MEDICAL DEVICE DAILY™

THE DAILY MEDICAL TECHNOLOGY NEWS SOURCE

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SHEDS $200M IN VALUE UPON NEWS

Wall Street punishes Endologix as it extends FDA timeline for Nellix system

By Stacy Lawrence, Staff Writer

Small cap Endologix Inc. lost about one-third of its valuation after it pushed back the U.S. regulatory timeline for its Nellix Endovascular Aneurysm Sealing System. The Irvine, Calif.-based company said that it needs to conduct a confirmatory clinical study for a second generation device.

That trial will start enrolling during the fourth quarter, with a target for PMA approval in 2020.

The company had previously expected a PMA approval for the Nellix EVAS system during the second quarter of next year. Nellix EVAS is a system to treat infrarenal abdominal aortic aneurysms (AAA); it is novel in that it works by

See Endologix, page 4

LONG ROAD FOR RECELL

Avita Medical's Recell spray-on-skin meets co-primary endpoints in pivotal burn trial

By Tamra Sami, Staff Writer

PERTH, Australia – Avita Medical plans to submit its Recell spray-on-skin premarket approval application to FDA in a few weeks following positive results from its pivotal burn trial.

The Perth-headquartered regenerative medicine company said that the

See Avita Medical, page 5

REGULATORY

Free-standing ERs a target for changes in congressional hearing

By Mark McCarty, Regulatory Editor

Free-standing emergency centers have proven to be a boon to makers of devices and medical equipment used in such facilities, but a hearing in the House Ways and Means health subcommittee suggests that Congress is looking for ways to put the brakes on the pace of growth of such facilities.

See Regulatory, page 6

LIQUID BIOPSY SPACE BOOMING

Med Fusion launches liquid biopsy service to help select patients eligible for therapy

By Omar Ford, Staff Writer

Med Fusion Inc., a full-service laboratory and clinical trials service organization, has launched a plasma-based epidermal growth factor receptor (EGFR) liquid biopsy service. The service uses Basel, Switzerland-based Roche Holding AG's

See Med Fusion, page 7

MEETING ELDERLY NEEDS

Robotics, AI driving elderly med-tech market

By Alfred Romann, Staff Writer

HONG KONG – Later this year, the robotic Lean Elderly Assistant (LEA) will literally roll onto the market.

LEA is unique. It looks, at first glance, like a high-end rollator or walker but it is much more: a robotic assistant that incorporates a range of smart technologies and makes it easier for users to remain or become more active.

See Robotics, page 8

IN THIS ISSUE

APPOINTMENTS AND ADVANCEMENTS

Infusystem Holdings Inc., Madison Heights, Mich.-based infusion pump provider, reported Eric Steen, director, president and CEO has resigned, effective immediately. In the interim, Gregg Lehman has been appointed by the board to serve as executive chairman, leading the transition until a new CEO is appointed.

DAILY M&A

Beijing-based **Concord Medical Services Holdings Ltd.**, a hospital management solution provider and radiotherapy and diagnostic imaging operator, said its subsidiary, Meizhong Jiahe Hospital Management Corp. Ltd., in a joint venture with Guofu Huimei Investment Management Ltd. Partnership, intends to acquire Shanghai Promed Cancer Center LLC. The purchase will include existing and new capital of the company, and requires shareholder approval and government filing.

OTHER NEWS TO NOTE

Btg plc, a London-based health care company, and Mountain View, Calif.-based **Healthloop Inc.**, provider of a cloud-based platform that automates follow-up patient care, reported their collaboration on Io Loop. This is an exclusive service from BTG that gives access to a turn-key digital support platform powered by Healthloop. Io Loop enables patients and their physicians to stay connected. It also provides the care team with patient-reported outcomes that help physicians meet the new reporting requirements of Medicare Access and CHIP Authorization Act.

Masimo Corp., of Irvine Calif., reported the full market release of Early Warning Score (EWS) on the Root patient monitoring and connectivity hub. EWS aggregates information from multiple vital signs and clinical observations to generate a score that represents the potential degree of patient deterioration. Early warning scores are based on multiple contributors, including vital signs such as oxygen saturation, pulse rate, respiration rate, body temperature,and systolic blood pressure – and contributors entered by clinicians, such as level of consciousness, use of supplemental oxygen, and urine output. Root can be customized for various predefined EWS protocols, or hospitals can configure their own set of required contributors, and their relative weights, to create an EWS unique to their care environment.

Medical Device Daily presents Patent Highlights, an excerpt of the most important med-tech patents from this week's Cortellis Patents Gazette. See the attachment at the end of this edition.

Seventh Wave Laboratories LLC, a Maryland Heights, Mo.-based contract research organization that assesses the safety and efficacy of pharmaceutical products and medical devices, reported a collaboration with Tualatin, Ore.-based **Yecuris Corp.**, a developer of humanized models in drug development research. Seventh Wave will now be the exclusive provider of services related to hepatitis B virus and C virus pharmacology studies using the Yecuris liver humanized Frg Ko model. Seventh Wave also will offer toxicology, metabolism and other pharmacology services using Yecuris models. Yecuris' models are highly repopulated with human liver cells, making them an ideal candidate for efficacy studies of human liver pathogens.

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BUSINESS OFFICE

Donald R. Johnston (Senior Director, Current Awareness), Penney Holland (Web Production Manager)

10 BIGGEST U.S. WINNERS FOR THE WEEK

By Percent		By Dollars	
Athenahealth	19.50	Intuitive Surgical	26.61
Seaspine	12.66	Athenahealth	21.28
Mazor Robotics	6.79	The Cooper Cos	5.03
Strata Skin Sciences	6.64	Teleflex	3.13
RTI Surgical	6.59	Abiomed	3.01
Checkcap	4.55	Mazor Robotics	2.73
Intuitive Surgical	3.15	Edwards Lifesci	2.30
Inogen	2.61	Henry Schein	2.19
Livanova	2.48	Inogen	2.14
The Cooper Cos	2.42	Stryker	1.99

10 BIGGEST U.S. LOSERS FOR THE WEEK

By Percent		By Dollars	
Endologix	-36.48	Illumina	-5.37
Pavmed Inc	-21.78	Zimmer Biomet	-3.59
Bovie Medical	-18.87	Dexcom	-2.76
Lianluo Smart Ltd	-17.14	Endologix	-2.55
Tearlab	-16.54	Penumbra	-1.95
Sunshine Heart	-10.96	Idexx Laboratories	-1.59
Invuity	-10.91	Conmed	-1.33
iCAD	-8.05	Haemonetics	-1.26
Meridian Bioscience	-7.17	Varian Medical	-1.24
Iridex	-4.65	Meridian Biosci	-1.05

MDD STOCK REPORT FOR PUBLIC MED-TECH COMPANIES

COMPANY	SYMBOL	CLOSE 5/12	CLOSE 5/19	%CHANGE WK	%CHANGE YTD	VOL (000)
Abbott Laboratories	ABT	43.96	43.16	-1.82	12.37	28458
Abiomed	ABMD	131.42	134.43	2.29	19.30	1744
Accuray	ARAY	4.1	4	-2.44	-13.04	4259
Agilent Technologies	A	56.16	56.13	-0.05	23.20	7928
Alere	ALR	46.7	47.48	1.67	21.84	4953
Align Technology	ALGN	138.67	138.43	-0.17	44.00	3769
Allscripts Healthcare	MDRX	12.32	11.9	-3.41	16.55	10599
Athenahealth	ATHN	109.13	130.41	19.50	24.00	8148
Baxter International	BAX	56.19	57.21	1.82	29.03	14778
BD	BDX	184.62	184.13	-0.27	11.22	10980
Biolase	BIOL	1.2	1.18	-1.67	-15.71	114
Boston Scientific	BSX	26.23	26.41	0.69	22.10	40623
Bovie Medical	BVX	2.65	2.15	-18.87	-40.11	1094
C.R. Bard	BCR	307.71	307.55	-0.05	36.90	4621
Cantel Medical Corp	CMD	71.29	71.86	0.80	-8.75	724
Cardiovascular Syst	CSII	31.97	31.49	-1.50	30.07	1231
Checkcap	CHEK	1.98	2.07	4.55	-11.91	146
Conmed	CNMD	51.05	49.72	-2.61	12.57	510
Delcath Systems	DCTH	0.03	0.03	0.00	-96.74	118129
Dentsply Internat	XRAY	61.65	61.62	-0.05	6.74	6058
Dexcom	DXCM	70.42	67.66	-3.92	13.33	5701
Dextera Surgical	DXTR	0.22	0.22	0.00	-77.08	7272
Echo Therapeutics	ECTE	0.04	0.04	0.00	-75.31	16
Edwards Lifesci	EW	110.59	112.89	2.08	20.48	9134
Endologix	ELGX	6.99	4.44	-36.48	-22.38	22038
Fluidigm	FLDM	5.65	5.46	-3.36	-25.00	917
Haemonetics	HAE	41.29	40.03	-3.05	-0.42	1245
Halyard	HYH	36.56	36.2	-0.98	-2.11	1537
Henry Schein	HSIC	175.62	177.81	1.25	17.20	2173
Hill-Rom Holdings	HRC	73.61	74.83	1.66	33.29	3135
Hologic	HOLX	42.63	43	0.87	7.18	17322
iCAD	ICAD	4.97	4.57	-8.05	41.27	261
ICU Medical	ICUI	164.05	163.15	-0.55	10.72	825
Idexx Laboratories	IDXX	163.22	161.63	-0.97	37.83	2331
Illumina	ILMN	182.38	177.01	-2.94	38.25	5431
Inogen	INGN	82.01	84.15	2.61	25.28	802
InspireMD	NSPR	0.58	0.56	-3.45	-77.60	1533
Integra Lifesciences	IART	46.38	47.39	2.18	10.48	2497
Intersect ENT	XENT	23.1	22.75	-1.52	88.02	1669
Intuitive Surgical	ISRG	843.72	870.33	3.15	37.24	1575
Invuity	IVTY	8.25	7.35	-10.91	27.83	2124
Iridex	IRIX	9.47	9.03	-4.65	-35.78	226
Labcorp	LH	139.32	139.35	0.02	8.54	3301
Lianluo Smart Ltd	LLIT	1.4	1.16	-17.14	-22.67	114
Livanova	LIVN	57.37	58.79	2.48	30.73	1996
Luminex	LMNX	20.83	20.71	-0.58	2.37	1478
Masimo	MASI	84.83	85.67	0.99	27.11	3675
Mazor Robotics	MZOR	40.22	42.95	6.79	95.94	4355
Medtronic	MDT	83.42	83.23	-0.23	16.85	24017
Meridian Bioscience	VIVO	14.65	13.6	-7.17	-23.16	2137
Novocure	NVCR	11.8	11.55	-2.12	47.13	2125
Nuvasive	NUVA	71.27	70.88	-0.55	5.23	3084
Nxstage Medical	NXTM	22	21.4	-2.73	-18.35	3548
Orthofix Internat	OFIX	41.73	41.77	0.10	15.45	969
Pavmed Inc	PAVM	4.73	3.7	-21.78	-46.38	9
Penumbra	PEN	83.75	81.8	-2.33	28.21	924
Quest Diagnostics	DGX	106.47	105.89	-0.54	15.22	4526
Quidel	QDEL	24.56	24.41	-0.61	13.96	805
RTI Surgical	RTIX	4.55	4.85	6.59	49.23	1512
Seaspine	SPNE	9.64	10.86	12.66	37.47	239
Senseonics Holdings	SENS	1.46	1.4	-4.11	-47.57	2716
Smith & Nephew	SNN	34.2	34.73	1.55	15.46	2602
Spectranetics	SPNC	28.25	27.6	-2.30	12.65	1772
Stereotaxis	STXS	0.62	0.62	0.00	-4.60	97
Steris	STE	75	75.58	0.77	12.15	1961
Strata Skin Sciences	SSKN	2.56	2.73	6.64	24.09	299
Stryker	SYK	134.82	136.81	1.48	14.19	5136
Sunshine Heart	SSH	0.73	0.65	-10.96	-93.81	1706
Syneron Medical	ELOS	10.9	10.9	0.00	29.76	5089
Tearlab	TEAR	2.54	2.12	-16.54	-59.22	887
Teleflex	TFX	193.46	196.59	1.62	21.99	969
The Cooper Cos	COO	207.59	212.62	2.42	21.55	2534
Thermo Fisher Sci	TMO	171.52	171.53	0.01	21.57	7810
Titan Medical	TITXF	0.3	0.29	-3.33	20.83	1594
Transenterix	TRXC	0.56	0.55	-1.79	-57.69	5011
Varian Medical	VAR	96.29	95.05	-1.29	5.87	3627
Wright Medical	WMGI	27.66	27.44	-0.80	19.41	4769
Zimmer Biomet	ZBH	121.26	117.67	-2.96	14.02	10237

NOTES

Trading volumes for Nasdaq, Amex and NYSE are recorded as the total number of shares traded (in thousands) on a weekly basis (cumulative Monday through Friday); the weekly and YTD % changes are from IPO completion, where applicable.

Average percent change week: -1.59%
Range: -36.48% to +2.42%; Number of companies: 78
(not market weighted)

Average percent change YTD: +6.02%
Range: -96.74% to +95.94%; Number of companies: 78
(not market weighted)

Endologics

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sealing off the entire aneurysmal sac.

WHAT'S NEXT?

The aortic disorders focused med-tech firm said it has sufficient cash to sustain it through that clinical and regulatory process. The regulatory delay does kick out its efforts to reach cash flow positive to mid-2019 from the prior expectation of mid-2018.

"We expect to collaborate with the FDA over the coming months on the confirmatory clinical study protocol and anticipate beginning patient enrollment in the fourth quarter of this year. Based on estimated timelines for enrollment, data collection, the submission and a panel meeting, we are forecasting a potential U.S. approval in the year 2020," said Endologix President Robert Mitchell on a conference call regarding the developments.

"Although the timing for potential approval is later than our original plans, we still feel the probability of success is higher essentially while the FDA agreed that the two-year results with the refined IFU (instructions for use) are encouraging. They still want prospective evidence and prefer the Gen-two device," he added. "We certainly could have pushed for an advisory panel meeting with the Gen-one device, but the continued risk and uncertainty is not worth it in our view. Instead, we believe the confirmatory study with the Gen-two device has a higher likelihood of success and will provide further evidence that EVAS with Nellix provides excellent patient outcomes."

Endologix is also working on another iteration of the device, Nellix Chevas that is aimed at AAA patients with complex anatomy, which it notes is the case for nearly one-third of diagnosed aneurysms. That development and regulatory timeline has been extended as well, with patient enrollment in a clinical trial now slated to start next year, and an approval targeted in 2021.

DOWNHILL SLIDE

This is just the latest in a series of setbacks for the company, which during the last half of 2016 faced a temporary suspension of its CE mark for its marketed product AFX as well as a related shipment hold. It was also required to narrow instructions for use for Nellix, which is marketed in the EU.

The company's revenues are largely driven by the Ovation Abdominal Stent Graft Platform, which is FDA-approved and has a CE mark. It also markets the AFX Endovascular AAA System, which combines anatomical fixation and graft material technology in an effort to treat a wide variety of anatomies. Its first quarter revenues of $42.6 million were almost entirely unchanged from the same quarter a year earlier.

Last month, Endologix signed a $170 million credit facility with high profile health care investor Deerfield Management. The company had $36 million in cash as of March 31, with a net loss of $21.3 million during the first quarter.

"Our previous projection for cash flow positive in the second half of 2018 now shifts back to the second half of 2019. Between the cash we have in the bank and our unused revolving line of credit, we are confident that we have sufficient funds and do not expect to raise additional capital until refinancing the $125 million in convertible bonds due in 2020," said Endologix CFO Vaseem Mahboob.

Endologix reaffirmed the 2017 revenue guidance offered earlier this year of between $193 million to $200 million, which would be a growth rate range of flat to 4 percent. But it did raise its anticipated GAAP loss per share to $(0.83) to $(0.86) from $(0.70) to $(0.76), which it attributed to interest expense and debt extinguishment charges.

Prior to its challenges during the last half of 2016, Endologix had a revenue growth rate in the high single digits and the company aims to recapture that performance rate.

The company (NASDAQ:ELGS) shed about $200 million in market cap on the Nellix delay news, falling to around $360 million from $560 million. Endologix went public in 1996 and last year completed a merger with Trivascular Technologies Inc.; its valuation exceeded $1 billion around the middle of last year. //

Avita Medical

Continued from page 1

30-patient trial met both co-primary and secondary endpoints in patients with severe burns.

The pivotal trial was conducted at seven leading U.S. burn centers between 2015 and early 2017. Co-primary endpoints were designed to demonstrate the effectiveness of Recell when combined with widely meshed (expanded) skin grafting to close deep-partial and full-thickness burn injuries. Treatment was randomly allocated to two separate parts of each patient's burn wound so that outcomes could be compared for conventional skin grafting versus the combination of Recell with a more expanded skin graft.

The first co-primary endpoint measured superiority of donor skin expansion to see if using Recell could lead to less donor skin being needed. This difference in donor skin expansion with Recell was found to be significant ($p<0.001$) and resulted in using 30 percent less donor skin than the control and a commensurate reduction in donor site size.

Avita CEO Adam Kelliher told *Medical Device Daily* that reducing donor skin is a "very important aspect because when patients have a large burn, it is a matter of life or death to get the skin coverage back again, and the standard of care is to put on a skin graft harvested from elsewhere on the body. This creates another wound on the body, so if you can reduce the size of that wound, that has massive significance for the patient in terms of reducing trauma."

The second co-primary endpoint measured healing, which was similar in wounds that received Recell compared to those that received the control treatment.

Three secondary endpoints evaluated patient preference of scar outcomes along with overall opinion ratings using a standardized scar assessment scale, and no statistical difference was observed between the two treatments.

Results of the trial coincide with other positive results seen in another supportive trial, and the company believes approval of the Recell Autologous Cell Harvesting device could come as early as 2Q18.

"We've shown that by combining grafting with the skin cell technique, you can get a better outcome on the wound itself and reduce the amount of donor skin required," the CEO said, noting that there have been no adverse events, and the device has been used "thousands of times."

"We're re-transporting skin cells back onto the patient," Kelliher said. "It's a very simple, elegant means to address complicated problems."

Recell allows in-theater preparation of a spray-on suspension consisting of cells derived from a small (2x2 cm), thin (0.15-0.20 mm) biopsy of a patient's own skin that is sufficient to cover an area up to 80 times the size of the biopsy. The Recell suspension contains basal keratinocytes, melanocytes, fibroblasts and Langerhans cells. The metabolically responsive epithelial cells migrate across the wound surface, leading to regeneration of skin of normal color and texture. Recell requires a minimal donor site and is immediately available as a cell-based spray at the patient's bedside.

The procedure itself is a four-step process that involves taking a skin sample, and introducing the cells to the Recell device that incubates the skin with certain enzymes to soften the skin and loosen the cells. The cells then search for other cells and create "islands of healing across the wound bed."

"Submission of the PMA, and FDA approval, will be the final steps on a long road to improve burn care," said James Holmes, from Wake Forest Medical Center, North Carolina, who led the pivotal trial.

The spray-on-skin product was originally invented in Western Australia. It was first used in 2002 to heal burn victims of the Bali terrorist attack who were flown to Royal Perth Hospital and treated by Fiona Wood, the co-inventor of the spray-on-skin.

The pivotal trial was supported by the Biomedical Advanced Research and Development Authority via a $61.9 million contract. The successful completion of the trial is a major Avita milestone under the BARDA contract supporting the Department of Health and Human Services mission toward burn care preparedness in the response to a mass casualty event.

Recell is available in the U.K., Germany, Australia and New Zealand and globally via distributors in France, Belgium, Netherlands, Turkey, China, Malaysia, Taiwan, Iran and South Africa. **//**

Regulatory

Continued from page 1

Rep. Pat Tiberi (R-Ohio), chairman of the health subcommittee, remarked that these clinics are popping up quite frequently of late, and Mark Miller, executive director of the Medicare Payment Advisory Commission (MedPAC), said the Centers for Medicare & Medicaid Services should find a way to collect claims data for on- and off-campus emergency centers "because we're really blind at the moment."

Miller said MedPAC is "very concerned about this," explaining that some of the growth of these centers is in markets that are already saturated with such services, or in high income areas, where they are less likely to take in uninsured patients. While the June MedPAC report will have no recommendations, it will spell out some considerations that will be followed by recommendations in subsequent reports, Miller said.

An off-campus emergency center "may not look like your standard on-campus ER" in terms of patient mix, Miller said, suggesting that one way to address these operations may be to institute a payment structure that addresses the patient mix these sites handle. He also said there is a provision in site-neutral legislation that might allow an operator to get around the prohibition that applies to hospitals that purchase a physician practice.

The provision in question prohibits the payment of the higher outpatient rates for services provided by a physician practice that has been purchased by a hospital, but it was not clear whether Miller was referring to the Bipartisan Budget Act of 2015 in his reference to site-neutral legislation. Miller said that one of MedPAC's concerns is that the legislation in question contains an exception that might allow a free-standing ER to bill at higher outpatient rates because they are not located on a hospital campus.

Despite the concerns, Miller said there may be a role for free-standing ERs in isolated areas where there are not enough patients to support a full-scale inpatient operation. One approach to the dilemma in low population density areas may be to restructure the inpatient subsidy to support these free-standing ERs. Miller said of free-standing ERs, "it's not that they have no role anywhere," but there is a need to address the incentives for such facilities in rural areas.

Miller noted that Medicare billing does not make a distinction between ER services provided by a free-standing clinic and a hospital ER, even if that free-standing unit is owned by a hospital with an on-site ER. "We are concerned about that," Miller observed which is why MedPAC has suggested that CMS insert a modifier on billing forms to make the distinction.

Miller said the dilemma with inpatient rehab facilities (IRFs) – one that is seen in the post-acute care sector generally, but which he said applies to IRFs "in particular" – is that the industry enjoys very high aggregate margins, but that there is a difference in financial performance between for-profit and non-profit operations. Patient mix seems to drive much of the difference in margins as well, Miller said, remarking MedPAC is aware of coding practices and patient selection practices "that raise questions." While total payments to IRFs can be lower without disrupting access, "they have to be redistributed across providers" to even out some of the related discrepancies.

One solution may be to tie payment to a patient type, such as medically complex patients, toward which payments would shift, but policymakers may want to consider an increase in the size of the high-cost outlier pool, which might also help balance out the disparity between low- and high-margin operations. Miller said coding practices should be examined as well, however, a task he said might be take up by the Office of Inspector General.

JOINT REPLACEMENT DATE PUSHED BACK

Rep. Tom Price (R-Ga.) had indicated his concerns about the Comprehensive Care for Joint Replacement (CJR) bundled care program set into motion by CMS, and Tom Price, Secretary of Health and Human Services, acted on that concern by pushing back the effective date of some portions of the program to Jan. 1, 2018.

CMS had announced the first iteration of the program nearly two years ago, setting out conditions by which it would handle payment for lower joint replacement in a program the agency said was mandatory for all practitioners in the affected geographic regions. (See *Medical Device Daily*, July 14, 2015).

The agency expanded the CJR program to include bundled payments for cardiac care in 2016, a move that was greeted by objections and expressions of concern from hospital groups and cardiologists. In response, Price and a fellow Georgian, Democrat David Scott, drafted legislation to apply the brakes to the program even as Price's name was on the short list for the Secretary of Health and Human Services job. (See *Medical Device Daily*, Dec. 22, 2016).

The second iteration of the CJR was initially set to go into force July 1, 2017, but the agency announced in March that the effective date would be pushed back to the first day of fiscal 2018. The latest announcement from CMS is to push that effective date back another three months in an effort to gather more comment, but the agency also pointed out that the first program period would have run six months (from July to December 2017), whereas the program would have run to the calendar year in the second and subsequent program periods.

CMS said "it would be less burdensome for participants to adhere as closely to the calendar year as possible when defining model payment years."

SENATE COMMITTEE APPROVES TELEHEALTH BILL

The Senate Finance Committee voted unanimously in a May 18 hearing to approve S. 870, a bill that would bolster telehealth services and give patients with chronic conditions more

See Regulatory, page 9

Med Fusion

Continued from page 1

FDA-approved cobas EGFR mutation test v2 to identify 42 mutations in genes, including T790M mutations. The Lewisville, Texas-based company's test could help physicians select eligible patients with non-small-cell lung cancer (NSCLC) for therapy with an EGFR tyrosine kinase inhibitor.

Med Fusion is a venture between four different organizations – Mckesson Specialty Health, Texas Oncology, Pathologists Biomedical and Baylor Healthcare System. Medfusion licensed the cobas EGFR test from Roche.

The EGFR liquid biopsy service augments Med Fusion's existing decision support tools for physicians treating NSCLC patients, Lungseq and 50SEQ Plus FISH. Using a simple blood draw, it provides a noninvasive alternative for EGFR mutation testing in NSCLC patients when tissue biopsies cannot be obtained or the available specimen is scarce.

Roche received FDA approval for the cobas EFGR test in June 2016.

"The test gives the opportunity to look at shaping a therapy in a situation where you don't have ready access to tumor tissue," Steve Paulson, president of Texas Oncology, told *Medical Device Daily*. "The expectation down the road ... is that you can do the full lung cancer panel to look at a variety of other things that could help direct your treatment for potentially less toxic therapy."

He added, "From a patient's point of view the [cobas EGFR] saves them from a second invasive procedure if there's not an inclination to do further testing. From a physician point of view, it really directs the treatment of the patient away from more toxic therapies and onto things that are better tolerated."

LIQUID BIOPSY AN ATTRACTIVE MARKET

Roche is part of a growing number of companies delving into the liquid biopsy space. Technology surrounding this space represents a major shift in cancer treatment and has attracted interest from companies of all sizes. Companies specializing in liquid biopsy technologies have also taken on significant venture capital funding.

In March, Illumina Inc.-spin-off Grail Inc. brought in about $900 million in a series B round. (See *Medical Device Daily*, March 2, 2017.)

Late last year, Grail launched the Circulating Cell-free Genome Atlas (CCGA) study, which will enroll at least 7,000 cancer patients and 3,000 healthy individuals. (See *Medical Device Daily*, Dec. 6, 2016.) The study will interrogate the biology of both tumor biopsy tissue samples and the circulating, tumor-derived nucleic acids in blood.

Large-scale studies like CCGA will support the development of a pan-cancer screening test for asymptomatic individuals, which could, according to Grail, make a major dent in global cancer mortality. The company said these studies have to include samples from tens of thousands of people in order for researchers to identify the patterns required to detect many types of cancer.

Earlier this month, Epic Sciences Inc. raised $40 million in a series D round, proving investors still have strong interest in the 9-year-old liquid biopsy specialist. (See *Medical Device Daily*, May 1, 2017.) The San Diego-based company has taken in about $85 million since it spun out of the Scripps Research Institute in 2008.

Other companies in the liquid biopsy space include Boreal Genomics Inc., Natera Inc., Personal Genome Diagnostics Inc., Pathway Genomics Corp. and Trovagene Inc. While both blood-based and urine-based assays qualify as liquid biopsy tests, the majority of players in the space are focused on blood, leaving San Diego-based Trovagene Inc. one of few contenders on the urine-based side of the market.

Epic has a long standing partnership with Redwood City, Calif.-based Genomic Health. Under the partnership, Epic's Oncotypedx AR-V7 liquid biopsy test would be marketed through Genomic Health's commercial channel. The blood-based test detects the V7 variant of the androgen receptor protein (AR-V7) in the nucleus of CTC- information that can help guide treatment selection in patients with metastatic castration-resistant prostate cancer.

RECENT DEVELOPMENTS IN LIQUID BIOPSY

The liquid biopsy space is brimming with activity and new developments. Companies are accumulating data to help validate liquid biopsy offerings.

In April, a paper published in Nature demonstrated promising early results from using Natera Inc.'s liquid biopsy test in the Tracerx study. Data from the study on the firm's mPCR test found predictors of relapse, recurrence and resistance in early stage NSCLC patients.

"We believe this data is promising and a validation of Natera's mPCR technology in the attractive liquid biopsy space," said Doug Schenkel, an analyst with Cowen and Co.

In March, Exact Sciences Corp. reported early top-line results of its blood-based lung cancer test it is developing with the Mayo Clinic. The Madison, Wis.-based company presented the associated data at the American Association for Cancer Research (AACR) annual meeting.

In the study, researchers identified a panel of 13 methylated DNA markers in a cohort of 295 individuals (231 apparently healthy smokers, 63 individuals with cancer) that was highly correlated with a lung cancer diagnosis. The test indicated a sensitivity of 90 percent to 94 percent and a specificity of 91 percent to 96 percent on average across all lung cancer subtypes and stages.

See Med Fusion, page 9

Robotics

Continued from page 1

LEA can move on its own, dance, facilitate human interaction and much more. It is categorized as a class I medical device and tailored to the needs of elderly users.

Another Israeli company, Intuition Robotics, is planning to launch Elliq, a robot with an artificial intelligence core that can interact with users, encourage mobility, project moods and much more.

They are just two of the many new products under development by companies around the world looking at meeting the health care needs of a growing elderly population.

"It's a very big market," said Maja Rudinac, who invented LEA and is the CEO and co-founder of Robot Care Systems, which is developing LEA in the Netherlands. "On the one hand you have a very rapidly growing population. What is being said, for example, is that in 2050 on a worldwide basis, there will be four people working for one in pension."

The numbers in Europe and North America suggest a much larger market, with likely one person working to one retired by around the same time.

"More and more devices will be needed to help them," Rudinac told *Medical Device Daily*.

The topic is significant enough to be a key focus at the MIXiii Biomed 2017 conference in Tel Aviv that begins on May 23. A whole track is dedicated to the issue of robotics and its application to elderly populations.

Rapid advances in robotics and artificial intelligence are happening just as their large contingent of elderly people is facing one side effect of improvements in health care: much longer life spans. The longer life spans, however, translate into longer periods at later stages of life when people might have different needs.

"I see robotics as the next market boom, like [the impact] computers had or cellphones had," said Rudinac. "Once components get cheaper and cheaper, I think we there will be more and more robotic devices... It's a new generation of machines."

Components are already getting cheaper and making it possible to produce sophisticated products that rely on new technologies to drastically improve the quality of life of patients.

Upnride, for example, is an Israeli company that produces various products for upride mobility. The company's latest product is a "wheeled robotic device," in the words of the company, that provides "upright and seated mobility." In other words, wheelchair-bound people can use Upnride in the standing position to move around.

The benefits are myriad, said Upnride CEO Oren Tamari. For one, there are psychological benefits to standing up rather than constantly sitting. Another is that being in an upright position can have multiple health benefits compared to constantly sitting.

"There are more and more old people who have to use wheelchairs," Tamari told *Medical Device Daily*. Upnride provides "functional upride mobility."

The company is now starting clinical trials in New York for its device, looking to demonstrate the health benefits of spending more time upright. Tamari also believes that there will be cost savings for insurance providers that will make the product attractive. Upnride is now working on a CE mark and a submission to the U.S. FDA.

Another Israeli company looking to tap this growing market is Intuition Robotics, which developed Elliq, "an active aging companion." Elliq uses robotics and AI to integrate a number of technologies that allow it to interact with users, facilitate connectivity and track healthcare requirements, among others.

Elliq uses natural communication and a type of body language to better communicate. Its interface includes movements and lights that can convey emotion and spur activity. It also integrates a tablet that facilitates communication and tapping into information.

"We are really taken aback by the reception," said Intuition Robotics CEO and Co-Founder Dor Skuler. "We searched for a design that was not intimidating."

The change in demographics is extreme, with the global population above the age of 65 years likely to reach 30 percent of the total in the near future. Both the needs and the market are quite large.

Given the size of the aging population and the modern technologies that already exist, products for this particular group of people should be coming up fast. But, said Tamar Flash of the Weizmann Institute of Science in Israel, there is a disconnect at the moment even though robotics, AI and neuroscience are all moving forward.

"We don't provide good enough solutions in terms of what is possible," Flash told *Medical Device Daily*. Still, there is "a lot of need and a lot of technology that is being developed ... there is also a lot of interest from the robotics community." **//**

Regulatory

Continued from page 6

attention from physicians. The bill was not difficult to support in fiscal terms, given that the Congressional Budget Office scored it as having no appreciable impact on direct federal spending.

The Chronic Care Act won rave bipartisan reviews in the May 16, 2017, hearing, and makers of tissue plasminogen activators and mechanical thrombectomy devices for stroke stand to gain from passage. Some provisions of the bill take up entirely new areas of Medicare coverage, although one provision served to extend a demonstration project for home care of patients with chronic conditions. (See *Medical Device Daily*, May 17, 2017).

S. 870 is unlikely to go through a full congressional vote as a stand-alone bill, given that the Children's Health Insurance Program, just one of several Medicare-associated spending bills on tap this year, is on the agenda for reauthorization. //

Med Fusion

Continued from page 7

"While larger studies will be needed in the future to validate these findings, we believe these early results signal promising future potential for the company's test," Schenkel said.

As to what the future holds for liquid biopsy, that is uncertain, but Paulson said he thinks the tests won't be an alternative for tissue biopsy offerings.

"I think the short answer is that liquid will not likely replace biopsy of tissue for the initial diagnosis of cancer," Paulson said. "I think what you may see is that anytime a patient progresses on treatment and you're looking at doing an analysis of the predominate tumor genotype, liquid biopsy might totally supplant repeat tissue biopsy." //

NEUROLOGY EXTRA

Keeping you up to date on recent developments in neurology

By Andrea Gonzalez, Production Editor

Smaller brain implants cause less scar tissue

Many diseases, including Parkinson's disease, can be treated with electrical stimulation from an electrode implanted in the brain. However, the electrodes can produce scarring, which diminishes their effectiveness and can necessitate additional surgeries to replace them. Previous studies have suggested that making the implants smaller or softer could reduce the amount of scarring, so Massachusetts Institute of Technology researchers set out to measure the effects of both reducing the size of the implants and coating them with a soft polyethylene glycol (PEG) hydrogel. The hydrogel coating was designed to have an elasticity similar to that of the brain. The researchers could also control the thickness of the coating. They found that when coated electrodes were pushed into the brain, the soft coating would fall off, so they devised a way to apply the hydrogel and then dry it, so that it becomes a hard, thin film. After the electrode is inserted, the film soaks up water and becomes soft again. In mice, the researchers tested both coated and uncoated glass fibers with varying diameters and found that there is a trade-off between size and softness. Coated fibers produced much less scarring than uncoated fibers of the same diameter. However, as the electrode fibers became smaller, down to about 30 microns (0.03 millimeters) in diameter, the uncoated versions produced less scarring, because the coatings increase the diameter. This suggests that a 30-micron, uncoated fiber is the optimal design for implantable devices in the brain. The question now is whether fibers that are only 30 microns in diameter can be adapted for electrical stimulation, drug delivery and recording electrical activity in the brain. The study appears in the May 16 issue of *Scientific Reports*.

Brain stimulation during memory training boosts performance

New research from Sandia National Laboratories published in *Neuropsychologia* shows that working memory training combined with a kind of noninvasive brain stimulation can lead to cognitive improvement under certain conditions. Improving working memory or cognitive strategies could be very valuable for training people faster and more efficiently. Using more than 70 volunteers divided into six groups, the researchers used different combinations of working memory training with transcranial direct current stimulation. Then they assessed the volunteers' performance on working memory tests and a test of problem-solving ability. Using electrodes placed on the scalp and powered by a 9-volt battery, a tDCS unit delivers weak constant current through the skull to the brain tissue below. Researchers think tDCS makes neurons a little bit more likely to fire, which can help speed up the formation of neuronal connections and thus learning, said Laura Matzen, one of the study authors. In the Sandia-led study, the volunteers played verbal or spatial memory training games for 30 minutes while receiving stimulation to the left or right forehead. That part of the brain is called the dorsolateral prefrontal cortex and is involved in working memory and reasoning. Since the right hemisphere is involved in spatial tasks and the left hemisphere is involved in verbal tasks, the researchers thought volunteers who received stimulation on the right side while training on spatial tasks would improve on spatial tests and those who received stimulation on the left side while training on verbal tasks would improve on verbal tests. The verbal task involved remembering if a letter had appeared three letters back in a string of letters, for instance A-C-B-A-D. The spatial task was similar but involved remembering the sequence that blocks appear in a grid. As expected, the spatial/right group got better at the spatial test but not verbal or reasoning tests. The spatial/left group performed about the same as the volunteers that received mock stimulation. The verbal/left group got better at the verbal test but not spatial or reasoning tests. However, the results from the verbal/right group were surprising, said lead author Mike Trumbo. This group got better at the trained task – remembering strings of letters – as well as the closely related task – remembering the sequence of boxes in a grid. They also improved on a reasoning test. The sample size was small, with only 12 volunteers, but the improvements were statistically significant, according to Matzen. One explanation Trumbo offered is that the right dorsolateral prefrontal cortex is particularly involved in strategy use during tasks. By stimulating the right side during the verbal task, the volunteers might get better at using a strategy.

Study shows rtACS may keep visual neurons alive after injury, but at a cost

Electrical stimulation of the brain by applying current to the eye may help retinal nerve cells to survive injury. While these neurons may not be restored to full function, they are prevented from dying. But to achieve survival, their interconnections, the dendritic tree, needs to disconnect rapidly for the protective action to unfold. In a study published in *Scientific Reports*, researchers from Magdeburg University in Germany) and The Chinese University of Hong Kong report that for rats and mice, repetitive transorbital alternating current stimulation (rtACS) may help preserve visual neurons from cell death after injury. Because the tissue at the back of the eye, the retina, is part of the brain, researchers can directly observe how brain cells react in the living animal. The researchers repeatedly monitored neurons in both rat and mouse retinas after an optic nerve injury and measured neuronal death after this lesion. Surprisingly, a neuroprotective treatment with electrical alternating current stimulation increased cellular survival in the eye´s retina, but it also induced a fast and complete stripping-off

Continues on next page

NEUROLOGY EXTRA

Continued from previous page

of the neuron's dendritic tree. The dendrites are like a tree receiving many thousands of signals from other neurons. This enables them to process visual information and then transmit the signals along the optic nerve towards the brain. By retracting its dendrites, the cell withdraws itself from this intercellular communication network and becomes silent – which helps its survival. The test animals were divided into groups and subjected to both real and sham treatments. For the rats, optic nerve crush (ONC) was used to induce an injury in some of the animals to mimic glaucoma. Some animals and not others (sham) were treated with rtACS, resulting in three test groups: ONC/rtACS, ONC/Sham, and Sham/Sham. Using in vivo confocal neuroimaging (ICON) and measurements of Visual Evoked Potentials (VEP), the researchers could determine whether a neuron had survived and whether it was still functioning. The ONC and the first rtACS stimulation were done on day zero. ICON was performed on day four, followed by rtACS or sham stimulation. On day seven post ONC another ICON was performed. For the mice, a confocal laser ophthalmoscope was used to image the dendritic structures of the retina for three groups of subjects, ONC/rtACS, ONC/Sham and Sham/rtACS. The mice received rtACS on days zero, three, six, nine and 12 after ONC and images were taken on days three, seven and 14. According to lead author Petra Henrich-Noack, "With our experiments, we have detected so far unknown 'silent survivor cells' in the brain, and it will be exciting to find out whether they later die or can be reactivated." Surprisingly, neurons in the retina of animals that survived better when treated with rtACS lost their dendritic tree completely within the first three days after the lesion. The authors suggest that this early structural isolation might protect the neurons from the "toxic" excitation that is known to appear soon after brain damage.

Epilepsy drug therapies to be improved by new targeted approach

New research from the University of Liverpool, in collaboration with the Mario Negri Institute in Milan, published in the *Journal of Clinical Investigation*, has identified a protein that could help patients with epilepsy respond more positively to drug therapies. Despite 30 years of drug development, approximately 30 percent of people with epilepsy do not become free of seizures with currently available drugs. Increasing evidence suggests that local inflammation in the brain may be important in preventing control of seizures. In most cases, the inflammation settles down, but in a small number of patients, the inflammation continues. The aim of the research study was to address the important question of how can inflammation be detected by using blood samples, and whether this may provide new ways of treating patients in the future to reduce the inflammation and therefore improve seizure control. The research focused on a protein called high mobility group box-1 (HMGB1), which exists in different forms in tissues and bloodstream (called isoforms), as it can provide a marker to gauge the level of inflammation present. The results showed that there was a persistent increase in these isoforms in patients with newly diagnosed epilepsy who had continuing seizure activity, despite anti-epileptic drug therapy, but not in those where the fits were controlled. An accompanying drug study also found that HMGB1 isoforms may predict how an epilepsy patient's seizures will respond to anti-inflammatory drugs.

MEDICAL DEVICE DAILY'S PATENT HIGHLIGHTS

FROM CORTELLIS' PATENTS GAZETTE
WEEK 19

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The Patents Gazette provides snapshot analysis and indexing of pharmaceutically relevant patenting within days of its publication by patent offices. Primarily focusing on material from the main three patents offices (ie the EPO, USPTO, and WIPO), it provides brief descriptions of a patent's content and seeks to link it to both prior patenting of relevance and to any commercial activity pertinent to the technology being described.

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Clarivate Analytics

US20170128273-A1: “Bandage.”

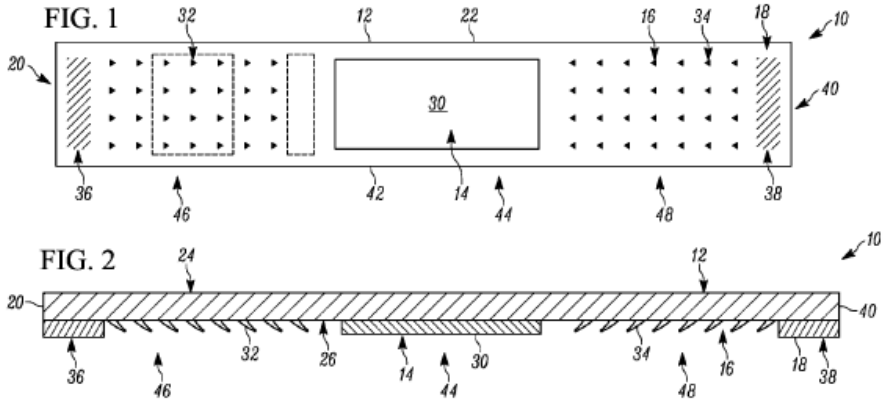
Assignee: Bandgrip Inc

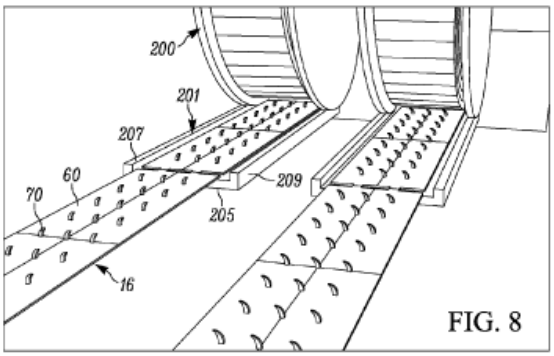
Inventors: Hoglund, Keith; Pruter, Tom; Smith, Fred

IPC Codes: A61F 13/02

Publication Date: 11-May-2017

Earliest Priority Details: US2015253898, 11-Nov-2015





Bandage which both provides a cover over a wound and also aids in the closure of a wound. The bandage incorporates curved microneedles that grip the skin, bring both sides of the wound towards one another to effectively seal the wound.

Represents the first patenting from the assignee and inventors in support of their BandGrip technology. In a video on the Chicago, Illinois-based company’s instantsuture.com website, BandGrip’s ease and speed of use is seen to be demonstrated, with it being able to be applied to close a wound in the same time taken to apply just one of four traditional stitches required to achieve the same wound closing effect afforded by a strip of the BandGrip product. BandGrip does not necessitate the use of anesthetics to be applied and results in less scarring than wounds closed ueing stitches. The company advertises its product by saying, “Instead of stitches, use BandGrip. The instant suture.”

WO2017079754-A1: “Modified transdermal delivery patch with multiple absorbent pads.”

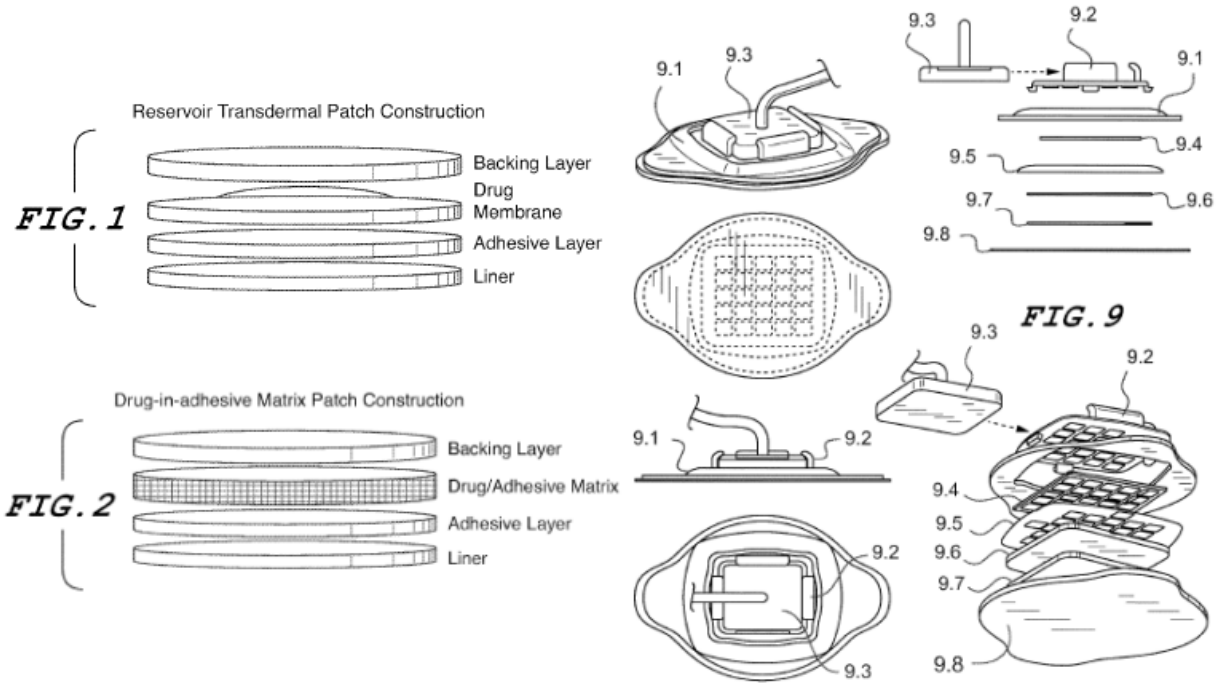
Assignee: BKR IP Hold Co LLC

Inventors: Redding, Bruce, K., Jr.

IPC Codes: A61M 37/00; A61L 15/16; A61B 5/00; A61M 35/00; A61K 9/00; A61K 41/00; B06B 3/00; A61B 8/12; A61N 7/00; A61B 8/00; A61M 5/00; A61K 9/70

Publication Date: 11-May-2017 (shares priority details with copublished WO2017079758, ‘760, ’761 and ‘764-A1)

Earliest Priority Details: US2015285668, 06-Nov-2015



Transdermal patch which has one absorbent pad stacked above another, or multiple absorbent pads within the patch, which thereby enable greater and longer drug delivery from the patch over time, avoid interaction with adhesive mixes and enhance the quantity of the dose which can be released from the patch, by either passive of active methods of drug release. The transdermal patch is connected to a wearable ultrasonic transmitter for the purpose of providing regulated and controlled doses of insulin and other medications for the treatment of diabetes, with Lispro insulin (Humalog from Eli Lilly) being seen to be exemplified.

Published alongside WO2017079758, ‘760, ‘761 and ‘764 describing aspects of this modified transdermal delivery patch technology for ultrasonic insulin delivery. The inventor previously described a means for measuring the dose remaining within such patches in WO2016004442.

Bruce Redding Jr is the founder of Pennsylvania-based Transdermal Specialties Inc whose U-Strip™ (Ultrasonic Strip) insulin patch is designed to apply insulin to the dermis via propagation of what it describes to be a unique and special alternating ultrasonic transmission. The ultrasound transmission first dilates the pores and then pushes insulin into the dermis region of the skin. It was described by Redding in US7440798-B2, that is set to expire in May 2026.

WO2017078831-A1: “Needles and related assemblies and methods.”

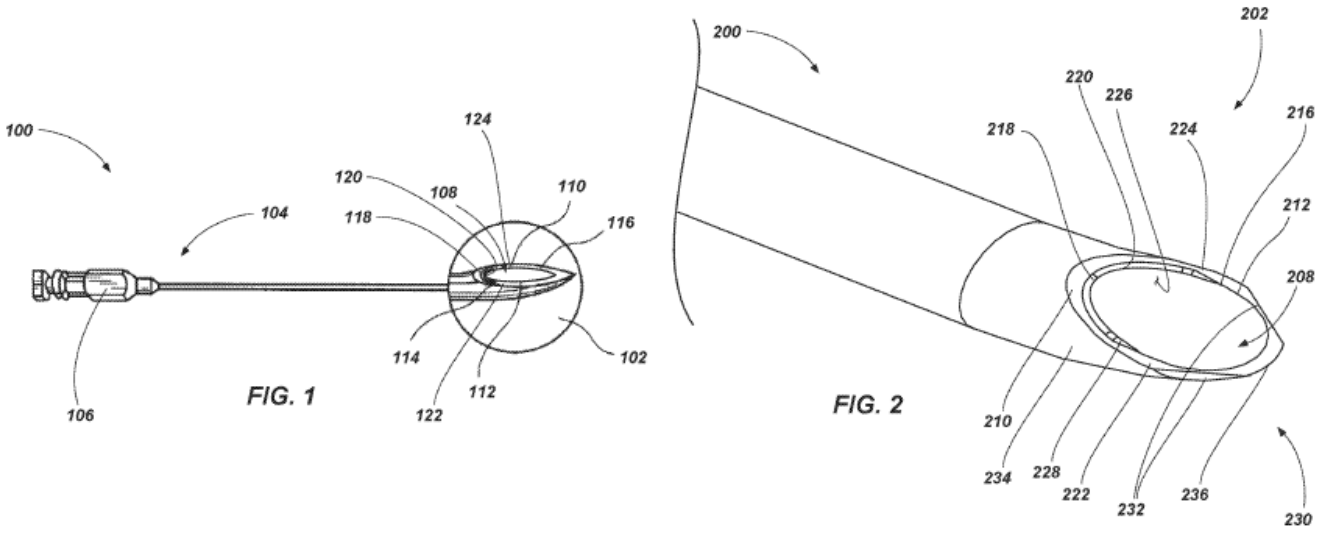
Assignee: Custom Medical Applications Inc

Inventors: Racz, N., Sandor

IPC Codes: A61B 17/34; A01M 5/00; A61M 5/32; A61M 25/06; A61M 5/158

Publication Date: 11-May-2017 (also published as US20170119974-A1, 04-May-2017)

Earliest Priority Details: US2015250866, 04-Nov-2015



Needles (eg introducer needles) that may be utilized to administer anesthetics and analgesic medications and/or utilized to deploy another device, such as a catheter, a lead, or other device. The needles are disclosed to be useful for administering one or more therapies to the nervous system of a subject.

It reports how many conventional introducer needles have a relatively wide cutting edge due to the large opening of the orifice or bore formed in the introducer needle needed to introduce catheters and leads. However, such a relatively wide cutting edge is often traumatic to tissues when the introducer needle is inserted into the subject. In particular, such a relatively wide cutting edge may act like a scalpel edge with a wide cutting surface and may cut and/or damage the subject's tissue during insertion. The introducer needles of the present invention include chamfered surfaces so as to minimize such tissue damage, with the needles tending to spread tissues, rather than cutting the tissues, when the needle is inserted into the subject.

The inventor can be seen to have quite an extensive history of patenting in the field of injection technologies, eg in EP2777729 (September 2014) he described a blunt surgical needle and/or blunt surgical assemblage that was described as being ideally suited for the injection into tissue of medicaments containing nucleic acids encoding a therapeutic agent (or cells containing such nucleic acids). When attached to an appropriate catheter or invention surgical assemblage it could be used to inject medicaments into internal organs, without substantial loss of the medicament at the surface of the body wall and without substantial damage to tissue at the injection site caused by injectate.

Racz is the owner of Epimed that has a plant in Johnstown, New York, whose address matches that of the assignee named here. In the area of pain management and anesthesia Epimed offers products including epidural introducer needles such as the RX-2® and Blunt Coudé® Introducer for nerve block needles. Custom Medical Applications Inc can be seen to be the owner of many of the trademarks used for Epimed’s products.

WO2017077537-A1: “Safety needles and methods of use thereof.”

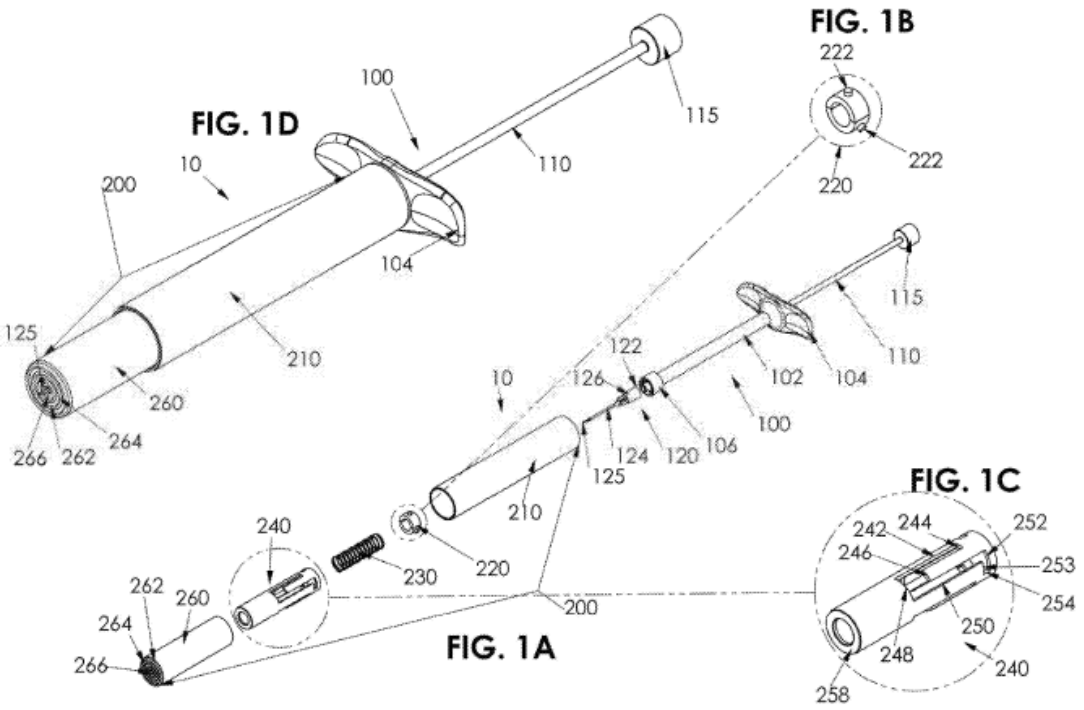
Assignee: Dali Medical Devices Ltd

Inventors: Daily, David; Drory, Hagay; Lewkonya, Gad; Raday, Lior

IPC Codes: A61M 5/32

Publication Date: 11-May-2017

Earliest Priority Details: US2015250033, 03-Nov-2015



A needle protection assembly, adapted to protect a tip of a hypodermic needle, comprising a shield, a locking element, a slot engaging element and a biasing element. Regardless of whether the user has fully pressed the syringe plunger (110) to inject the full fluid dose, or whether the user injected only partial amount of the fluid, the safety mechanism is activated once the triggering surface has been reached or passed, by guiding pins on a guiding and locking ring (220).

The inventors previously described a safe auto-needle injection device in WO2016128977.

Daily and Rady are the Israeli company’s co-founders - its name, DALI Medical Devices, representing a combination of their first names (DAvid and LIor) and a nod towards the surrealist Salvador Dali’s highly imaginative way of looking at familiar objects and scenes. Its SAN (Safe Auto-Needle) family of injectors deliver easy injection of a wide range of formulations for patients with a wide range of needs. The injectors are designed for use with all types of syringes or primary drug containers: conventional plastic hypodermics, single- or dual-chamber prefilled syringes made of glass or plastic, or vials. Within said family it is deverloping the SAN-L as a single-use sterile hypodermic needle for use with luer syringes for subcutaneous or intramuscular drug administration. They report the SAN-L to be the only disposable device to combine automatic needle insertion, passive sharps protection, and a hidden needle, which allows manual control of injection speed.

WO2017077312-A1: “Connector for a medical device.”

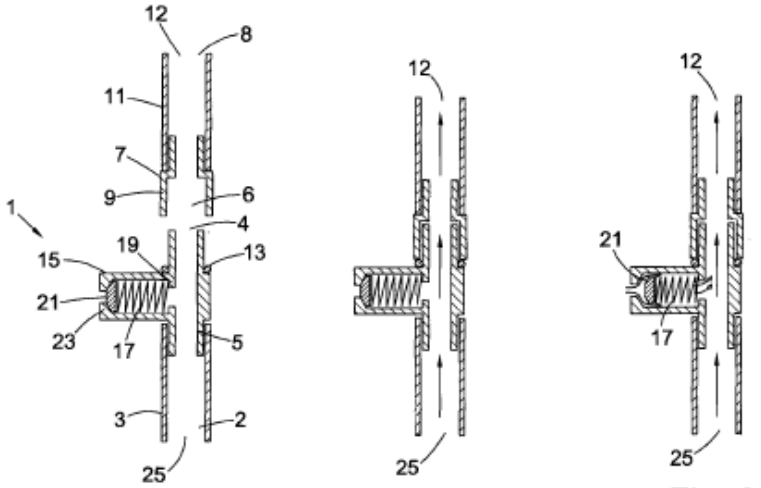
Assignee: i2r Medical Ltd

Inventors: Hardman, Ian James; Heaton, Keith Patrick

IPC Codes: A61M 1/00

Publication Date: 11-May-2017

Earliest Priority Details: GB201519388, 03-Nov-2015



Connector incorporating a valve for use with a negative pressure wound therapy (NPWT) device. It states that housing a mechanical valve close to the wound site, eg in the dressing, has potential risks in damaging the already compromised skin. The invention aims to overcome these disadvantages by incorporating the valves in the connector that couples the dressing to the fluid container. The connector is required because there is a different frequency of dressing changes to fluid container changes. The present invention therefore seeks to provide: accurate pressure control at the wound without the need for multiple tubes and sensors to the wound site and the associated level of complexity in the electronic control system and software; incorporation of a NPWT device into the connector that is close to the wound site which reduces head pressure differences; a means to allow fluid to be drawn away from the wound at a constant flow preventing the fluid "pooling" at the wound site; a valve system which prevents the fluid from escaping from the tube set and dressing when therapy is turned off because the seals are normally closed; and, a system with an optimum size and that minimises the potential for skin damage.

It reports that a key advantage of the present invention is that it seeks to address the fundamental problems associated with NPWT treatment (which was originally developed for the hospital market) for use in the home and community.

The inventors are both registered with the UK’s Companies House as being directors of the Bournemouth-based company, as well being directors of Nexa Medical Limited that appears to operate from the same address. I2r Medical’s website reports that Nexa Medical is a medical device company specialising in NPWT and that i2r Medical was the design and regulatory contractor that successfully designed a Class 11a electromechanical device, a Class 11b sterile dressing and a Class 1 Fluid Container pack. The product is reportedly CE marked, patented and in commercialisation. Said patenting would presumably be WO2014045047 in which the same inventors as here described a portable NPWT system.

US20170127945-A1: “Respiratory medicament and therapy data system and method of use.”

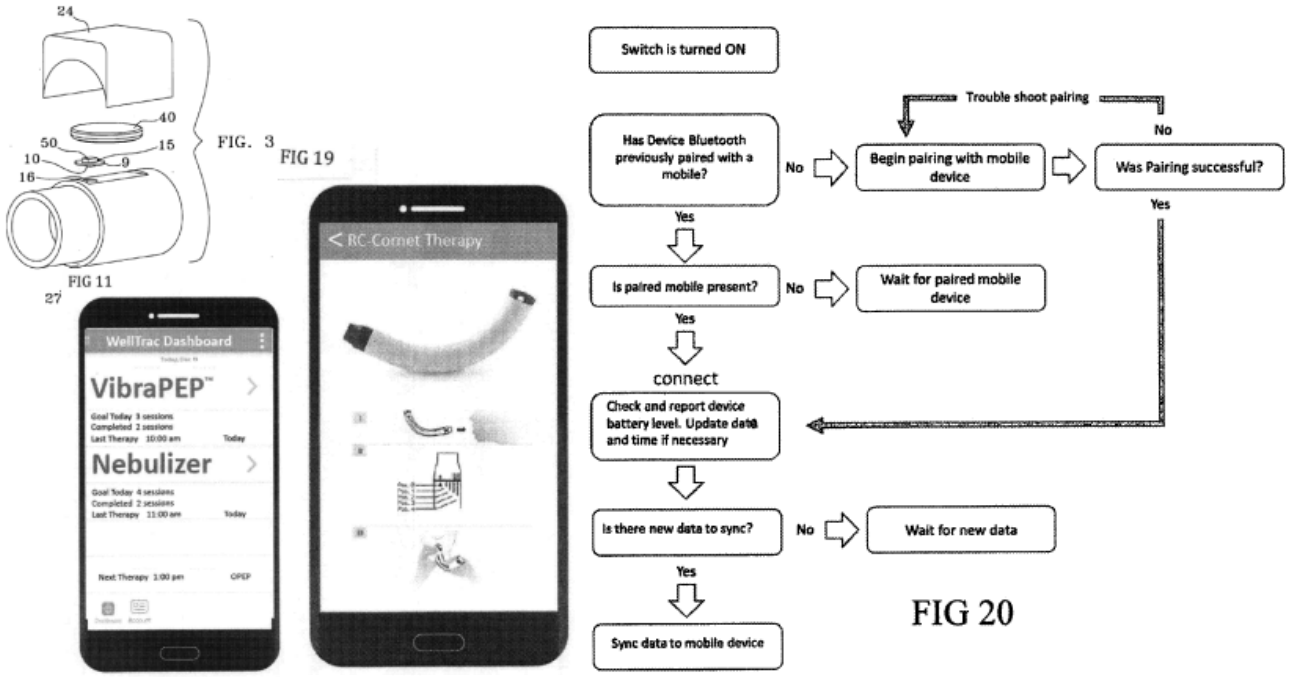
Assignee: Medica Holdings Llc

Inventors: Reed, George Ashford

IPC Codes: A61B 5/00; A61M 11/00; A61B 5/08; G06F 19/00

Publication Date: 11-May-2017

Earliest Priority Details: US2015938805, 11-Nov-2015



Breath actuated monitoring device (figure 3) that monitors patient interactions with all respiratory therapy and drug delivery devices. It generates a signal based on the magnitude, direction and duration of the inhalation and exhalation pressures generated by a patient. This allows the tracking and wireless reporting of the various therapeutic and medicament delivery sessions with respect to such parameters as delivery date, time, duration, and total delivered dose.

Medica Holding’s VibraPEP™ is a Positive End Expiratory (PEP) device in which the user exhales through the device and the device generates expiratory pressure (resistance) and the tube valve oscillates creating a range of frequencies within the air column to the patient which help to promote secretion clearance. The VibraPEP™ has been designed to be very similar to the predicate RCCornet device. The basic design, form, function and performance have been compared to the predicate and have been demonstrated to be functionally equivalent and with the same intended use as the predicate.

The VibraPEP™ is a curved tube in which a long valve is inserted. As the patient blows through the VibraPEP™, the hose pressure increases and buckles at the bending of the tube. When the peak pressure is reached, the hose end opens and is catapulted against the wall releasing its pressure. This process is repeated, providing an oscillation effect during the entire exhalation phase. By rotating the therapy selector, pressure and flow can be adjusted to increase or decrease the pressure and frequency of PEP therapy. The design for VibraPEP™ was seemingly provided by the inventor in the design patent USD768285-S that was published October 2016 and filed in June 2015.

US20170128672-A1: “Medical device.”

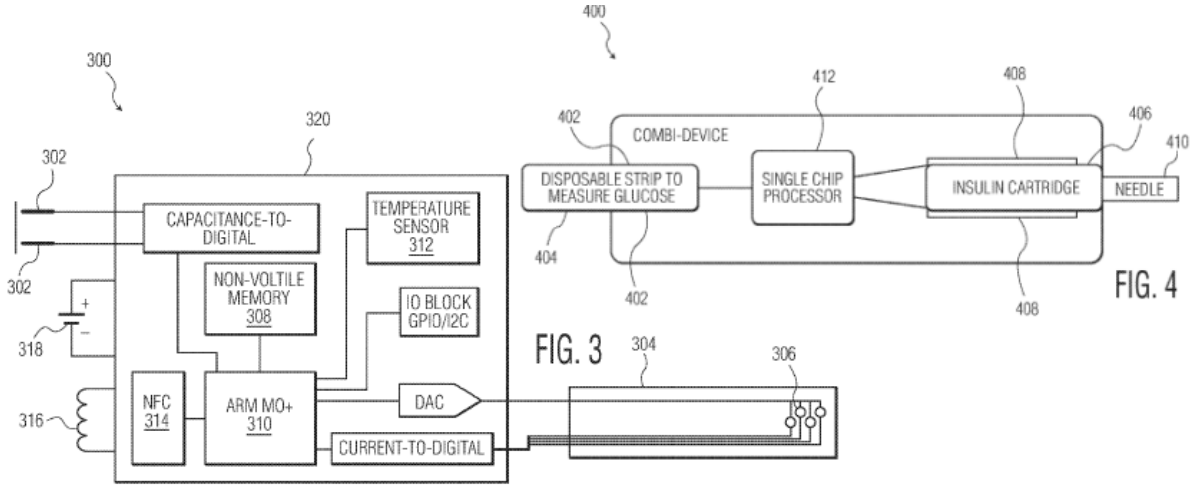
Assignee: NXP BV

Inventors: De Loore, Bart; Frederix, Filip

IPC Codes: A61M 5/31; A61M 5/315

Publication Date: 11-May-2017

Earliest Priority Details: US2015936170, 09-Nov-2015



Handheld medical device that includes both a patient attribute sensor (namely a patient glucose level input signal) and a dosage injector (insulin injector). In one emboduiment, the handheld medical device first measures a patient's glucose level in their blood, urine, tears, or any other body fluid. Second, the medical device calculates an amount of insulin to inject, perhaps using a digitally stored look-up table. Third, the device measures an amount of insulin level in a syringe that the patient will actually use to inject the insulin. The device can either be reusable or for one-time use. It states that advantages of such a medical device include: only one device is required for glucose measurement (eg meter/reader) and dosage (eg injection volume) measurement; the handheld device has a smaller form-factor; the bill of materials is reduced; and, algorithms in the device can tell a user immediately how much they should inject without requiring the user to consult a dosage table, thereby reducing a human error component.

The device may be: paired with a smartphone or cloud service over a communications link where the medical device does not need to have an output display or perhaps even a battery; remotely powered by either a wireless signal or an NFC signal; and, include flexible components enabling a user to wear the device, such as during exercise.

For prior NXP patenting describing biosensors comprising one or more biocompatible electrodes for interacting with a biologic fluid that may be used for detecting glucose, see EP2738551 that was published in June 2014.

NXP Semiconductors is a global semiconductor manufacturer headquartered in Eindhoven, Netherlands, that provides semiconductors and software that deliver sensory services. Within the healthcare/medical markets, NXP offer a wide range of embedded products to meet the unique needs of medical designs (eg the need to balance processing requirements with power consumption, and the need for secure wireless connections and product longevity). Its offerings include specific microcontroller units (MCUs, featuring integrated analog blocks and ZigBee®) and proprietary wireless solutions that support home-based blood glucose monitoring devices. Its Kinetis® portfolio of ARM® Cortex™ MCUs provide highly integrated, low-power, connected solutions suitable for continuous blood glucose monitoring purposes.

WO2017079397-A1: “Dry powder inhalation device.”

Assignee: OtiTopic Inc

Inventors: Yadidi, Kambiz

IPC Codes: A61K 9/00; A61M 15/00; A61M 15/06; A61K 9/72; A61K 9/14

Publication Date: 11-May-2017

Earliest Priority Details: US2015251240, 05-Nov-2015

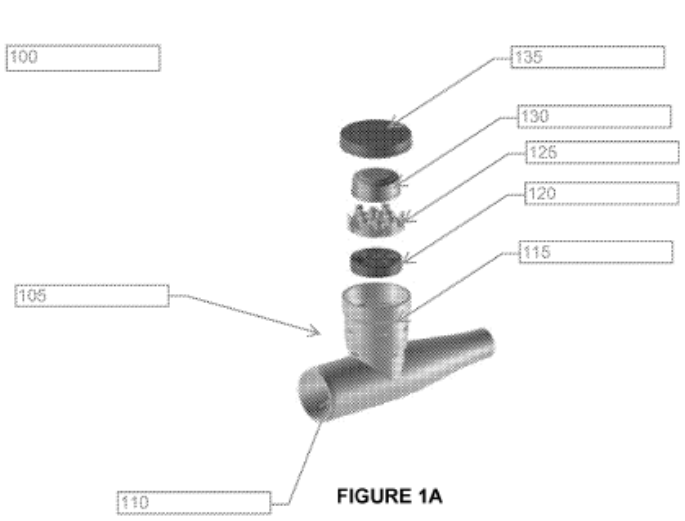


FIGURE 1A

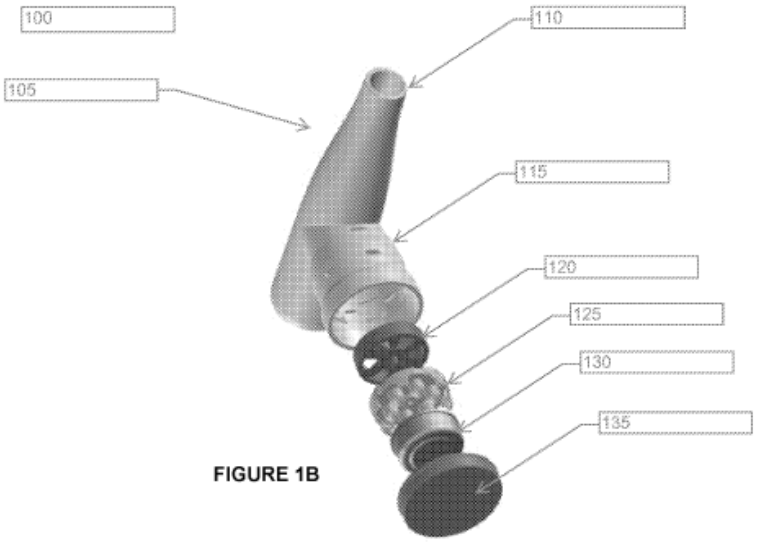


FIGURE 1B

Device for the delivery of a dry powdered or aerosolized substance that comprise eg a non-steroidal antiinflammatory drug (NSAID) such as acetylsalicylic acid as the active ingredient. Within the disclosure it states how the dose of NSAID delivered may be effective so as to reduce the risk of a thromboembolic event in a patient.

Picks up from WO2016176552 describing a respirable dry powder composition comprising dry particles of acetylsalicylic acid and phospholipids, in which it discusses how the compositions may be effective in the treatment of thromboembolic events such as myocardial infraction or a stroke.

The patenting would appear to be in support of a product named ASPRIHALE™ for which OtiTopic of Westland Village, California, has obtained the trademark for it described to be an inhaler filled with NSIADs, namely aspirin. The inventor is the founder and President of General Pharma Partners Inc, an independently funded healthcare and pharmaceutical focused investment firm based in Los Angeles, California. Its typical investments are said to range from $1 million to $20 million, and its focus to be medical device, life science and healthcare service organizations, particularly drug delivery devices, pharmaceuticals and specialty compounding pharmacies.

Prior to the formation of General Pharma Partners, Mr Yadidi was the founder and CEO of Sinus Dynamics (now ImprimisRx), a specialty pharmacy dedicated to offering acute and chronic sinusitis sufferers a topical intranasal form of therapy.

WO2017077529-A1: “Lockable advanceable oral dosage form dispenser containers.”

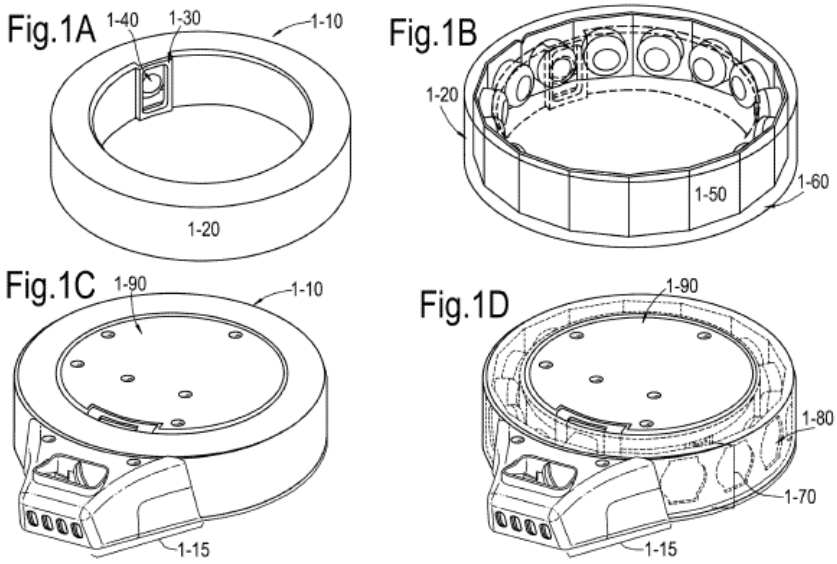
Assignee: PCoA

Inventors: Paz, Alan

IPC Codes: A61J 1/03; B65D 83/04; A61J 7/00

Publication Date: 11-May-2017

Earliest Priority Details: US2015249373, 02-Nov-2015



Advanced lockable oral dosage form dispensing containers, preferably a blister pack dosage form container for dispensing pills. The container comprises an advanced blister pack holder, a series of access portals sized to accommodate the dosage forms, a holder configured with a depilling structure, and a lockable outer container. The system provides controlled sequential delivery of pills with a predetermined prescribed minimum time interval between each pill delivery.

It is disclosed that the regulated, locakable dosage form containers of this invention may be used as part of the dosage form containing structures, as part of the systems or in conjunction with the devices and apparatuses described in WO2014006620 and WO2014020594.

As noted three weeks ago in MDD-CPG 1716, the Israeli address provided for PCoA matches that given on the website of DosentRx. PCoA/DosentRx is focused on the development of intelligent medication management systems and to that end it has developed what it calls the ReX device (that bears a strong resemblance to the devices discussed within this series of patenting) for tracking and managing the passage of pills all the way from a pharmacy to very point of entering a patient’s mouth. Its ReX medication management device and associated app can be used to enable better clinical trials to be achieved through being able to accurately monitor patient adherence, in real time, and provide reminders only when needed to users and carers. ReX is also designed to safeguard against overdosing - whether by intentional misuse, unintentional overdose or pills accidently swallowed by minors.

From a clinical trial conducted by DosentRx (NCT03134001) to evaluate a novel pill dispensing system, the ReX system may also have been known by the name PCoA™ Acute. It having been used in the trial to dispense oral analgesics and compared to the conventional procedure of a nurse administering the analgesics.

US20170128740-A1: “Phototherapy device with real-time morphologic feedback and guidance.”

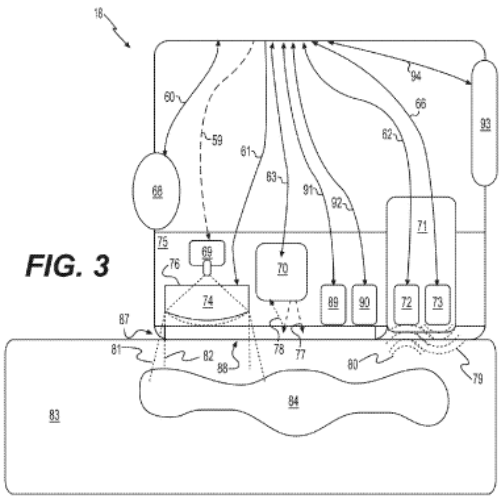
Assignee: QC LLC

Inventors: Stephens, Bryan James

IPC Codes: A61N 5/06

Publication Date: 11-May-2017

Earliest Priority Details: US2015253916, 11-Nov-2015



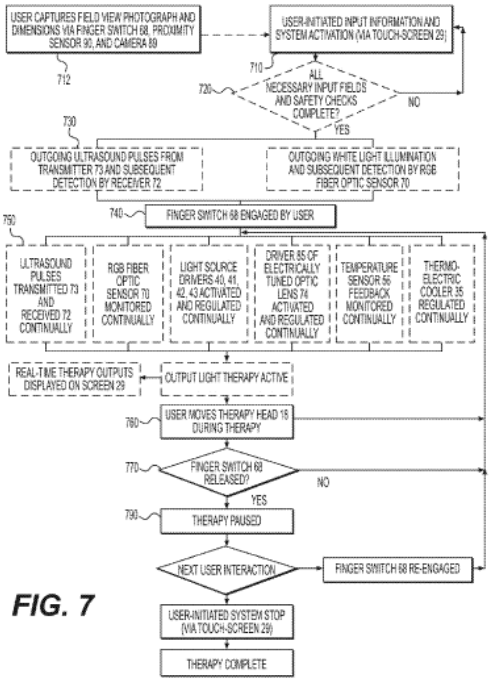


FIG. 7

Phototherapy device for promoting wound healing and treating pain associated with soft-tissue and musculo-skeletal injuries. The phototherapy device may deliver therapeutic light outputs that are variable, in real time, based in part on morphologic data of the patient measured by the device in real-time.

With reference to figure 3, the phototherapy head (18) may include an ultrasound transducer (71) having ultrasound transmitter (73) with its electrical leads (66), and ultrasound receiver (72) with its electrical leads (62). When the therapy head is brought into contact with a patient's body (83), the ultrasound transducer contacts the skin of the patient. Gels or creams used for improving ultrasonic pulse transfer between the transducer and patient's body may be applied to the patient's skin to facilitate transmission of ultrasound signals and to minimize friction as it is moved over the skin.

Appears to represent the first patenting to emerge from the assignee and inventor from Franklin, Tennessee. Stephens would also appear to hold a position with Carlsbad, California-based Sound®, that produces digital radiography and PACS systems for diagnostic imaging in the veterinary industry. With a PhD from Vanderbilt University in Nuclear and Radiation Physics, Radiation Oncology, prior to joining Sound® Stephens worked for another Franklin, Tennessee-based company, K-Laser USA, that provides laser phototherapy devices for use in both the medical and veterinary sectors.

US20170128663-A1: “IV set and IV set system management.”

Assignee: Somnus Medical Llc

Inventors: Bulloch, Edwin T.; Harward, Anthony Clark; Reichert, Lucas

IPC Codes: A61M 5/14

Publication Date: 11-May-2017

Earliest Priority Details: US2015934030, 05-Nov-2015

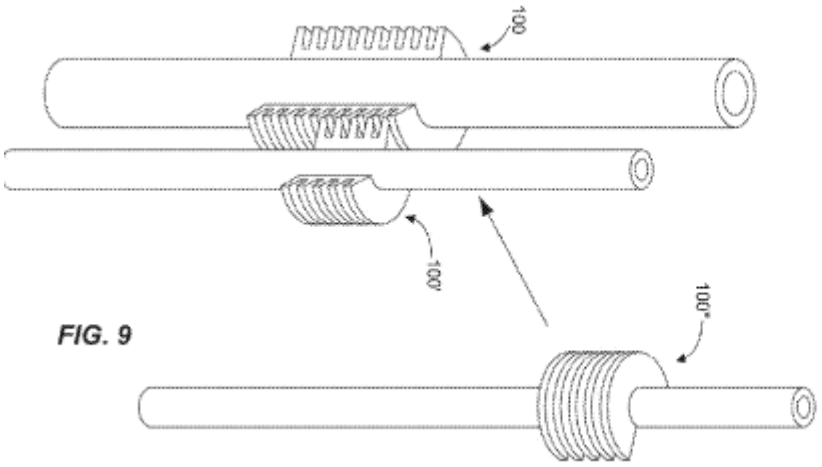


FIG. 9

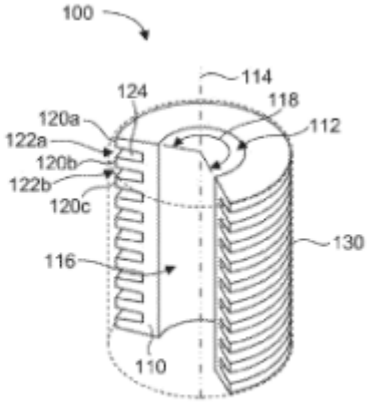


FIG. 2

An intravenous (IV) set and IV set system management device comprising a body portion with extended protrusions. The protrusions can be configured to mate with the one or more recesses of the IV set and IV set system management device, thus facilitating coupling of the IV set and IV set system management device with a similarly configured second IV set and IV set system management device. The invention facilitates control, management, and organization of one or more IV sets during use, avoiding entanglement issues. The IV set and IV set system management device can enable an IV set to be easily joined with other IV sets to build IV set systems, which can be subsequently separated and rebuilt by end-users in other locations within a hospital, as desired.

The inventors Bulloch and Reichart are certified anesthetists and the co-founders of Pleasant Grove, Utah-based Somnus Medical that seeks to improve anesthesia process efficiency and control through the development, and commercialization of cost effective medical devices. As evidenced by their patenting, its initial innovation is an improved administration set that will improve anesthesia process efficiency and control of drug administration.

Somnus’ patent pending IV set solution promises no more line entanglement. Features of its IV sets include “separably connected” lines allow end-users to “detatch” each individual line from the others for customization while maintaining IV set integrity. “Uniform markings” at both the proximal and distal ends, as well as at each individual infusion access port, to allow for rapid line/port identification. Infusion access ports located at the distal end form a “merging infusion pathway” to minimize fluid bolus needed to achieve desired drug response. External manifolds can be integrated into existing IV sets creating a temporary “bypass”, without breaking the primary line. Accessing existing infusion access ports decreases the risk of contamination and infection.

Said patent pending IV set solution that appears to be being further built upon here would seemingly have been described by the same three inventors within a cluster of three co-published applications, namely WO2015023701 (IV set system with coded components), WO2015023705 (IV set system with separably joined, strippable IV sets and merging fluid pathway), and WO2015023706 (IV set system with bypass manifold).

US20170128017-A1: “Smart phone having functions of diagnosing and treating illness.”

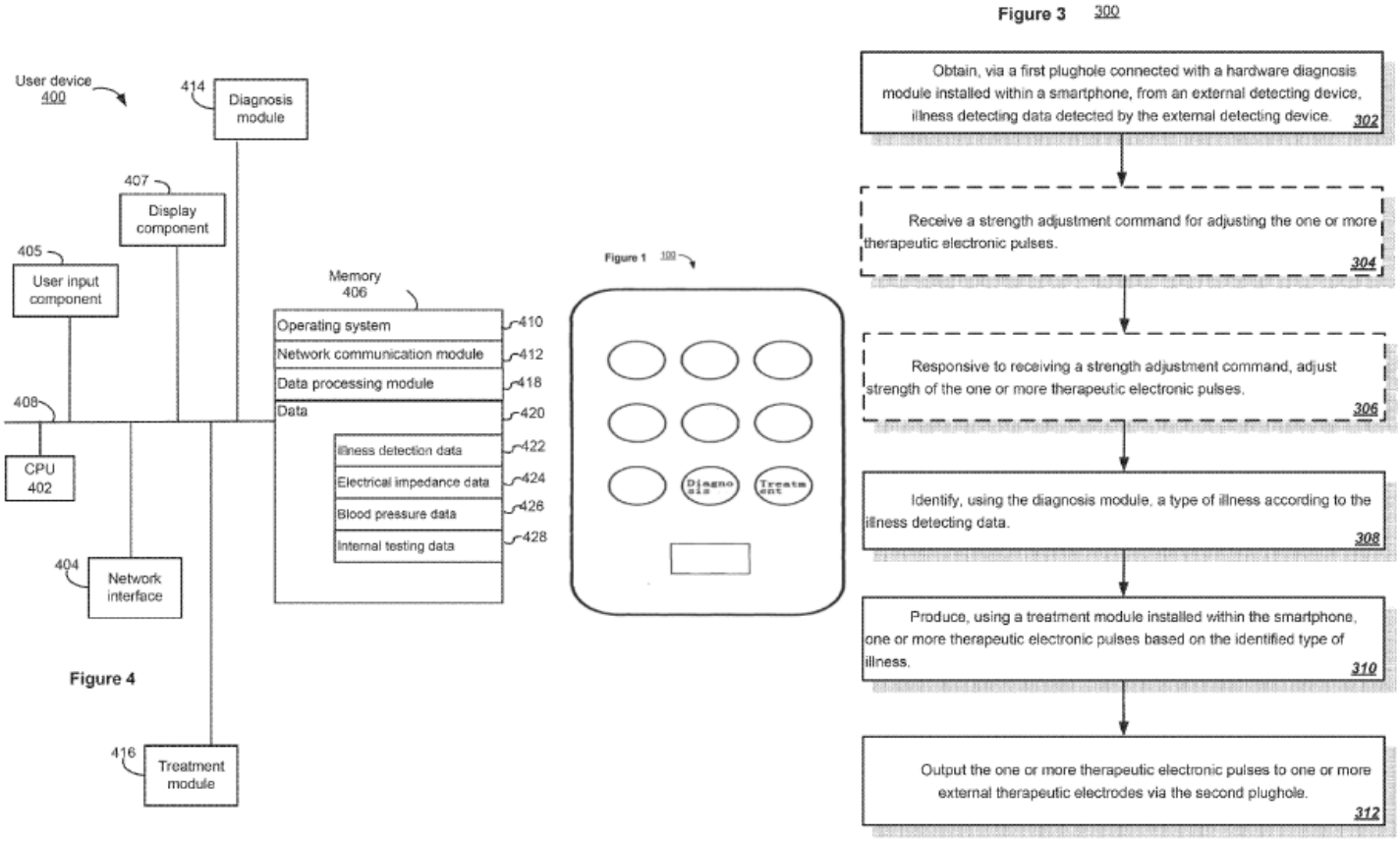
Assignee: Zheng, Mingde

Inventors: Zheng, Mingde

IPC Codes: H04M 1/725; A61B 5/00; A61N 1/36; A61B 5/053; A61B 5/0205; A61B 5/145; A61B 5/02; A61H 39/00; A61N 1/02

Publication Date: 11-May-2017 (also published as CN105361881-A, 02-Mar-2016)

Earliest Priority Details: CN201510755618, 10-Nov-2015



Smartphone capable of detecting electrical impedances of and providing electronic pulse stimuli to acupuncture points such as ears, hands and feet. The diagnosis module may receive electrical impedance data detected from protruding parts of the body and determine the type of illness according to the analog electrical impedance data. The smartphone may also detect blood pressure, heart rate, blood oxygen value and blood glucose values of the human body.

Represents a nerw patenting interest for the inventor who would appear to the President of the Chinese company Beijing Golden Huahan New Technology Co Ltd that markets a number of acupoint stimulators for different parts of the body. One such device is its Huahan low frequency acupoint stimulator, an electronic acupuncture apparatus for home and hospital use that can stimulate acupoints through the ears, hands and feet for the relief of pains and illness.

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