built-in connectivity gateway for Root that allows other devices to utilize it.

Root Interoperability Each Root can be used with an Iris™ connectivity gateway for connecting multiple standalone devices, such as IV pumps, ventilators, hospital beds, and other patient monitors (when used as part of the optional Iris connectivity package in Masimo Patient SafetyNet™).

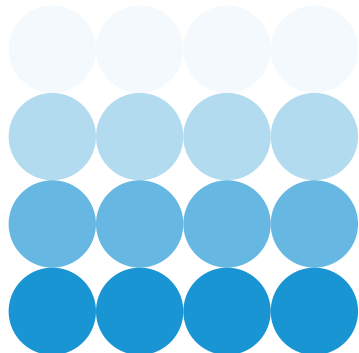
Iris™ allows standalone device information to be remotely viewed with Patient SafetyNet, transmitted through notification systems or sent to electronic health record (EHR) systems to facilitate better patient care.

Iris™ connectivity enables standalone devices to leverage existing network infrastructure and reduce costs while enhancing clinical workflow and decision support to improve patient safety, whether the clinician is at the bedside, down the hall, or in another city.

ISA Capnography MOC-9 Module

"With the new FDA clearance for Root, Masimo is eager to help U.S. clinicians usher in a new era of patient care and improved patient safety with a platform that should measurably

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improve the performance and cost curve,” said Joe Kiani, founder and CEO of Masimo. “Root can be a hub at the bedside, enable Masimo’s breakthrough noninvasive measurements to be used by experts and novices with the trend and analog views, take advantage of a rich set of additional measurements, and allow other companies a robust platform on which to develop other innovative measurements via MOC-9.”

The ISA CO₂ module for Root provides etCO₂ and respiratory rate measurements with crisp waveforms and fast warm up time. In addition, customers can use the Nomoline™ “No Moisture” fluid protection sample line, which is specially designed for low-flow applications and excellent response time -- making gas measurement possible even at high respiratory rates.

Nomoline supports single-patient use in high humidity environments or multi-patient use in lower-humidity environments to reduce disposable costs, and can be used for all types of patients from infants to adults.

MOC-9: OEM Platform for Expanded Measurements

Root is also designed to allow other companies to expand the platform’s

measurements with their own measurements through MOC-9 by following Masimo’s established development and validation process.

Market barriers and development costs often keep small, innovative companies from delivering their products to clinicians and patients who need them most. With Root’s OEM accessible patient monitoring platform, Masimo is offering an open invitation to other companies to develop and commercialize their innovations through Masimo’s ever-expanding customer base. (Companies interested in developing a MOC-9 measurement can request more information online at: <http://www.masimo.com/root/index.htm>).

Masimo Rainbow™

In 2005, Masimo introduced rainbow (R) Pulse CO-Oximetry™ technology, allowing noninvasive and continuous monitoring of blood constituents that previously required invasive procedures. Since then it has added total hemoglobin (SpHb), oxygen content (SpOC), carboxyhemoglobin (SpCO), methemoglobin (SpMet), PVI, and perfusion index (PI), in addition to measure-through motion SpO(2) and pulse rate capabilities.

Patient SafetyNet™

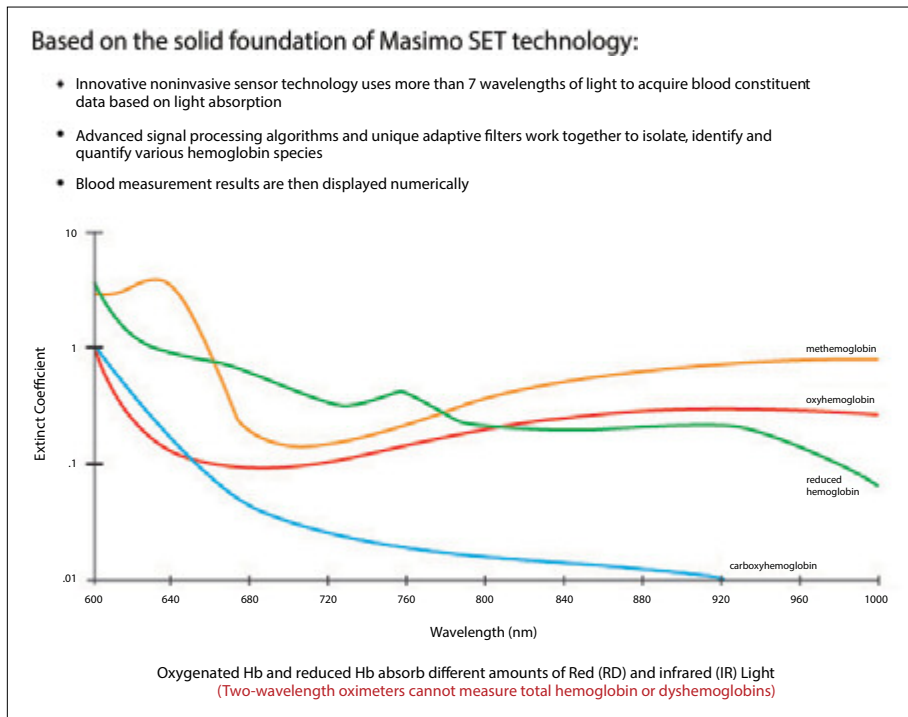
In 2008, Masimo introduced Patient SafetyNet, a remote monitoring and wireless clinician notification system designed to help hospitals avoid preventable deaths and injuries associated with failure to rescue events. In 2009, Masimo introduced rainbow(R) Acoustic Monitoring™, the first-ever commercially available noninvasive and continuous monitoring of acoustic respiration rate (RRa). Masimo SET and Masimo Rainbow technologies also can be found in over 100 multi-parameter patient monitors from over 50 medical device manufacturers around the world.

Additional information about Masimo and its products may be found at www.masimo.com.

About Masimo Founded in 1989, Masimo has the mission of “Improving Patient Outcome and Reducing Cost of Care ... by Taking Noninvasive Monitoring to New Sites and Applications(R).” Masimo entered the market in 1995, debuting Measure-Through Motion and Low Perfusion pulse oximetry, known as Masimo SET®, which greatly reduced false alarms and increased pulse oximetry’s ability to help clinicians detect life-threatening events.

More than 100 independent and objective studies suggest that Masimo SET(R) outperforms other pulse oximetry technologies, even under the most challenging clinical conditions, including patient motion and low peripheral perfusion. This has resulted in a steady growth in market acceptance and increase in company revenues.

Masimo is now the second largest supplier of pulse oximetry technology, behind Nellcor/Covidien, which is now Medtronic. We see nothing on the horizon at Medtronic that provides any risk of stopping the Masimo market growth in the near future. Δ



Vendor Short Takes

CLASS 1 RECALL ON NELLCOR VENTILATOR SYSTEM

Nellcor Puritan Bennett, 980 Ventilator System - Software Issue May Stop Ventilator

Recall Class: 1. **Date Recall Initiated:** October 1, 2014. **Devices:** Puritan Bennett 980 Ventilator System. **Manufacturing Dates:** March 3, 2014 through August 19, 2014. **Distribution Dates:** March 3, 2014 through August 22, 2014

See list of recalled serial numbers by visiting: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=130226>

The Nellcor Puritan Bennett 980 Ventilator System provides constant breathing support for adults, children, and premature babies that weigh at least 10.6 ounces. The ventilator is used in hospitals or during patient transport.

Recalling Firm: Nellcor Puritan Bennett Inc. (doing business as Covidien LP), 6135 Gunbarrel Avenue, Boulder, Colorado 80301-3214.

Reason for Recall: Puritan Bennett 980 Ventilator Systems with software versions below 2.8 may have a software problem that causes the ventilator to stop working after the air and oxygen gas supply lines are disconnected and then reconnected. This can lead to serious health problems or death if the healthcare provider does not connect the patient to another ventilator or to a different form of breathing support.

Public Contact: For assistance, contact Covidien's Technical Support Department at 1 (800) 255-6774, option 4, and then option 1, Monday through Friday, 6 a.m. to 4 p.m., Pacific Time.

FDA District: Denver District Office

More Information about this Recall:

- A Covidien representative will update the software on the ventilators as soon as possible.
- Covidien sent an Urgent Field Corrective Action letter dated October 3, 2014 to its customers with the following information.

Important Safety Reminders:

- Always follow the instructions found in the operator's manual. See Section 3.5.2 for information about disconnecting and reconnecting gas sources.
- Always closely watch patients on ventilators.
- Always keep another source of breathing support nearby when using the ventilator.
- Always connect at least two gas sources to the ventilator to make sure a constant gas supply is ready for the patient in case one of the gas sources fails.

- Maintain the ventilator at the suggested times as found in Table 7-1 in the operator's manual.

Additional Instructions:

- Customers may continue to use these ventilators until Covidien updates the software as long as two gas sources are connected to the ventilator at all times.
- Always keep at least one gas source connected to the ventilator when disconnecting and reconnecting gas sources.
- If the ventilator stops, provide another source of breathing help according to the hospital's rules to reduce patient risk.
- To receive the software update, complete the acknowledgement and receipt form attached to the correction letter. Fax it to the Covidien contact found on the form.
- Forward a copy of the Urgent Field Corrective Action letter to other healthcare settings or individuals who received the Puritan Bennett 980 Ventilator.

Source: http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm422326.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

HELPING ACO'S OVERCOME THEIR CHALLENGES: REMOTE PATIENT MONITORING

(Posted by Andy Westby on Oct 18, 2012) As ACO's continue to face pressure to improve outcomes while reducing costs, many believe that technological advances in remote patient monitoring can help achieve those goals. While some skeptics opt to keep remote patient monitoring on the sidelines for the time being, others see the need to change how patient care is delivered and are eagerly jumping in.

The concept of monitoring patients remotely is not a new one by any means, however the technology with which it can be done today is most certainly not your grandfather's holter monitor.

Holter vs BG resized 600 Let's first consider some of the growing use cases for remote patient monitoring, and then look at some of the advantages it can bring.

Use Cases It is important to first understand that remote patient monitoring is a concept that is broadly applicable across a wide variety of conditions, disease states, and treatments. Some of the more common use cases for this technology tend to focus on cardiac conditions and identifying arrhythmias such as Atrial Fibrillation.

A number of other scenarios are finding their way into everyday conversations with providers, payers and life science companies alike. Surprising to some perhaps is that remote patient monitoring solutions are being deployed for both outpatient and inpatient settings.

Take for example the following use cases:

Outpatient settings: Monitor the ECG, weight, blood pressure and medication adherence of Congestive Heart Failure patients for early detection of acute decompensation in order to reduce hospital re-admissions

Monitor the blood glucose readings and weight of diabetes patients to identify compliance and trends that could otherwise lead to complications

Monitor the ECG, heart rate, blood pressure, and cardiac rhythm of patients diagnosed with Aortic Stenosis to monitor status prior to and during treatment

Monitor the oxygen saturation (SP02), heart rate, and respiration rate of patients to screen for (or potentially diagnose) Obstructive Sleep Apnea, a leading co-morbid condition of other serious conditions

Inpatient settings: Discharge patient to step-down units hours or even days earlier than they otherwise would have been discharged from intensive care units by monitoring their vitals with cheaper, less invasive remote monitoring technologies

Monitor post-surgical patients to assess patient progress and activity levels before discharge

Monitor patients with indwelling catheters or other high risk patients for infection

Advantages of Remote Patient Monitoring Whatever the scenario might be, the advantages of remote patient monitoring are numerous and have been covered on this blog before. Some of the primary benefits however include:

Improved insight: Remote patient monitoring solutions are typically excellent at aggregating large amounts of data regarding the physiological health of a given patient. Keep in mind that this is only beneficial if the large volume of data can be turned into actionable insight (something discussed in the 2nd blog entry for this series). Without intelligent systems that can filter and triage the relevant data, it's very likely that clinicians will be left to drown in an ocean of data.

Anytime, anywhere access to near real-time data: Today's remote patient monitoring solutions typically include some type of cloud-based technology and asynchronous data exchange which allows healthcare professionals to gain easy access to near real-time patient data from anywhere in the world at anytime they desire. Physicians on vacation can take out their iPad and securely see how their patients are currently doing with a few simple swipes of their finger.

Clinical impact: Many studies exist about the clinical benefits of remote patient monitoring. Some research highlights include:

A study in the UK found remote patient monitoring dropped ER admissions by 40% among patients on a telehealth program.

The Veterans Health Administration (a leader in remote monitoring) has found remote monitoring leads to a 25 percent reduction in the number of bed days and a 20 percent reduction in hospital admissions

An international group of researchers found that with remote monitoring, mortality rates for chronic heart patients was 102 deaths per 1,000 people compared with 154 deaths per 1,000 in the standard care group (a 34% reduction)

Financial impact: It should be no surprise that benefits on the clinical side often lead to equally impressive benefits on the financial side. For example, according to Juniper Research, cost savings of \$1.96 to 5.83 billion can be realized by the year 2014 through mobile health monitoring (with most of the savings coming from the US and Canada).

The technology of remote patient monitoring continues to get simpler, smarter, and smaller. As the benefits begin to prove themselves as well, it is reasonable to assume that this will become a standard part of medical practice within every ACO. While significant hurdles and challenges to widespread adoption do exist, we at Preventice believe the benefits of remote patient monitoring are far too great for this type of technology to sit on the sidelines for long.

Source: <http://www.preventice.com/blog/bid/234846/Helping-ACO-s-Overcome-Their-Challenges-Remote-Patient-Monitoring>

MASIMO ANNOUNCES FDA 510(K) CLEARANCE OF RADIUS-7™ -- FIRST RAINBOW® SET® NONINVASIVE WEARABLE, WIRELESS MONITOR FOR ROOT®

Continuous, Untethered Monitoring of Oxygenation and Respiration Designed to Mobilize Patients

IRVINE, CA--(Marketwired - Dec 1, 2014) - Masimo today announced FDA 510(k) clearance of Radius-7™ for the Root® patient monitoring and connectivity platform, the first and only wearable, wireless monitor with Masimo's breakthrough rainbow® SET® technology, offering patients continuous monitoring with freedom of movement.

With rainbow® SET® noninvasive measurements, Radius-7 with Root can alert clinicians -- at the bedside or remotely, through the Masimo Patient SafetyNet™ remote monitoring and notification system -- of critical changes in a patient's oxygen saturation and pulse rate -- even during states of motion and low perfusion -- as well as respiration through acoustic respiration rate (RRa®). Lightweight at only 0.34 lbs. (155g), the Radius-7 attaches to the patient's arm or can be placed alongside the patient

in their bed, allowing untethered monitoring while they are in bed or out. With no need to disconnect and reconnect the cable to get out of bed, the Radius-7 reduces the need for nursing assistance. And the Radius-7's wireless communication functionality -- either short-range via Bluetooth back to Root or with upgradeable WiFi for long-range communication -- ensures the patient can be continuously monitored and connected to caregivers wherever they are in the hospital.

Studies have shown that patient mobility is a key factor in more rapid patient recovery.¹ Radius-7 allows clinicians to continuously monitor their patients when they are mobile.

1 Needham D, Korupolu R, Zanni J, Pradhan P, Colantuoni E, Palmer J, Brower R, Fan E. "Early Physical Medicine and Rehabilitation for Patients With Acute Respiratory Failure: A Quality Improvement Project." Archives of Physical Medicine and Rehabilitation Vol 91, Issue 4, PP 536-542, April 2010

MEANINGFUL USE PENALTIES START JANUARY 1ST ATTEST TO AVOID FUTURE PAYMENT ADJUSTMENTS

Payment adjustments for Medicare eligible professionals who have not successfully achieved Meaningful Use will begin on January 1, 2015.

- If you are an eligible Medicare professional who did not successfully demonstrate Meaningful Use in 2014, you will be subject to a 1% payment adjustment on your Medicare Part B Reimbursements in 2015 and 2% in 2016
- Eligible professionals who do not successfully attest for a full year in 2015 will see a 3% payment adjustment in 2017
- The maximum payment adjustment amount can reach as high as 5%

NEW BRAIN STUDY CONFIRMS ANESTHESIA RISK IN ELDERLY

Los Angeles, CA (October 19, 2012) The warnings given for decades by noted anesthesiologist Dr. Barry Friedberg about the risk of brain damage during major surgery have been validated by a recent study announced by the National Institutes of Health.

Study findings published in October 2012 provide clear and indisputable evidence that use of a brain monitor while a patient is anesthetized during surgery significantly reduces the risk of delirium and postoperative cognitive dysfunction (POCD).

The study in 921 elderly patients (www.ncbi.nlm.nih.gov/pubmed/23027226) confirms the self-evident claims made by Dr. Friedberg about the dangers of over-medication during surgery. Dr. Friedberg authored a book on the subject and formed the non-profit Goldilocks Anesthesia Foundation <http://www.goldilocksfoundation.com> to educate the public about avoiding the hidden dangers from anesthesia over-medication by the use of brain monitors during surgery.

Says Friedberg, "Over 2,000 years ago, the Greeks carved this concept into stone, 'All things in moderation, nothing in excess.'"

Written for the general public, *Getting Over Going Under: 5 Things You MUST Know Before Anesthesia* (ISBN 978-0-9829169-0-2, 2010, Goldilocks Press, 116 pages, \$18.95) Dr. Friedberg explains that every time a patient has anesthesia for surgery there are dual risks of under-medication (anesthesia awareness) or over-medication (brain scrambled) -- preventable risks when using a brain monitor.

This large clinical study in major, non-cardiac surgery also projected that for every 1,000 patients brain monitoring would prevent delirium in 83 patients and POCD in another 23 within 30 days after surgery.

"Elderly patients' brains are more sensitive to anesthesia over medication. More boomers and their parents are aging and having surgery under anesthesia. Substantial financial costs caring for mentally damaged post-op patients could be averted by implementation of routine brain monitoring," according to Dr. Friedberg.

"The study findings validate my commitment to inform patients facing surgery that it is their right to insist upon brain monitoring to prevent the horrors of over-medication and under-medication," said Dr. Friedberg. "As I noted in my book, too many anesthesiologists still gauge anesthesia response using the classical but notoriously unreliable signs of heart rate and blood pressure changes. Most do not rely upon a brain monitor, the best technology available."

Two decades ago, Dr. Friedberg, developed a safer anesthesia protocol, subsequently made numerically reproducible with the brain monitor and earning him a U.S. Congressional award. Among the findings in *Getting Over Going Under* is that about 80 percent of the surgeries in the U.S. put patients at risk of being afflicted with delirium, POCD or even permanent brain damage because a brain monitor is not used.

SOURCE Dr. Barry Friedberg via <http://www.prnewswire.com/news-releases/new-brain-study-confirms-anesthesia-risk-in-elderly-175387641.html>

NEW STUDY REVEALS HOW QUICKLY VIRUSES CONTAMINATE BUILDINGS; CLEARSTREAM OFFERS ANTIMICROBIAL SOLUTIONS

Researchers at the University of Arizona, Tucson, recently revealed the results of a new study on viral contamination, presenting their findings at the 54th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in September. In response to the study, Clearstream, LLC -- a diversified provider of environmentally friendly antimicrobial products and services -- proposes proactive, technologically advanced measures to kill germs and prevent microbial transmission.

To determine the speed and extent of virus contamination in health care facilities, office buildings and hotels, the University of Arizona research team examined the transmission of bacteriophage MS-2 – a harmless tracer virus that is similar to the human norovirus in terms of its shape, size and resistance to disinfectants. The researchers applied the bacteriophage to one or two commonly touched surfaces, such as a doorknob or tabletop, at the beginning of the day. Then at various intervals throughout the day, they sampled dozens of surfaces (including light switches, countertops, handles, phones and computer equipment) to see if the virus was present. Their findings showed that within two to four hours, the virus had contaminated between 40 to 60% of the sampled surfaces⁽¹⁾.

A second phase of the study examined the effectiveness of disinfectants in preventing transmission of the virus. “The results show that viral contamination of [surfaces] in facilities occurs quickly, and that a simple intervention can greatly help to reduce exposure to viruses,” reported researcher Charles P. Gerba of the University of Arizona⁽²⁾.

The scientists recommended using a disinfectant registered by the Environmental Protection Agency (EPA) in combination with hand hygiene to prevent the spread of viruses (1). While the study specifically examined the use of disinfecting wipes containing quaternary ammonium compounds (QUAT), organizations can choose from a range of EPA-registered disinfectants and antimicrobial surface treatments – including Clearstream mPact products and services – to combat the spread of viruses.

“Infectious diseases spread rapidly through health care facilities, offices, schools, hotels and mass transportation. The [University of Arizona] study has proven that widespread contamination can occur in just a couple of hours,” said Clearstream CEO Jim Praechtl. “These findings underscore the importance of preventative measures in halting the spread of viruses and bacteria.”

Praechtl emphasized the role of intervention, explaining, “Proper hand washing is essential for individuals to protect themselves from contagions; however, organizations also have a responsibility to protect their customers and the public by doing all they can to help reduce the surface transmission of viral, bacterial, and fungal cross-contamination.”

According to Betsy McCaughey, former Lt. Governor of New York State and Founder of the Committee to Reduce Infection Deaths (RID), common infectious diseases such as MRSA and C. diff are racing through U.S. hospitals, killing an estimated 75,000 patients every year⁽³⁾ – signaling a widespread need for a standardized, synergistic approach designed to reduce the spread of infectious diseases on a national level, per Praechtl.

Clearstream offers an array of products together with the mPact line of antimicrobial products and services including select product technologies that are approved by the

EPA and by the U.S. Food and Drug Administration (FDA). They are formulated to reduce the risk of cross-contamination from a variety of sources, including and extensive and growing compendium of viruses, bacteria, mold, mildew, fungi, algae and yeast. There are two key steps in the mPact antimicrobial system – first, clean and disinfect with a biocide and second, treat targeted substrates with a long term (bound) static antimicrobial surface protection technology.

Clearstream’s first step begins with their mPerial detergent/disinfectant. mPerial disinfects and sanitizes surfaces to eliminate a broad spectrum of bacteria, fungi and viruses. It is proven effective against many viruses including, but not limited to, the norovirus (Norwalk virus), HIV-1, and bacteria such as E-coli, Salmonella, and Methicillin Resistant Staphylococcus Aureus (MRSA).

The second step, mPale Antimicrobial with AEGIS Microbe Shield®, is a surface-protection technology that renders offending microbes inactive without chemical poisons. Its unique design allows the formula to bond with virtually every porous, non-porous, organic or inorganic surface, providing non-toxic, non-leaching, long-term protection that will not persist in the environment.

Clearstream’s mPale antimicrobial technology helps to keep infection transmission rates low due to its unique property of creating an antimicrobial surface. Once cured on the surface, mPale will continue to protect those treated surfaces by physically disrupting cellular activity. The non-leaching static properties of mPale will not allow microorganisms to colonize, mutate, or to form adaptive strains.

Clearstream is currently in contact with the UN, the World Health Organization, Doctors Without Borders, US AID, the US Military, and Samaritans Purse in an effort to help reduce the suffering from the Ebola Virus in West Africa.

To learn more about Clearstream’s antimicrobial product technology, including their mPact products and services, visit <http://www.thinkclearstream.com>.

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To learn more about Clearstream’s antimicrobial product technology, including their mPact products and services, visit www.thinkclearstream.com.

Source (as well as footnote references): <http://www.prweb.com/releases/2014/10/prweb12282905.htm>

NONINVASIVE ASSAY MONITORED TREATMENT RESPONSE IN PATIENTS WITH METASTATIC PROSTATE CANCER

Deciding the ideal treatment for patients with metastatic prostate cancer that stops responding to initial therapy could be guided by certain analyses of cancer cells isolated from the patients’ blood, according to new research.

Deciding the ideal treatment for patients with metastatic prostate cancer that stops responding to initial therapy could be guided by certain analyses of cancer cells isolated from the patients’ blood, according to data published in Cancer Discovery, a journal of the American Association for Cancer Research.

“The growth and survival of prostate cancer cells are very dependent on signals that the cancer cells receive through a protein called the androgen receptor,” said Daniel A. Haber, M.D., Ph.D., director of the Massachusetts General Hospital Cancer Center in Boston and project leader of the Stand Up To Cancer Bioengineering and Clinical Applications of Circulating Tumor Cell Chip Dream Team. “Treatments that deprive the androgen receptor of its signals are initially highly effective in most patients with metastatic prostate cancer. Unfortunately, prostate

cancer, like all cancers, undergoes evolution during therapy, and this can confer resistance to treatment.”

Haber and his colleagues established a way to isolate cancer cells from the blood of patients with prostate cancer and to measure readouts of androgen receptor signaling in each of the individual cancer cells in the blood.

Prior to the initiation of androgen-deprivation therapy, the androgen receptor signaling pathway was turned on in most of the cancer cells in the blood of patients with newly diagnosed metastatic prostate cancer. After the initiation of androgen-deprivation therapy, the pathway turned off in the circulating tumor cells.

However, in patients whose prostate cancer had progressed after initially responding to androgen-deprivation therapy, the cancer cells in the blood were highly variable. Some cells had the androgen receptor signaling pathway turned on while other cells had it turned off. Yet other cells had characteristics of the signaling pathway being both on and off. The presence of cells with a mixed androgen receptor signaling pattern was associated with an adverse treatment outcome.

In addition, in patients treated with a new drug, abiraterone, which achieves more complete androgen deprivation than earlier treatments, an increased percentage of circulating tumor cells with androgen receptor signaling turned on despite abiraterone treatment was associated with decreased overall survival.

“This study is a proof of principle that it is possible to monitor, in patients with metastatic prostate cancer, the androgen receptor signaling pathway in real time, repeatedly and noninvasively,” Haber said. “Our approach allowed us to monitor whether initial androgen-deprivation therapy was keeping the androgen signaling pathway shut down or whether the tumor was becoming resistant, and if so, by what mechanism.”

“As more drugs are developed that target the different pathways that drive the recurrence of metastatic prostate cancer in different patients, it will become essential to know which drug and which pathway is relevant in each patient,” he said. “Our assay will be an effective way to interrogate the tumor and follow it during the course of treatment to monitor therapy response and the emergence of drug resistance.”

Source: American Association for Cancer Research. “Noninvasive assay monitored treatment response in patients with metastatic prostate cancer.” ScienceDaily. ScienceDaily, 23 October 2012. <www.sciencedaily.com/releases/2012/10/121023101023.htm>

TEXAS EBOLA HOSPITAL LOSING MEDICARE REIMBURSEMENTS NEXT YEAR

Saturday, 20 Dec 2014 12:13 PM, By Sandy Fitzgerald

Texas Health Presbyterian Dallas, where two nurses were infected with the Ebola virus and the site of the only death from the disease, is among several North Texas hospitals that will lose a portion of their Medicare reimbursements through an Obamacare provision that penalizes hospitals for care issues.

The safety problems included in scores for the Dallas hospital the others were for issues taking place between 2011 and 2013, not for this year's incidents, reported the Dallas Morning News.

The Dallas hospital, along with a dozen other hospitals including Medical City Dallas, Baylor University Medical Center and Parkland Memorial Hospital stand to lose one percent of their reimbursements, totaling millions of dollars, in 2015.

The news comes as business seems to be returning to normal at Texas Health Presbyterian just two months after it was at the center of an Ebola crisis that sparked nationwide panic this fall, the newspaper also reported.

Daily net revenue and surgeries at the hospital have returned to where they were before Liberian patient Thomas Eric Duncan was diagnosed there. He died on Oct. 8, and two nurses who cared for him, Nina Pham, and Amber Vinson, contracted the disease but both have made a full recovery.

It will still likely take some time for Texas Health to recover from its losses from this past fall, though. Weeks after Duncan's death, the hospital reported its net revenue had dropped by \$8.1 million, or 25.6 percent, over the first 20 days of October. Surgeries went down by 25 percent and emergency room visits took a 50 percent drop.

Medicare released its assessments on Thursday, with around 700 hospitals nationwide to take a hit in Medicare funding next year, the newspaper reported.

Under Obamacare, the nation's hospitals receive scores that reflect the number of patients that end up with infections, bed sores, or other problems resulting from hospital care.

In fiscal year 2015, about a quarter of the nation's hospitals with the worst scores will lose one percent of their Medicare funding, which could total millions of dollars lost nationwide, as most hospitals rely on Medicare to make up to two-thirds of their revenue, the paper reported.

Texas Health Presbyterian received about \$170 million, according to txpricepoint.org, the Texas Hospital Association's price transparency website.

Texas Health Presbyterian officials did not comment to the newspaper about the Medicare report.

Medicare has been rewarding and punishing hospitals through reimbursements since 2008, and three years ago also began penalizing facilities for patients who are readmitted within 30 days after they are discharged.

Source: <http://www.Newsmax.com/US/texas-health-presbyterian-ebola/2014/12/20/id/614235/#ixzz3MkulpQux>

VERIZON WIRELESS INTRODUCES SURE RESPONSE

Wireless technology sometimes comes in packages other than smartphones and tablets. One solution aims to keep people connected in times of emergencies.

The new Verizon SureResponse™ Mobile Personal Emergency Response System (MPERS) helps provide security and convenience. With a simple touch of a button, it places a call to a SureResponse Care Agent.

Worn as pendant around the neck, on the wrist like a watch, or clipped to a belt so it won't get in the way of activities, the SureResponse features a call button to contact emergency personnel or family members without looking up contacts or reading a screen. Pressing the call button connects the wearer to a SureResponse Care Agent who is available 24 hours a day (with support in English or Spanish) and can direct their call to the right person for help.

If the wearer is away from home, SureResponse uses GPS to provide location services to agents and emergency response units easing concerns. It also offers the ability to store personal information online that can be used in emergency situations.

The most recent study conducted by the Centers for Disease Control found that two-thirds of all accidental injuries in the United States occurred in the tub or shower. Seniors and caregivers shouldn't have to worry about water limiting the ability to bring their MPERS with them. SureResponse is the only MPERS equipped with a built-in water resistant shell.

Customers and families can visit the SureResponse FAQ page at http://www.verizonwireless.com/support/faqs/Equipment/sure_response.html for additional information.

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Time is Short -- What Will the Shemitah of 2014/2015 and Yovel of 2015/2016 Bring?

An Editorial By Art Gasch

In the Jewish calendar, counting from Creation, the first Shemitah occurred in the year 3829, 68–69 CE on the secular calendar. By counting sevens from then, we see that the current Shemitah year is the year 5775 after Creation, which runs from Sept. 25, 2014, through Sept. 13, 2015.

Just as the seventh day was laid out by God as a day of rest in the Hebrew Old Testament, every seventh year was designated as a Sabbath year. The word Shemitah is most often translated as “the release” or “the remission” and applied to the wiping away of debts as well as the resting of the land. The Shemitah – sabbatical year – is observed every seven years. Every seventh Shemitah (in other words, 49 years), follows a year of jubilee, known as Yovel. The next year of Yovel will occur about the time of the next U.S. presidential election.

A series of interesting events have occurred during Shemitah years over the past 98 years. The two previous Shemitah years occurred in 2000-2001 and 2007-2008 and some of the more recent events include: the 2008 Real Estate Investment Trust (REIT) market crash and ensuing recession; the 2002 attack in Yemen where a suspected Islamic fundamentalist killed three U.S. workers and wounded one in a hospital in Jibla; and the 2001 attack that destroyed the World Trade Center and engaged the U.S. in the longest and least successful war in history.

2015 and 2016 may bring unexpected events that could topple America as a world power, and plunge the world into turmoil, confusion and darkness. I suggest you read two books by Jonathan Cahn, *The Harbinger*, and *The Mystery of the Shemitah*. You can purchase them both through Nook, Amazon or at Barnes and Noble -- if you like to read the old fashion way. Books are much cheaper on Nook.

America is much like the great ship RMS Titanic. We are proceeding at full speed, in the dark, icy waters, heedless of hidden dangers, and ignorant of fatal flaws that will destroy us by a single event. America needs to slow down, ponder our disastrous course and turn back to God before we hit an iceberg and go down with the ship. It's not about economic forecasts -- ours versus others -- there are lives at stake. The Shemitah year of 2015 is a tale of two courses for America with two different outcomes. On the present course is unexpected destruction. On another, is a return to God's protection, blessing and safe harbor - veering away from destruction ahead.

The easiest choice is to deny the truth that God prospers America and continue on our present course, believing we did it all ourselves. This is the course steered by Caption Obama and his crew. So far, their voyage has been a false, reckless and rebellious journey of constitutional violations, made smugly, and the rekindling of extreme racial divide. It has been a journey away from God, which will lead to America's collapse - rather than the false promise of prosperity.

Look around at the decks and ask, “Are their enough lifeboats to rescue all of us if the ship encounters serious obstacles or begins to sink? If the ship hits an economic iceberg now, like the 2008 market crash, can we simply print more money and continue on? If there is an attack on America's power grid, rendering portions of America powerless for months, what will happen to the economy and society?” The power grid is vulnerable to solar flares and enemy attack. An America that denies God is a vulnerable America.

If America sinks will the “lower class” again be locked away in the lower decks of the ship, prevented from any hope of reaching the life boats, like they were on the Titanic originally?

The harder, but correct course is to stop and rethink America's allegiance to God and reverse the apostasy and rejection of our Founder's principles and Christian foundations expressed in the Declaration of Independence, the Constitution and the heart of the God-fearing people. In old fashioned terms, we need a revival, and we need it nationwide in 2015. Who will lead it?

During the 2014 elections Captain Obama said that, “My policies are on the ballot in every state,” and Americans voted out those who had supported Obama's policies. Unphased, Captain Obama arrogantly replied to those newly elected, “Welcome aboard! America has elected you to cooperate with ME in getting what I want done!” Does that sound like someone who intends to change course?

When the Employer Mandate kicks in, every voyager will have the official Obamacare healthcare life-jacket, their key to access healthcare. But there is a deception (pointed out earlier in this issue), the key doesn't provide the access it claims. *Those with Obamacare can't afford or use it due to high out-of-pocket costs. They have paid so much for Obamacare that they have nothing left to pay for out-of-pocket expenses, which have greatly increased under Obamacare policies for individuals and for families.* They are being charged dearly for Obamacare's false promise of access, premiums that middle class Americans are struggling to pay and the poor cannot afford. Obamacare is based on lies, which according to one of its architects, Prof. Jonathan Gruber¹, “Americans were too stupid to recognize”. Since 2013 premiums have increased 41 percent and 18 percent respectively to those forced to accept Obamacare, which Obama promised would be a voluntary program. The recovery of the 2008 crash has been so weak that the average household income has dropped, and more Americans find themselves in financial bondage to Uncle Sam.

America needs to change course immediately, in healthcare and in its spiritual direction that separates it more and more from God. MSP's Patient Controlled Care (PCC) healthcare program mentioned below is such a change. No politician from either party, will fix America's problems, because they are spiritual, not political problems. The year 2015 is a year of Shemitah and 2016 a year of Yovel. Together they may sink America! Don't you believe gas prices will be \$2.00 at the end of 2016, or employment will do down?

God has empowered MSP with two ways to help America. First, a PCC healthcare business model to replace Obamacare with a system that finances access to healthcare through savings and annuities, restores the patient-doctor relationship, secures patient PHI data, which removes the government from healthcare and is cost-effective for everyone.

Second *Triad Dataspace*TM, which is a new technology that makes cloud data centers immune to data loss from remote external cyber attacks. No other storage technology offers such breach protections. No other technology offers searchable double-blind encryption of all stored data. Both PCC and TriadTM need to be deployed in 2015. MSP is looking for pilot projects in 2015 - will you partner with us?

¹ Jonathan Holmes Gruber is professor of economics at the MIT. He is also Director of the Health Care Program at the National Bureau of Economic Research

MSP Industry Alert[™]

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