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(54) **THERAPEUTIC DEVICE FOR LOCAL AREA STIMULATION**

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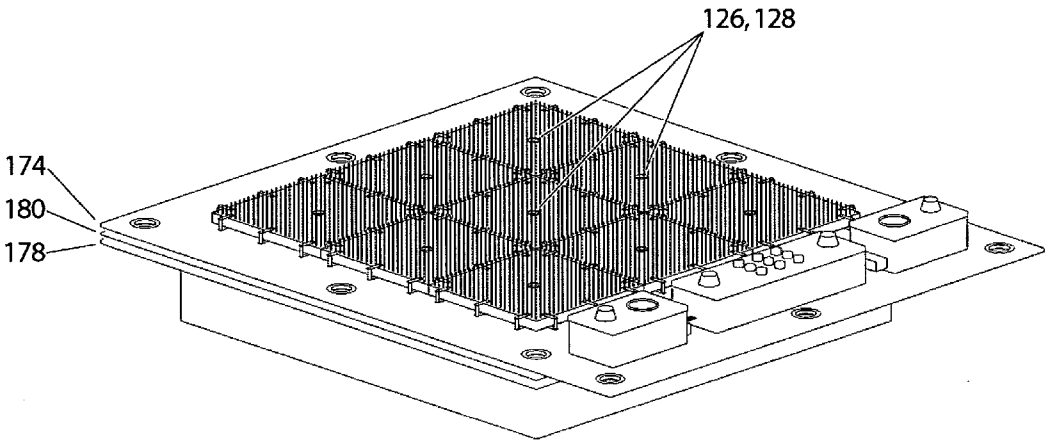
A61N 2/00 (2006.01)

(52) **U.S. Cl.** **600/9**

(57) **ABSTRACT**

This invention, fundamentally a regular array of points, is applied non-invasively to a subject and it induces, monitors and controls a variety of therapeutic stimuli. It is effective in novel and non-obvious ways when the points are spaced approximately 3 to 6 mm apart. Further development includes patterns of electromagnetically dissimilar metal points, a magnetized support, and configurable electrical connections along with various controllers and stimulus sources. This device can administer an unprecedented variety of therapeutic stimuli in unprecedented combinations. Effects arise galvanically, through interaction of point arrays with the magnetized support, and by application of electromagnetic forces. It can electronically monitor both stimuli and local subject response through the points themselves enabling effective controls and an avenue for research. Its flat shape accomodates accessories to apply other stimuli such as heat. A clinical version accomodates invasive treatments and bulky external devices.



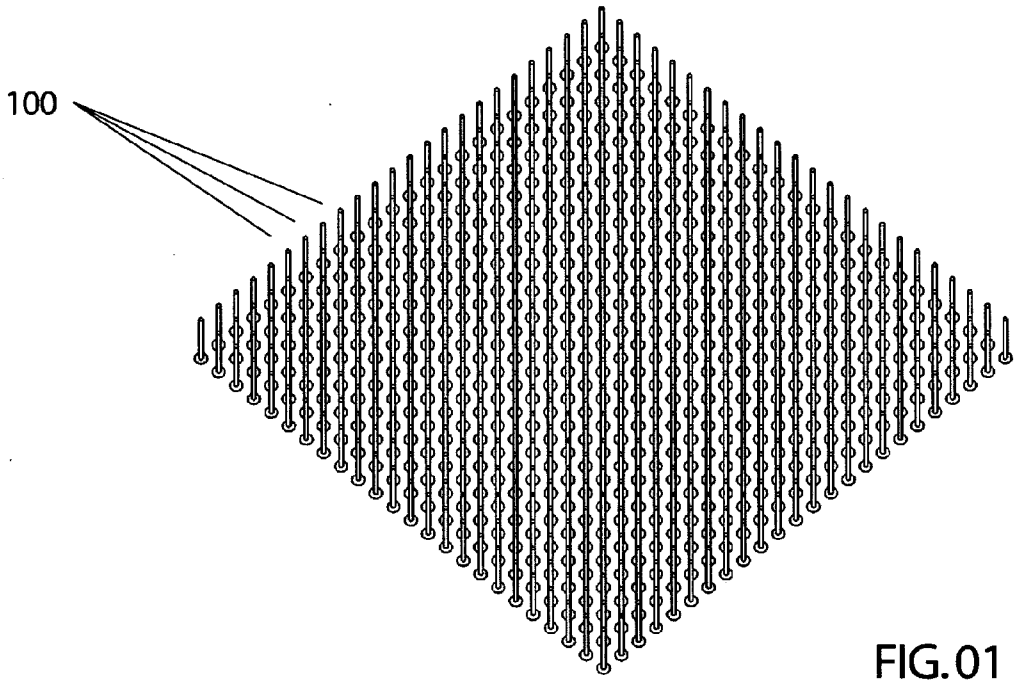


FIG.01

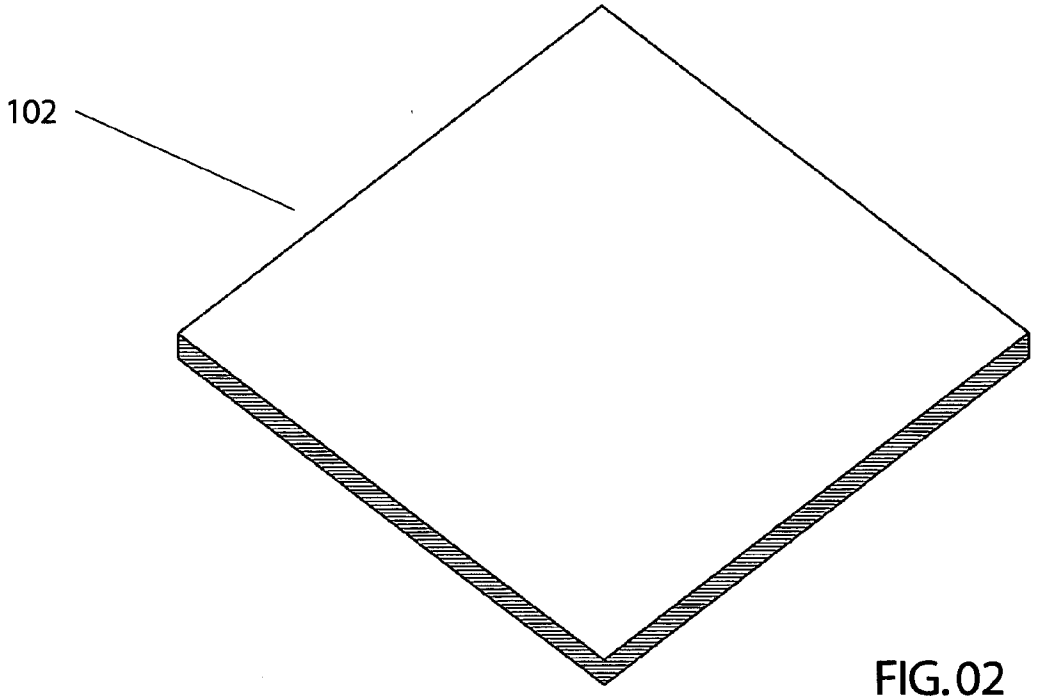


FIG.02

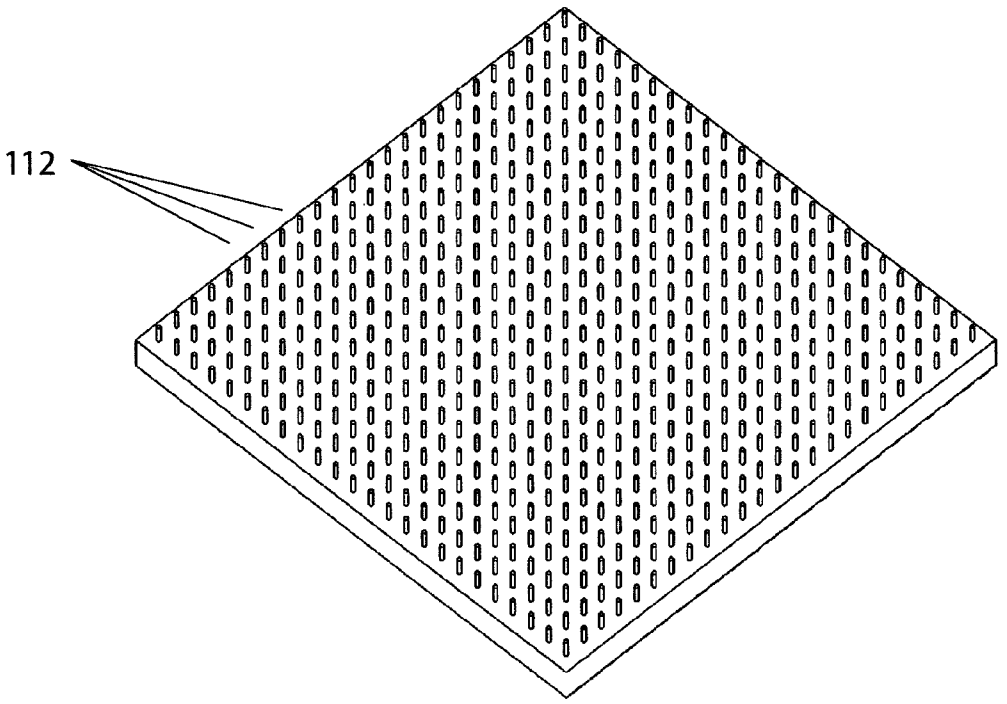


FIG.03

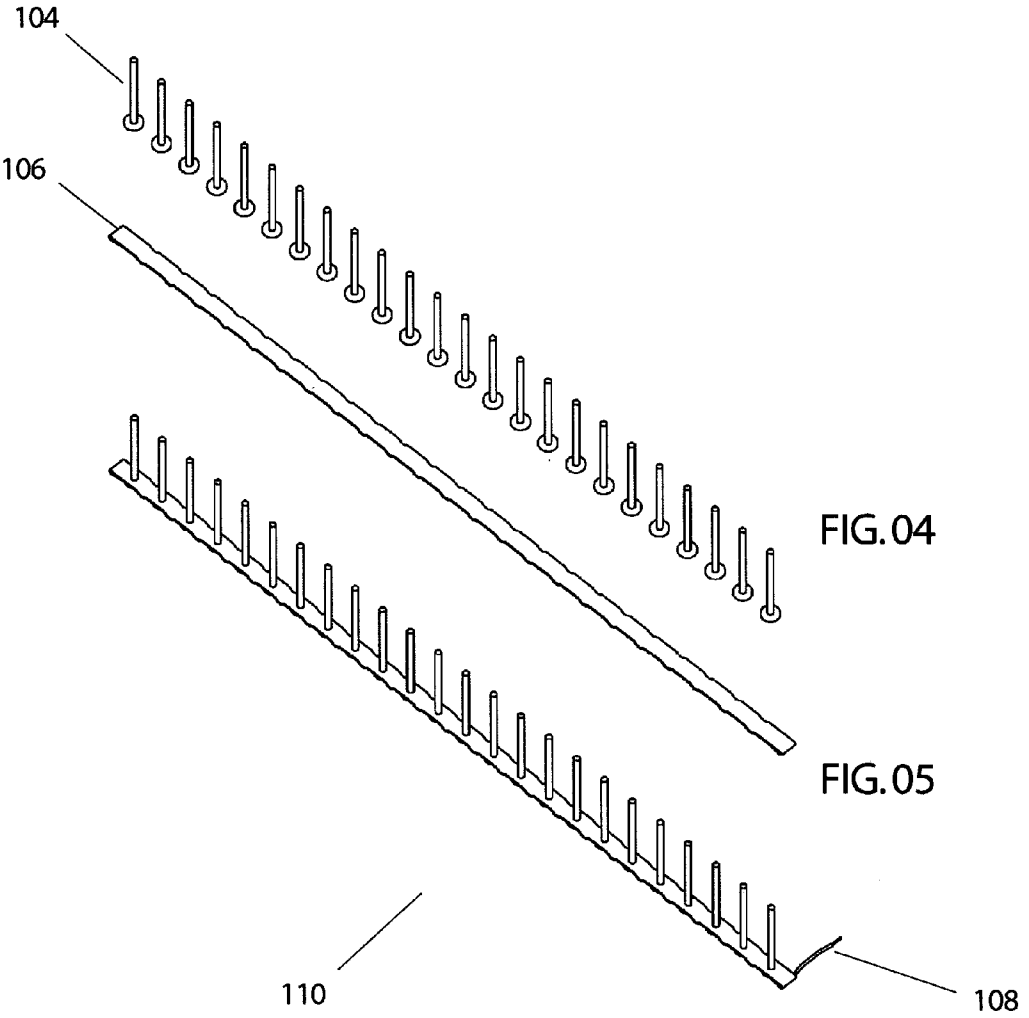


FIG. 04

FIG. 05

FIG. 06

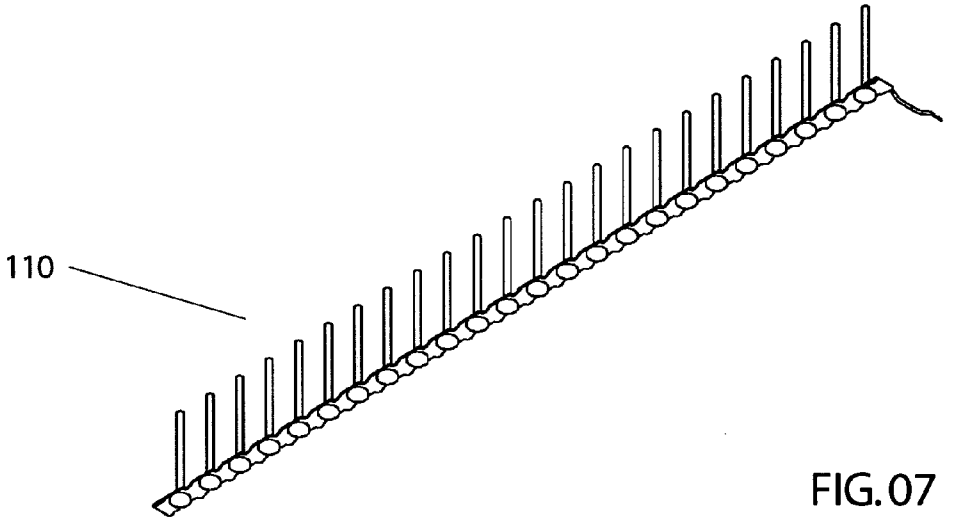


FIG. 07

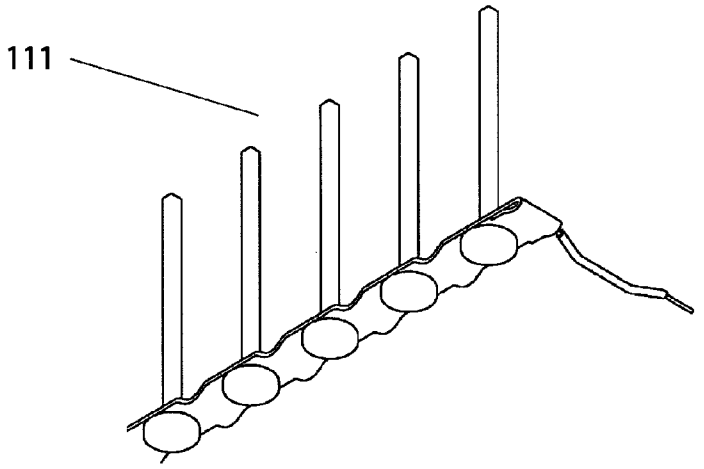


FIG. 08

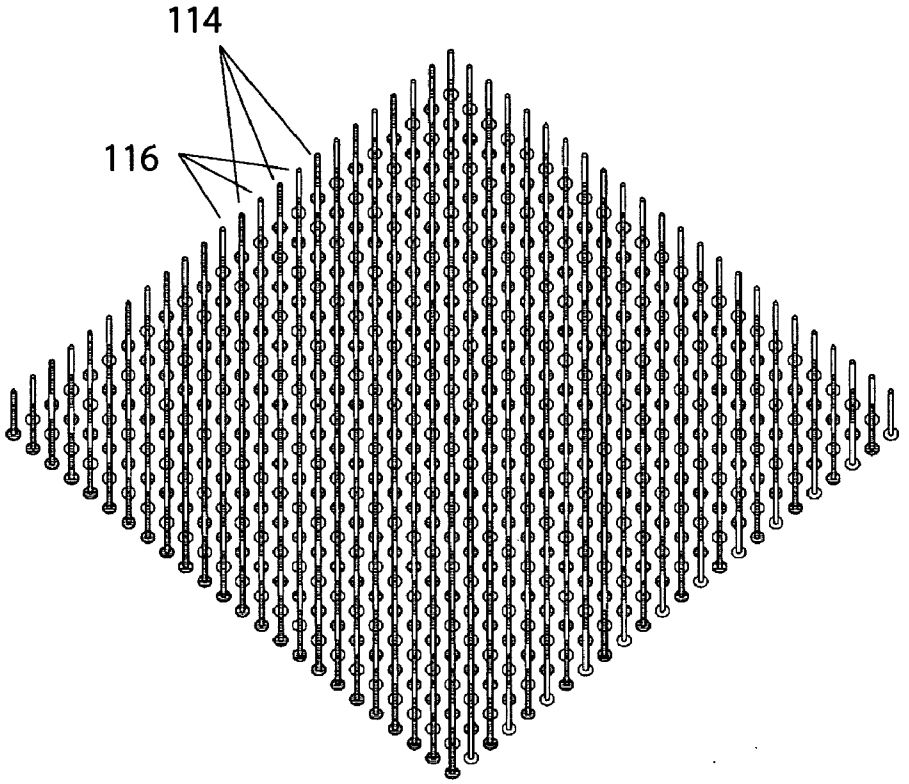


FIG.09

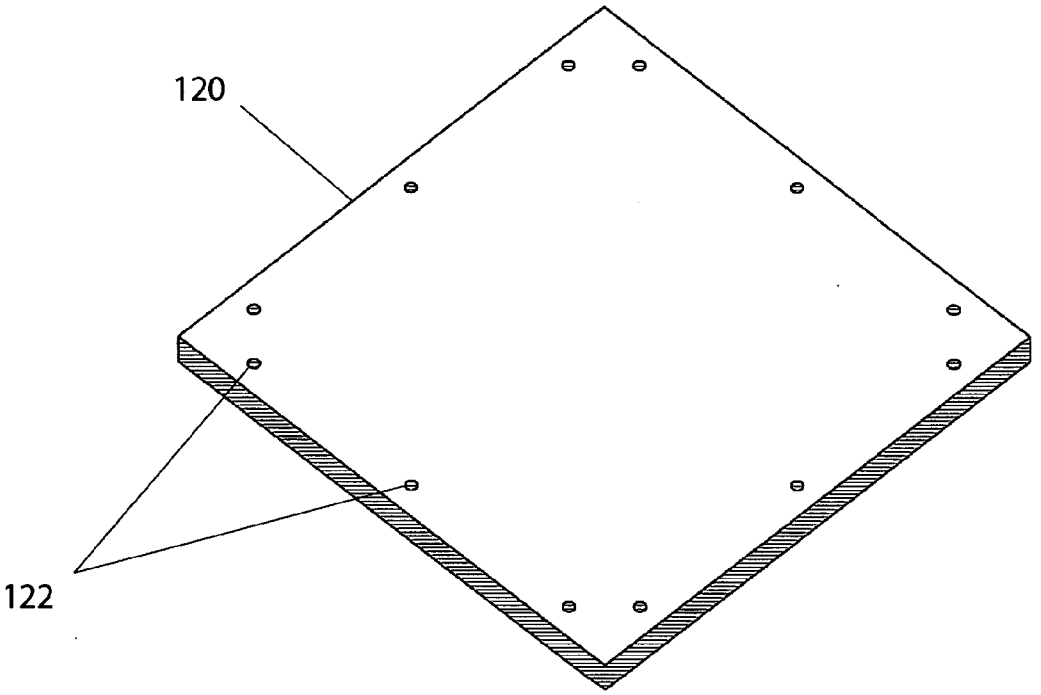


FIG. 10

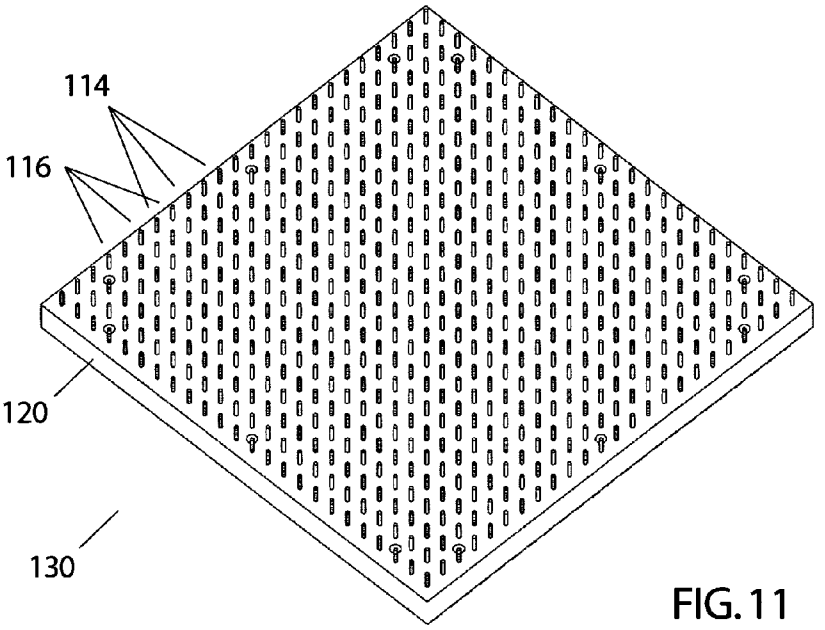
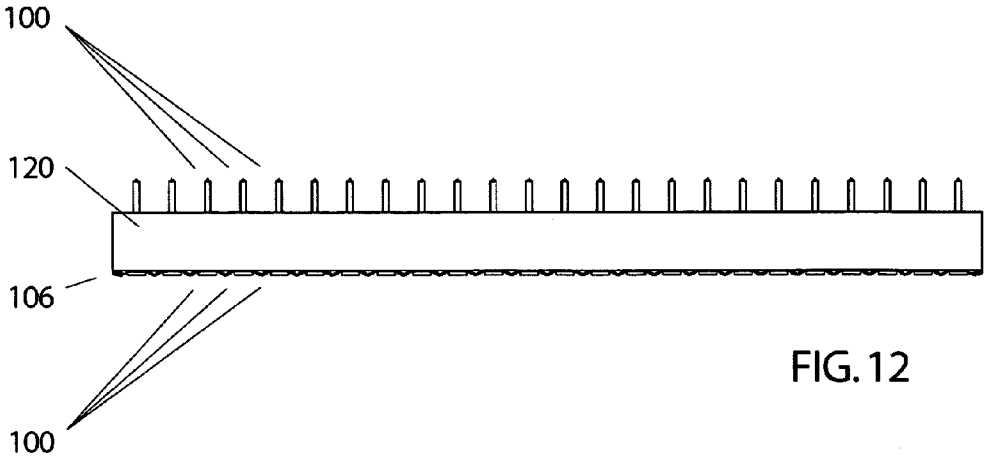


FIG. 11



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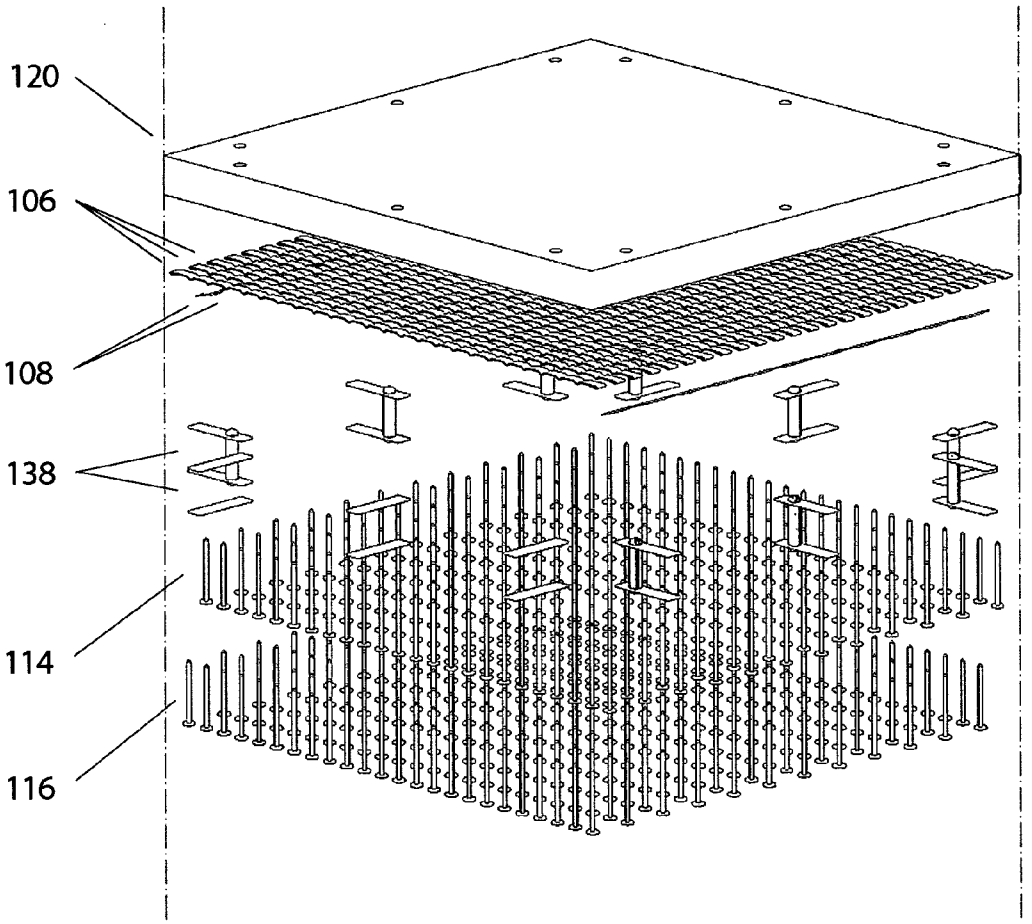


FIG. 13

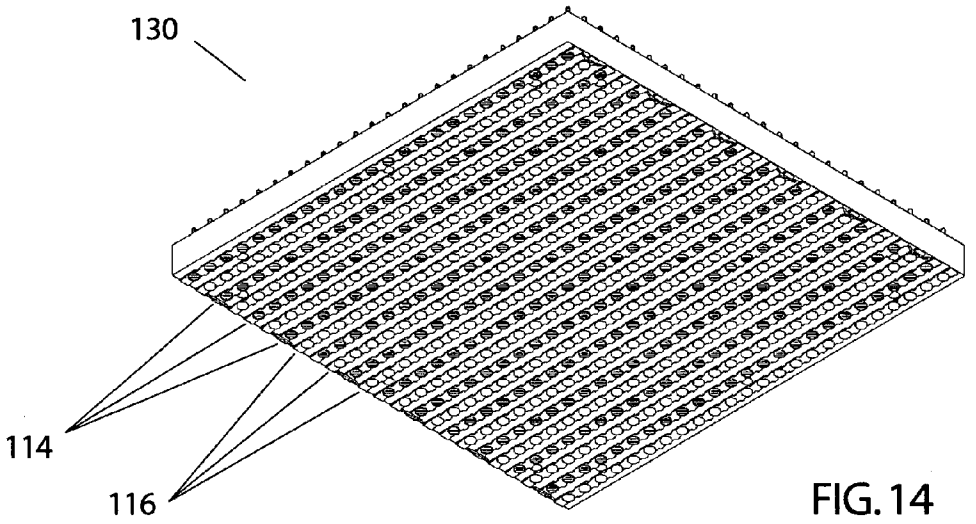


FIG. 14

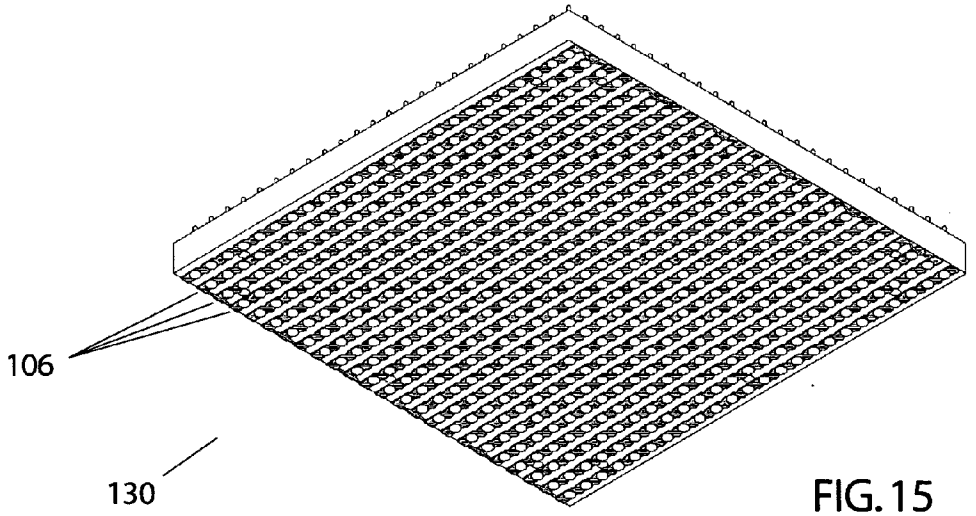


FIG. 15

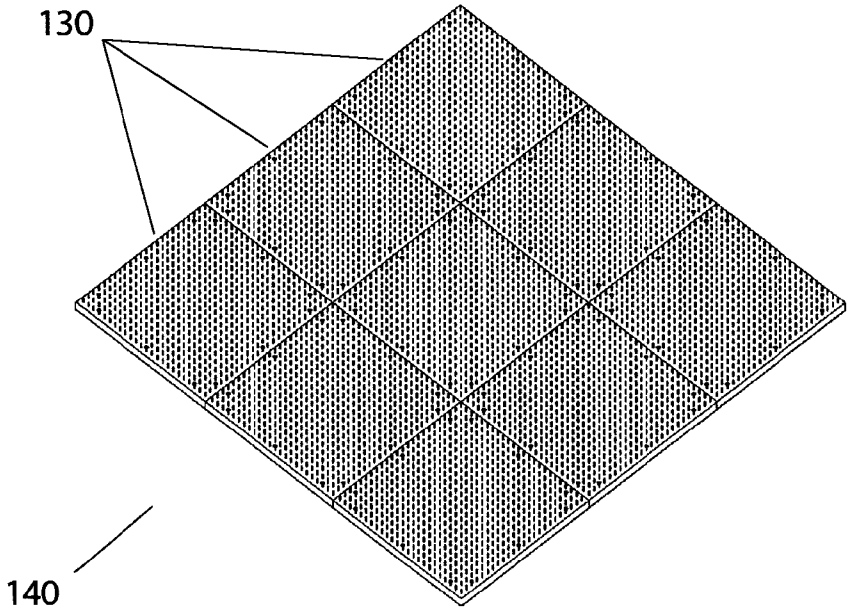


FIG. 16

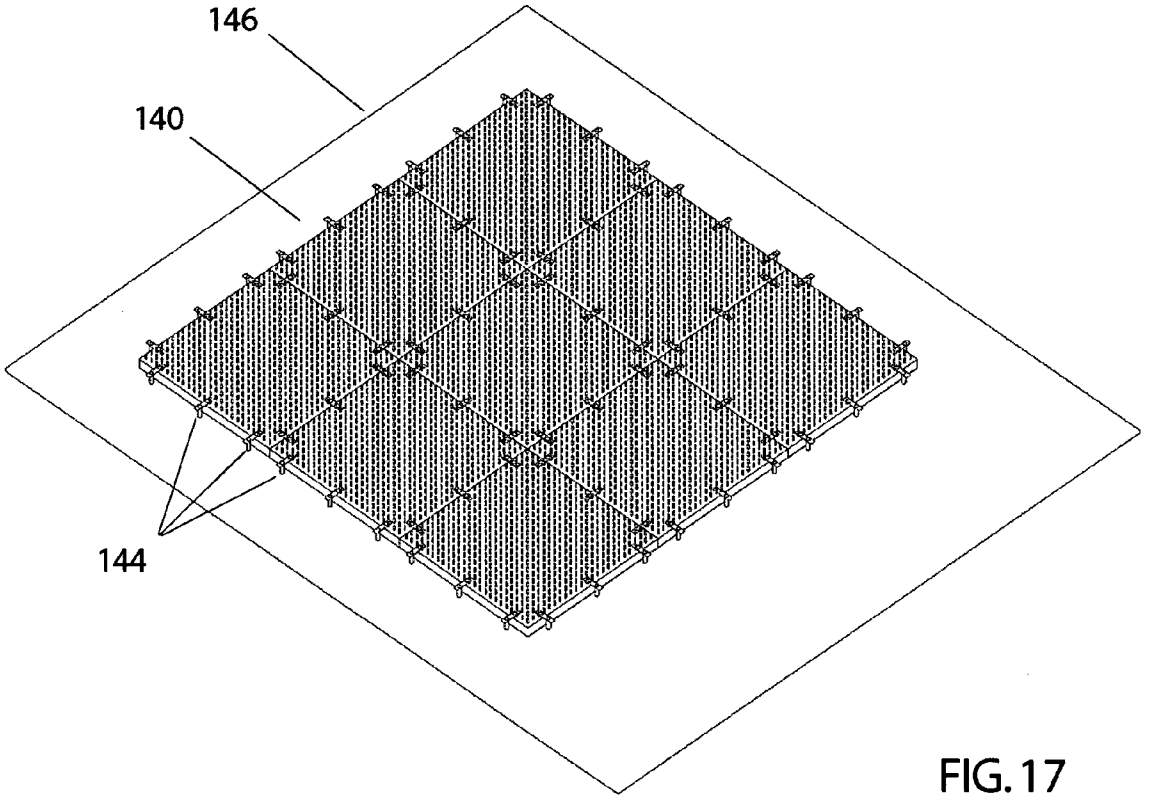


FIG. 17

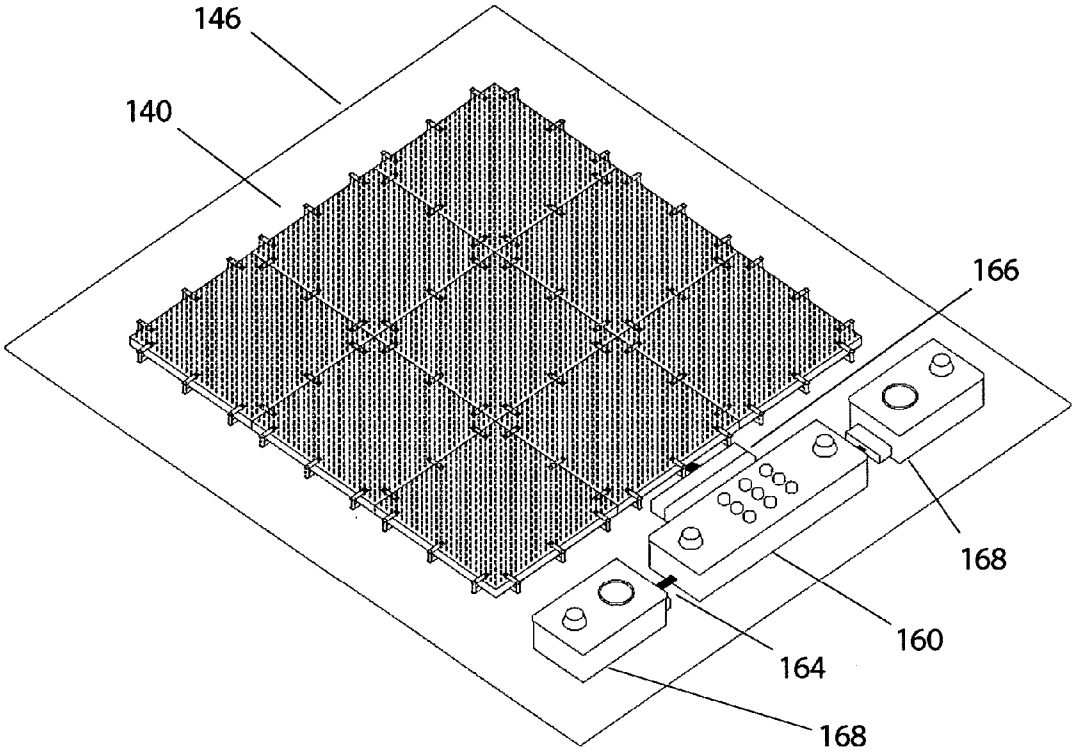


FIG. 18

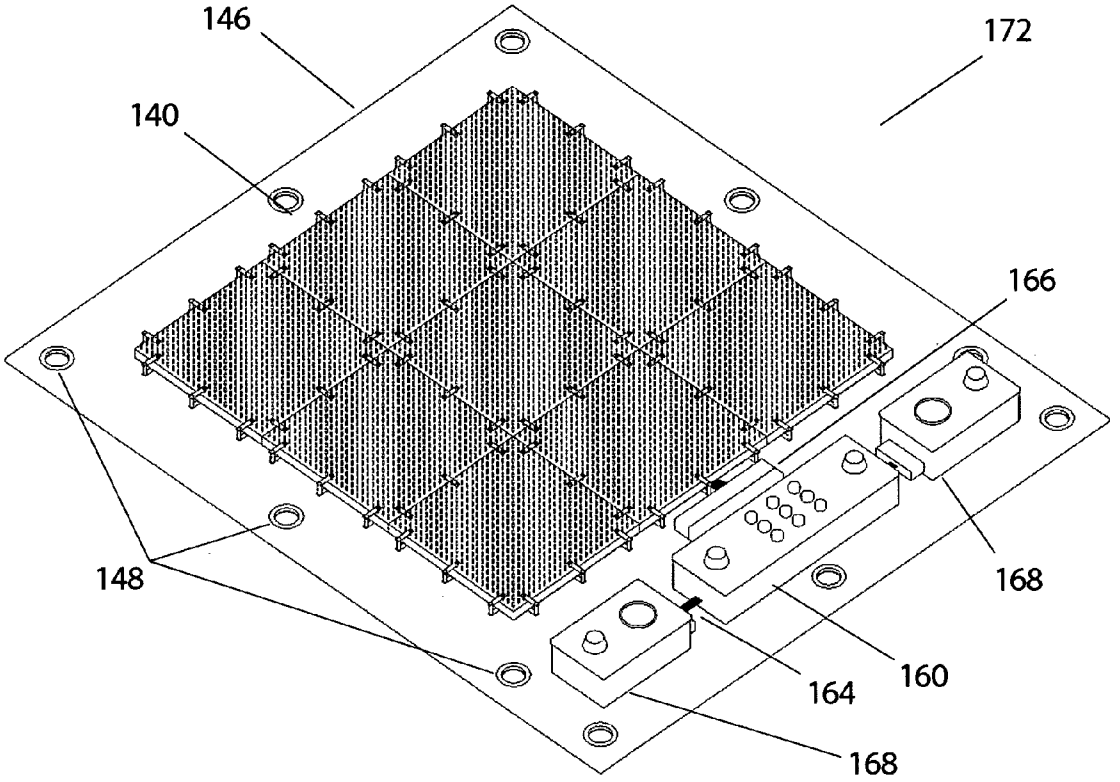


FIG. 19

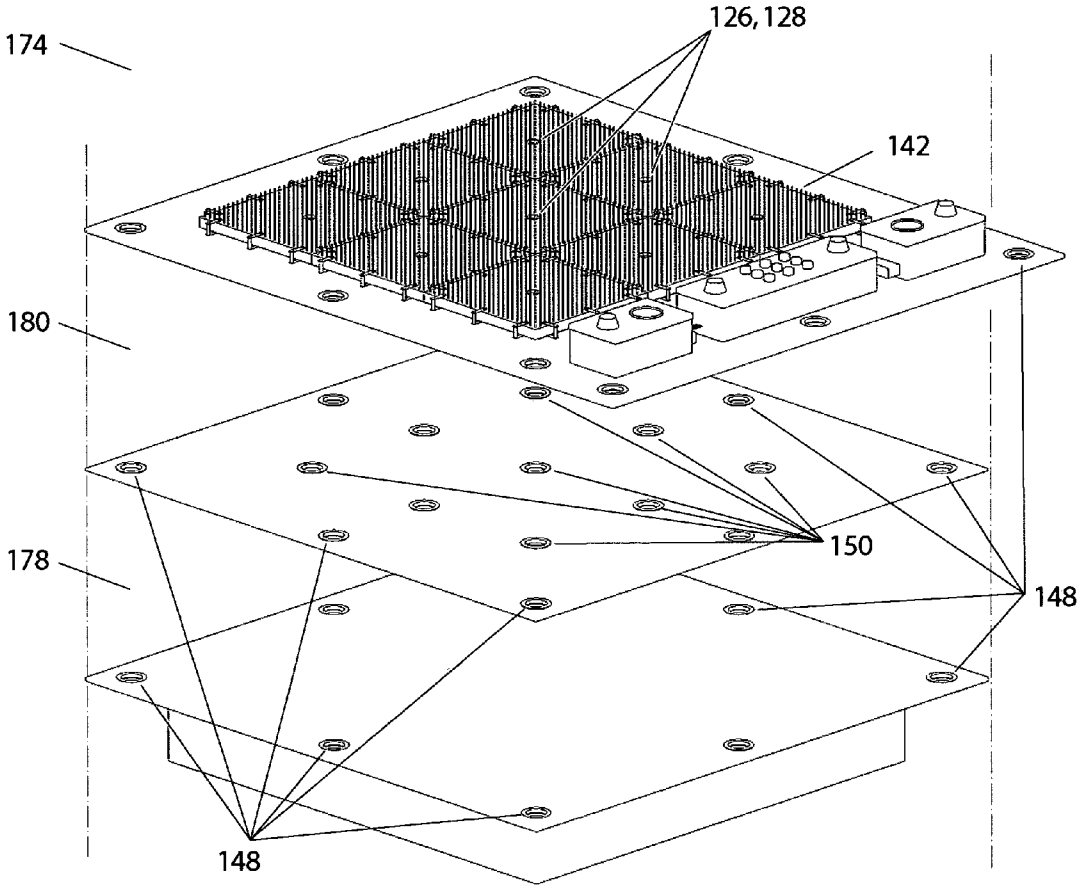


FIG. 20

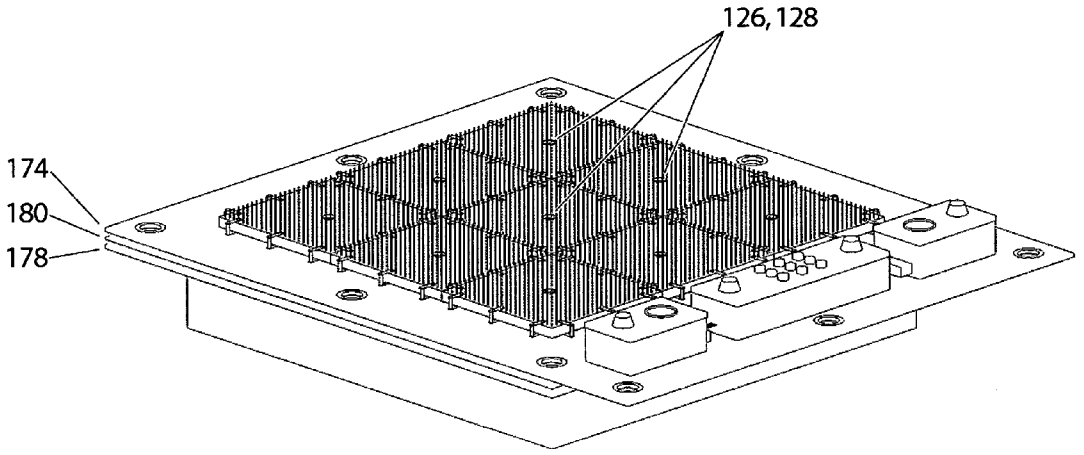


FIG. 21

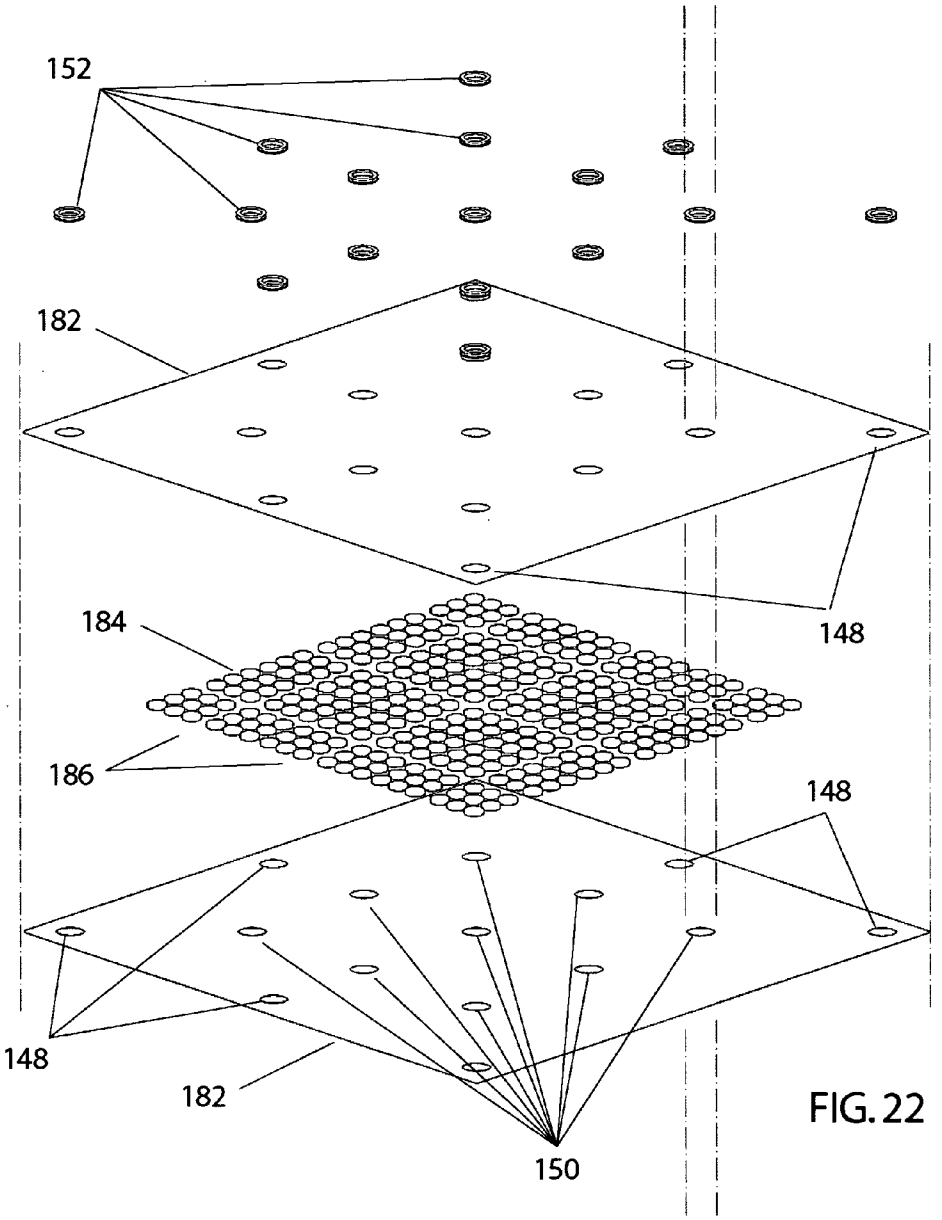
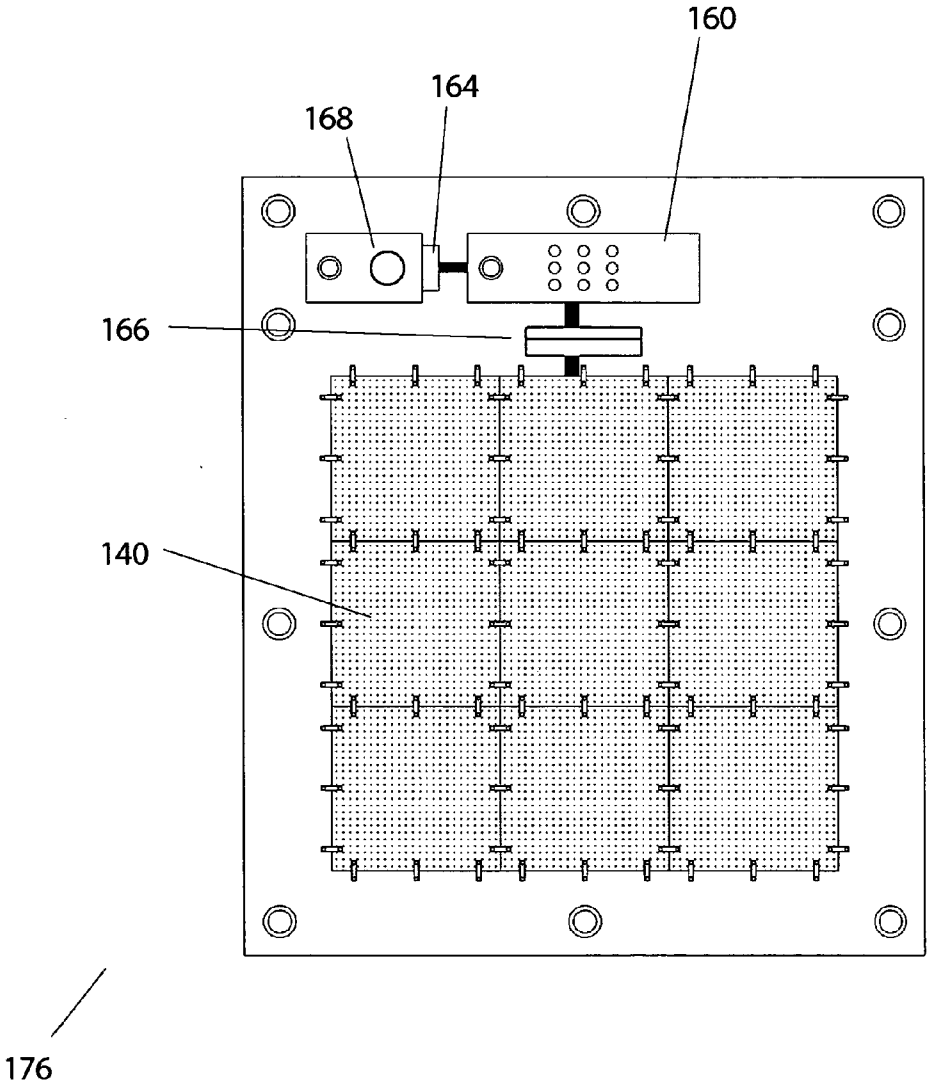


FIG. 22



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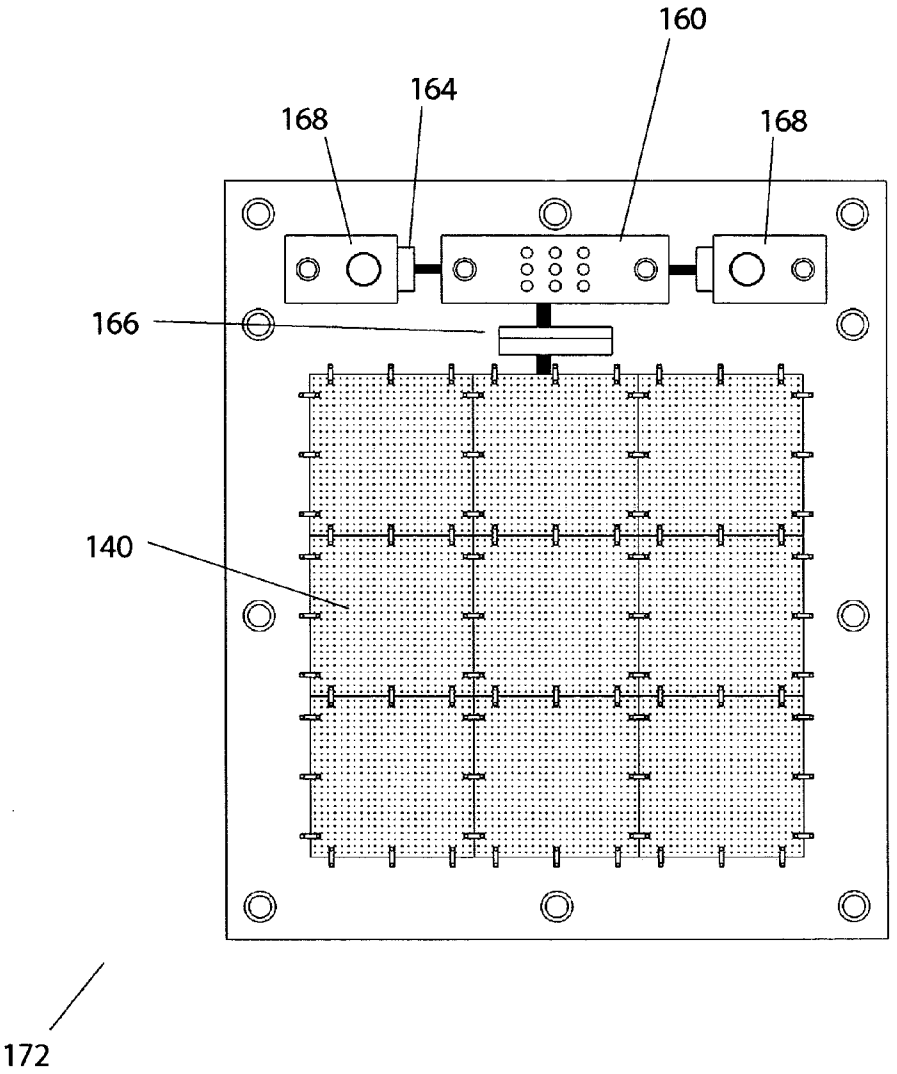

FIG. 24

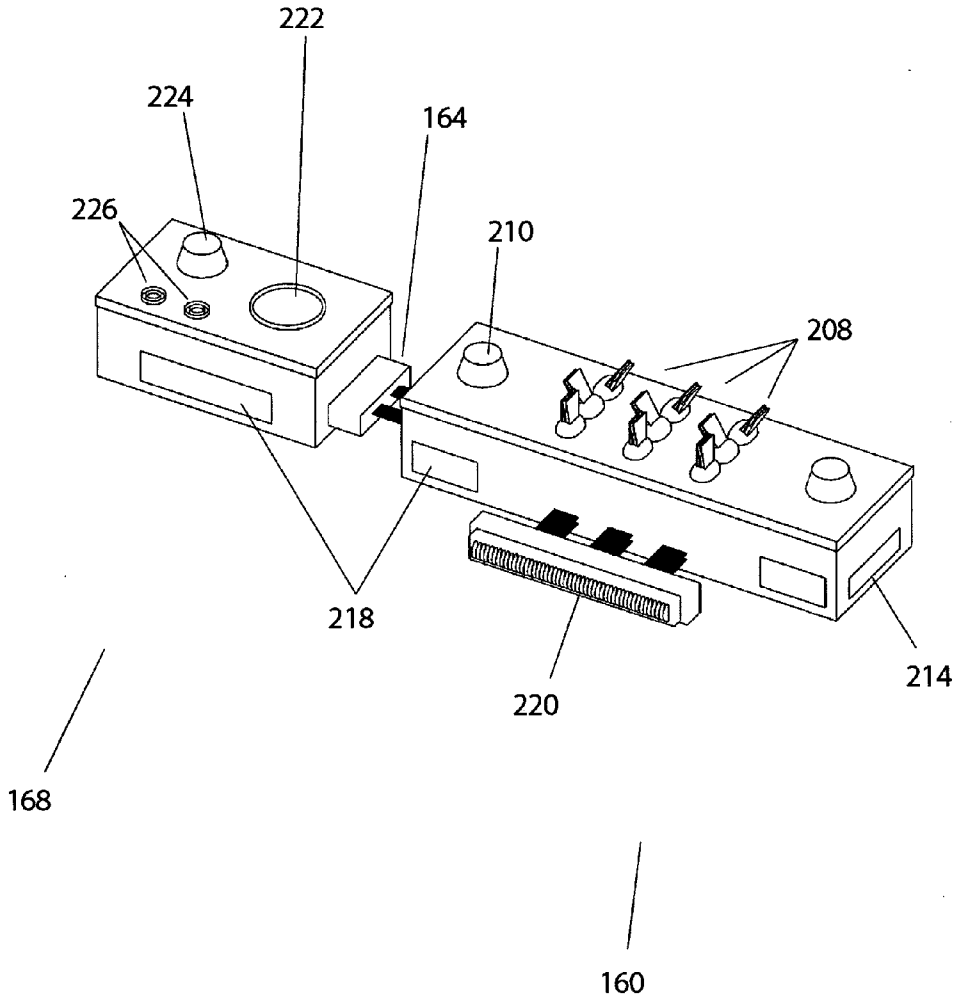

FIG. 25

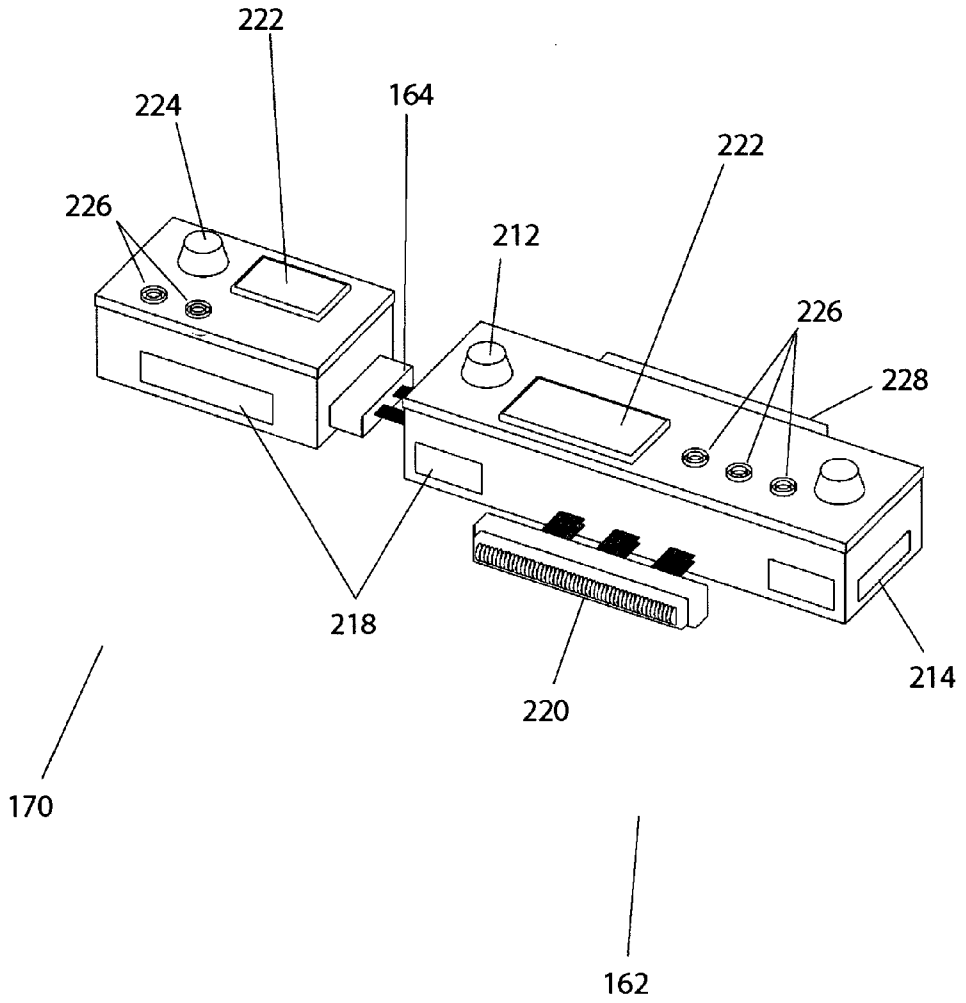

FIG. 26

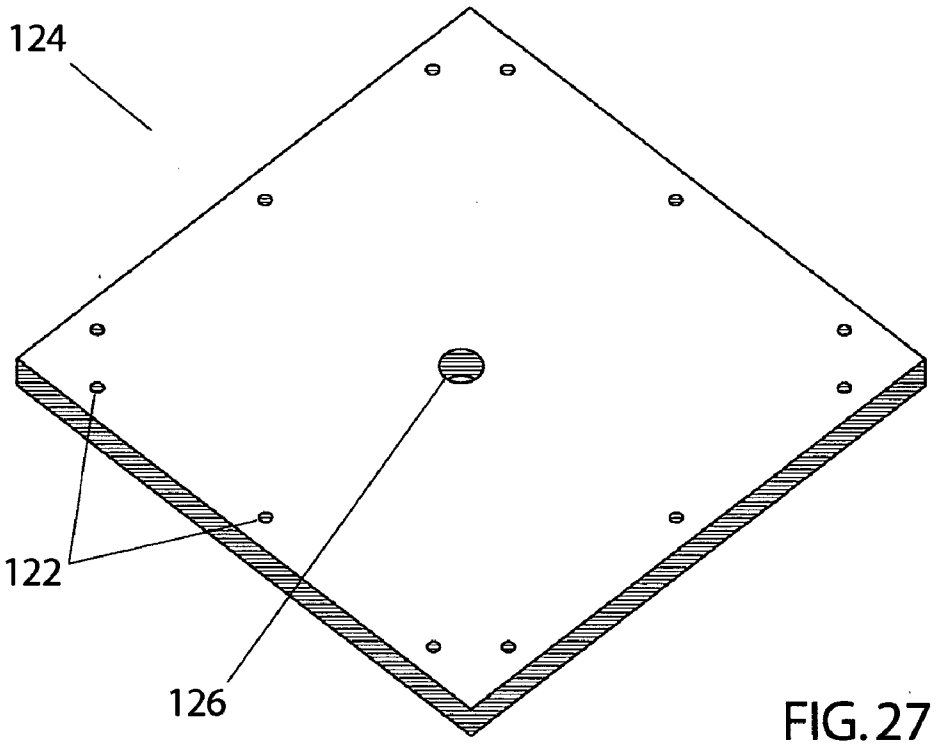

FIG. 27

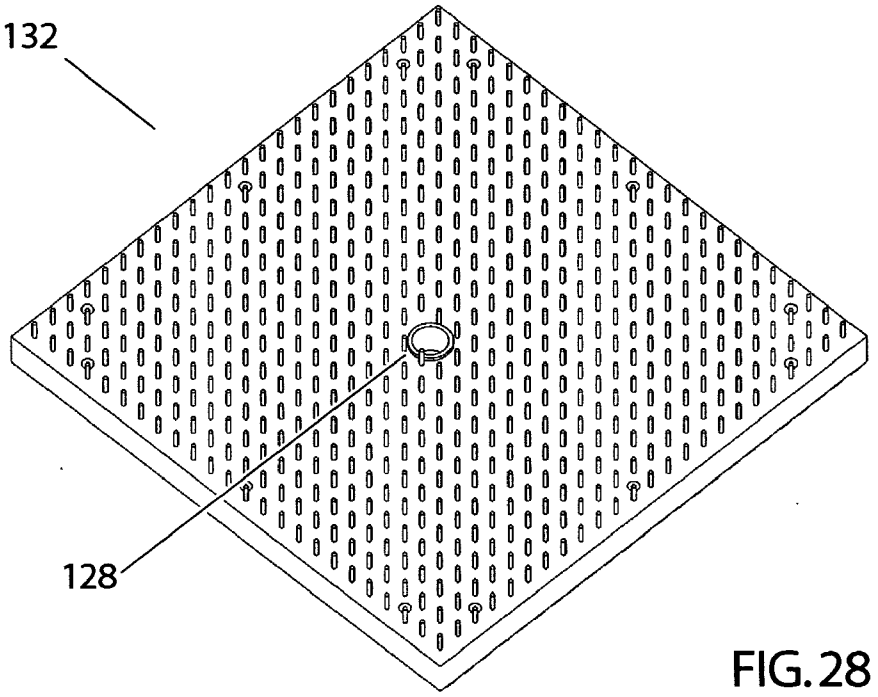

FIG. 28

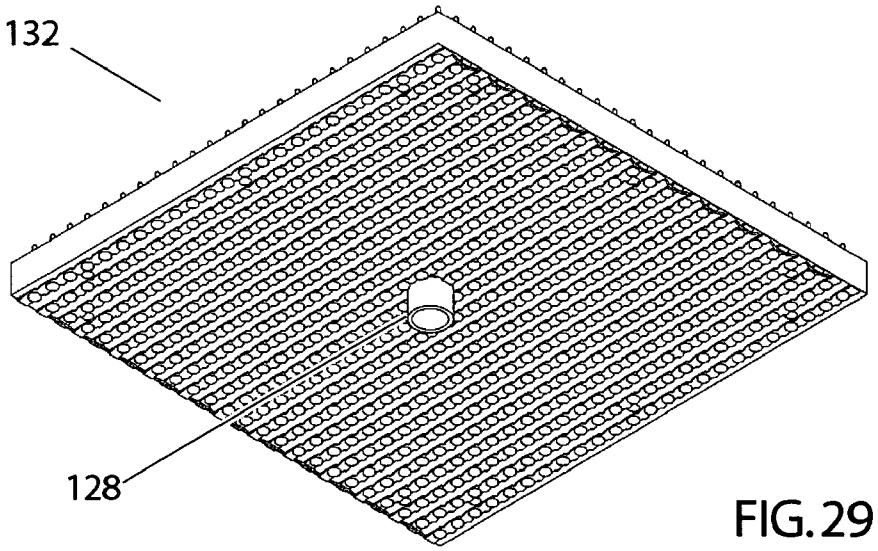

FIG. 29

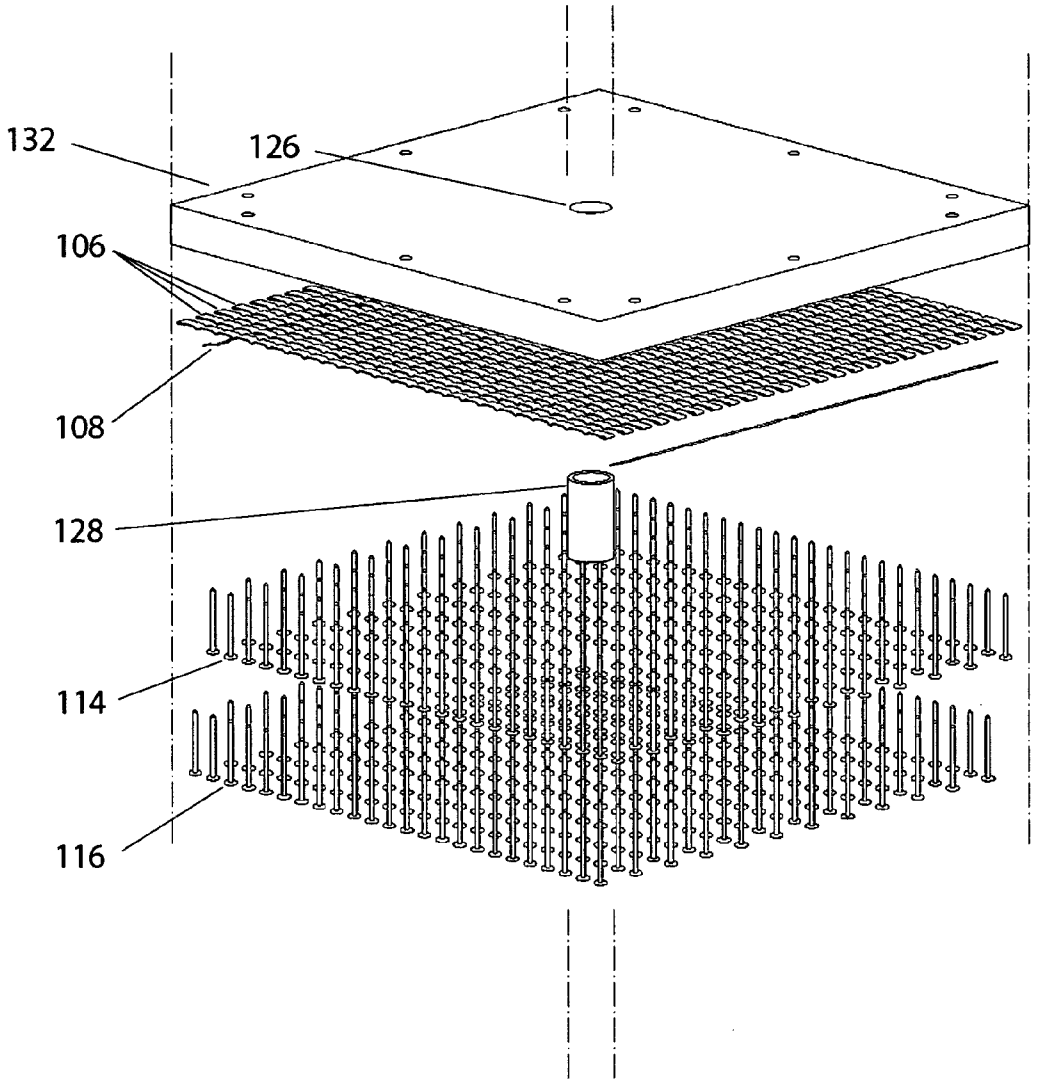

FIG. 30

THERAPEUTIC DEVICE FOR LOCAL AREA STIMULATION

[0001] This application is a continuation in part of application U.S. Ser. No. 11/002,781, filed Dec. 2, 2004.

[0002] The Inventor is Nikolay Alekseyenko, a citizen of the United States, residing at 154 Out-look Circle, Pacifica, Calif., 94044

CROSS REFERENCE TO RELATED APPLICATIONS

[0003] Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0004] Not Applicable

REFERENCE TO SEQUENCE LISTING, A TABLE, OR A COMPUTER PROGRAM LISTING COMPACT DISC APPENDIX

[0005] Not Applicable

BACKGROUND OF THE INVENTION

[0006] This invention pertains to the field of devices used by healing arts and medical practitioners to stimulate healing responses and promote health in their subjects as well as the field of devices used to investigate biophysical phenomena, including phenomena associated the use of this instrument to apply a variety of stimuli.

[0007] Healing Arts practitioners in a wide variety of disciplines and traditions have long observed the therapeutic value of a great variety of local stimuli.

[0008] From hot water bottles to acupuncture needles, from electrical currents to magnetic fields, and from massages to plasters, many stimuli are recognized as helpful components in therapy. They are administered continuously or intermittently, constant or modulated, over a wide range of intensities from extremely fine to much higher, and, in the case of electrical and magnetic stimuli, with constant or alternating polarities.

[0009] Fields of practice using such stimuli include sports and rehabilitative medicine, physical therapy, acupuncture, acupressure, therapeutic massage, and less traditional practices such as magneto-therapy and reflexive therapy.

[0010] A number of devices have been invented to aid in administering therapeutic stimuli. Following are descriptions of four such devices cited as examples of prior art.

[0011] A device for intramuscular stimulation therapy applies local electric currents and is described in U.S. Pat. No. 6,058,938 to Chu and Styles (1998). It has an electric battery power source connected to conductive tips held on Teflon handles and inserted subcutaneously.

[0012] Shortcomings of this device include:

[0013] a. It is necessarily invasive, requiring insertion of the points.

[0014] b. It lacks control over the polarity and amount of current applied.

[0015] c. The device itself is not responsive to changes in the patient, such as polarization and resistivity around the inserted electrodes, during the course of administration.

[0016] d. It is dependent upon external power supplies.

[0017] e. It does not administer other stimuli such as heat and constrains their simultaneous application.

[0018] Another related device is proposed in U.S. Pat. No. 4,590,939 to Sakowski (1984). It is used to reduce pain according to acupressure principles through application of local mechanical pressure.

[0019] Shortcomings of this device are that its use precludes simultaneous administration of other stimuli singly or in combination. The gross mechanical motions it induces are incompatible with numerous conditions including lesions, surgical wounds, bruising, ulcerations, or infections.

[0020] A third device is proposed in U.S. Pat. No. 4,319,574 to Sun and Sun (1980). It also applies physical pressure and is used to stimulate "Biologically Active Spots" (BAS). It consists of a flat plate with two protruding parts that move against each other by means of an electromagnet. The parts have adjustable positions set by selectable stops.

[0021] Shortcomings of this device include:

[0022] a. It neither provides nor permits simultaneous application of other stimuli singly or in combination.

[0023] b. It requires an external electrical power supply.

[0024] c. It requires time-consuming procedures to set up.

[0025] d. It is dependent upon external power supplies.

[0026] e. It does not administer other stimuli such as heat and precludes their simultaneous application.

[0027] These three above-described devices are limited to administration of one type of stimulus and make simultaneous administration of other stimuli impractical. They are localized to one point, or, in the case of the first device, a line between two points.

[0028] The fourth device, actually a range of devices based on one fundamental feature, superficially resembles the present invention but fails to exhibit the novel, unexpected and useful properties seen in my invention. Inventor and healing practitioner Igor Kuznetsov developed his "IPLIKATOR" (an acronym sounding like the word "applicator") in Russia in 1980. Kuznetsov's writings and marketing materials cite ancient traditions such as the India's fakir's lying on beds of nails or walking on beds of burning coals and Chinese acupuncture as precedents for his invention. All versions of his device employ points (thermoplastic) spaced 1 cm or more apart, or—uncommonly—needles (metal) spaced at least 8 mm apart. A variation of the IPLIKATOR dubbed Panacea has been offered for sale in North America and is comprised of a pad with integral molded points, similarly spaced.

[0029] Kuznetsov's device, in the form sold over the counter in Russia until the collapse of the Soviet Union, has molded plastic points spaced approximately 1 cm apart. A version with metal needles set 8 mm apart was used in clinical settings. Kuznetsov's instructions for using his

device reflect the fundamental difference between it and the present invention. Unlike the present invention, Kuznetsov's instructions for use reveal a singular feature of his device: it depends on physical pressure being applied at maximum tolerable pain levels until no longer tolerable followed by release of the pressure for relief followed by a repeat application of maximum tolerable pressure and so on until the desired response is noted, or, in cases of local application, the underlying musculature becomes entirely limp and "the points press against bone." Following proper application, subjects' skin, though not lacerated, is characteristically marked by epidermal abrasions where the points have pressed and surrounded by "stretch marks" indicating acute distention of the skin radiating out from the points. The device works through mechanical distention of skin and underlying tissue in a species of massage and by inducing intense pain. Both aspects depend on mechanical pressure being applied to points that are spaced far enough apart to significantly deform the skin surface.

[0030] Kuznetsov and his followers cite the mechanical deformation and the pain as intrinsic to the use of the device and its effects. They conjecture in addition that pushing 100's or 1,000's of spots will inevitably hit a few "acupuncture points" as well, with therapeutic benefit. This claim is considered thoroughly absurd by practitioners of acupuncture whose treatments are sub-dermal and skillfully directed to a few carefully selected locations.

[0031] Use of IPLIKATOR—Panacea devices without intense pain and pressure give results akin to meditative or training practices such as wearing a hair shirt or repeated skin pinching.

[0032] Kuznetsov's marketing materials claimed protection for the device through a Russian author's certificate but anecdotal reports averr his certificate was for an unrelated invention in the early 1970's. Whatever his certificate covered I have not seen it precisely identified in connection with IPLIKATOR-Panacea devices, perhaps because it was in fact unrelated to them.

[0033] Shortcomings of this fourth device include:

[0034] a. It depends on mechanical manipulation and induced pain for its effects.

[0035] b. The points must be spaced far enough apart to accomplish mechanical distension and induced pain, precluding the novel and unexpected effects produced by the present invention which depends on a higher density of points.

[0036] c. The high number of regularly spaced points precludes effectiveness according to the principles of acupuncture and acupressure, contradicting claims made for it.

[0037] d. If it is used to apply electrical stimuli, the stimuli, being applied so far apart, fail to function in the novel and unexpected manner seen in use of the present invention,

[0038] e. Despite claims made for it, application of electrical stimuli with the device also fail to function according to principles of acupuncture and acupressure.

[0039] f. Galvanically-induced electromagnetic effects are not induced or employed by this device. No field variations or arrangements of differing materials is used.

[0040] g. Applied magnetic fields have not been incorporated with this device, and the wide spacing of its points, lack of interconnections between them, and lack of arrangements of electromagnetically dissimilar materials precludes the field modulations observed with the present invention.

[0041] h. No provision is made for concurrent use of subcutaneous injectors or other applicators or sensors with this device.

[0042] i. Kuznetsov's writings clearly assert that induced pain and mechanical pressures are necessary to the device's effectiveness.

[0043] j. The device, when used according to its inventor's instructions, creates epidermal abrasions and local dermal trauma.

BRIEF SUMMARY OF THE INVENTION

OBJECTS AND ADVANTAGES OF THE PRESENT INVENTION

[0044] Accordingly, besides the objects and advantages of the devices described in the above description of prior art, several objects and advantages of the present invention are:

[0045] a. to provide gentle and non-invasive therapeutic stimuli across areas of a subject's body surface with points in arrays—to some degree or entirel—regular and spaced 3-6 mm apart novel and unexpected benefits unique to such arrays and other benefits;

[0046] b. to galvanically provide fine degrees of electrical potential or current and electromagnetic fields without external power sources;

[0047] c. to apply stimuli evenly over an area of application while varying them at smaller scales, further varying them at these smaller scales by optionally incorporating differing materials, arrangements and interconnections of the point arrays;

[0048] d. to optionally apply stimuli in differing degrees or kinds to selectable sub-portions of the area of application;

[0049] e. to optionally apply various types of electrical, modulated, or magnetic stimuli as required;

[0050] f. to optionally apply heat or cold to the area of application;

[0051] g. to monitor physical changes in the device, e.g. field polarities, magnetic moment, or electrical resistance at selectable areas of application during a course of treatment;

[0052] h. to provide electrical and magnetic stimuli in any strength needed;

[0053] i. to provide variation, modulation, and control of electromagnetic stimuli over time;

[0054] j. to accommodate simultaneous topical or subcutaneous administration of medicinal substances and/or additional, highly localized stimuli;

[0055] k. to activate, potentiate, or synergistically enhance medicinal substances by means of electrical, magnetic and/or thermal fields;

[0056] l. to optionally function autonomously without external power sources or with external power sources as appropriate;

[0057] m. to provide optional self-regulating or ad hoc regulation of therapeutic stimuli;

[0058] n. to provide a variety of practical advantages including immediately available alternate configurations, portability, and minimal setup;

[0059] o. to provide the above functionality in separable components or modules which operate singly or in combination;

[0060] p. to provide optional means for additional therapeutic administrations including, but not limited to, invasive techniques, additional controls, or monitoring devices;

[0061] q. to "do no harm" by functioning safely in proximity with inflamed, injured, lacerated, sensitive, or delicate subject tissues;

[0062] r. to provide, through replaceable modules, a wide variety of sources of stimuli and controllers—both manual and automated—for said stimuli, as well as to provide con-current means of monitoring the stimuli, their biophysical effects, and biophysical conditions or responses within the instrument's domain of influence;

[0063] s. to provide a platform for quantifiable, scientific research into extended ranges and combinations of hitherto mutually incompatible therapies. By using the unprecedented variety of field effects available through its use, this invention, with supporting instruments, may open doors to new fields of biophysical research, and, it is hoped, thereby lead to deeper understanding of life, health and healing.

SUMMARY OF THE PRESENT INVENTION

[0064] In accordance with the present invention the therapeutic device for applying local area stimuli is an array of metal points set approximately 3 mm to 6 mm apart, arranged in rows alternating between ferromagnetic and diamagnetic materials, and held in a flexible, magnetized support, the combined parts so connected and deployed as to effectively administer and monitor a wide variety of physical stimuli singly or in combination and provide means to effectively monitor coincident and concurrent biophysical responses to these stimuli both for therapeutic purposes and as a tool for scientific research into phenomena revealed through this invention's development and use.

DRAWINGS

[0065] Drawing Figures with brief descriptions are listed here below.

[0066] FIGS. **19** or **21** may be considered suitable Front Page Views:

[0067] **FIG. 01** is an array of points.

[0068] **FIG. 02** is a flexible base block.

[0069] **FIG. 03** is a point array embedded in a flexible base block, viewed from the active, proximate [front] side.

[0070] **FIG. 04** is a point row.

[0071] **FIG. 05** is a conductive strip.

[0072] **FIG. 06** is the point row and the conductive strip assembled into a point row assembly with a conductive wire attached.

[0073] **FIG. 07** is a distal [rear] view of an entire point row assembly.

[0074] **FIG. 08** is a close-up of a point row assembly, distal side.

[0075] **FIG. 09** is an array of points with alternating rows of two materials, ferromagnetic and diamagnetic metals.

[0076] **FIG. 10** is a flexible base block with mounting points.

[0077] **FIG. 11** and **12** are point row assemblies in the flexible base block—active side view and side elevation, respectively.

[0078] **FIG. 13** is a unit point block assembly, exploded view, in the preferred [portable] embodiment.

[0079] **FIG. 14** and **15** show a unit point block assembly in distal [rear, away from patient] views highlighting the alternating point materials and the conductive strips, respectively, in the preferred [portable] embodiment

[0080] **FIG. 16** shows a 3×3 assembly of unit blocks, an arbitrary array of separably controllable unit point block assemblies—in three rows of three in this example, in the preferred [portable] embodiment.

[0081] **FIG. 17** shows a 3×3 unit block assembly attached to a flexible base (e.g. a sturdy fabric) in the preferred embodiment.

[0082] **FIG. 18** is a 3×3 unit assembly on its base with electrical connectors to two source modules supplying electromagnetic stimuli through an intermediary adapter module in the preferred embodiment.

[0083] **FIG. 19** is an example of a finished operational assembly showing accessory attachment points in its flexible base in the preferred [portable] embodiment.

[0084] **FIGS. 20 and 21** shows an operational assembly, in the alternative [clinical] embodiment, with two attachments in an exploded view and assembled, respectively. The visco-elastic pad attachment is usually employed with both embodiments. Optional accessories fit between the operational assembly and its visco-elastic pad attachment.

[0085] **FIG. 22** is an exploded view of a typical attachable accessory, in this case providing supplementary magnetic fields by means of permanent magnets. Access holes and gaps within the accessory assembly make it fully compatible with both the preferred [portable] and the alternative [clinical] embodiments of this invention.

[0086] **FIGS. 23 and 24** show plan views of an electromechanical adapter with one and two source modules, respectively, attached to the preferred embodiment of this invention.

[0087] **FIG. 25** is a standard electromechanical 3×3 adapter module with one source module.

[0088] **FIG. 26** is a 3×3 data and real time adapter module with a data source module, permitting simultaneous monitoring and control of each point block separately.

[0089] **FIG. 27** shows the alternative [clinical] embodiment support block. The opening in the flexible base accommodates a mounting fixture for accessories including hypodermic needles, topical medicinal applicators, and sensors to monitor physical parameters such as temperatures, or electromagnetic and galvanic, conditions.

[0090] **FIGS. 28 and 29** show an alternative embodiment unit point block assembly in active and distal side views, respectively.

[0091] **FIG. 30** is a unit point block assembly of the alternative [clinical] embodiment in an exploded view.

DRAWING REFERENCE NUMERALS LISTED AND NAMED

[0092] **100**: Point Array

[0093] **102**: Simple Support Block

[0094] **104**: Row of Points

[0095] **106**: Conductive Strip

[0096] **108**: Wire Lead for Conductive Strip

[0097] **110**: Point Row Assembly

[0098] **111**: Point Row Assembly, partial view [close-up]

[0099] **112**: Points Assembled in a Support Block

[0100] **114**: Ferromagnetic Metal Point Rows

[0101] **116**: Diamagnetic Metal Point Rows

[0102] **120**: Support Block, Preferred Embodiment

[0103] **122**: Support Block Mounting Points

[0104] **124**: Support Block, Alternative Embodiment

[0105] **126**: Opening for Clinical Accessory Mount

[0106] **128**: Clinical Accessory Mount

[0107] **130**: Unit Point Block Assembly, Preferred Embodiment

[0108] **132**: Unit Point Block Assembly, Alternative Embodiment

[0109] **138**: Fasteners for Combining Unit Blocks

[0110] **140**: 3×3 Unit Assembly, Preferred Embodiment

[0111] **142**: 3×3 Unit Assembly, Alternative Embodiment

[0112] **144**: Fasteners

[0113] **146**: Flexible Base

[0114] **148**: Accessory Attachment Points, Grommeted-Style

[0115] **150**: Clinical Accessory Mount Access Openings, Grommeted

[0116] **152**: Grommets

[0117] **160**: Adapter Module, Electromechanical

[0118] **162**: Adapter Module, Data and Real Time

[0119] **164**: Electrical Connector: Adapter to Source Module

[0120] **166**: Electrical Connector: Adapter to Unit Assembly

[0121] **168**: Source Module, Parallel

[0122] **170**: Source Module, Addressable Control

[0123] **172**: Operational Assembly. Dual Source Option, Preferred Embodiment

[0124] **174**: Operational Assembly, Dual Source Option, Alternative Embodiment

[0125] **176**: Operational Assembly, Single Source Option, Preferred Embodiment

[0126] **178**: Visco-Elastic Pad Attachment

[0127] **180**: Attachable Accessory

[0128] **182**: Flexible Support

[0129] **184**: Permanent Magnet Array

[0130] **186**: Gaps in Array Accommodate Attachment Access Lines

[0131] **208**: Source Selector Switch [Single-Pole, Triple-Throw]

[0132] **210**: Source On-Off-Option Switch [9-or-Greater Pole, Multi-Throw]

[0133] **212**: Function Selector Switch [18-or-Greater-Pole, Multi-Throw]

[0134] **214**: Multi-Circuit Jack for Source Module Connections

[0135] **218**: Attachment Points to Flexible Base

[0136] **220**: Multi-Circuit Connector Plug to Unit Blocks

[0137] **222**: Metering and Status Display

[0138] **224**: Variable Control

[0139] **226**: Input/Output Ports

[0140] **228**: Multi-Circuit Analog Port

DETAILED DESCRIPTION OF THE INVENTION

[0141] The novel and non-obvious essence of this invention is an array of points (**FIG. 01**) supported (**FIG. 02**) so as to be assembled together in an array (**FIG. 03**), some or all of the points regularly spaced approximately 3 mm to 6 mm apart. This point array is used to provide a physical stimulus at the skin surface to the subject under treatment. It has been observed that this novel arrangement is unexpectedly able to induce useful responses not seen in other forms of stimulation that have been used to induce and support healing.

[0142] The approximately 3 to 6 mm spacing of arrayed points is key to the device's novel and unexpected effects. If the points are too close or too far, induced stimuli do not give rise to the results observed in the present invention. The galvanic effects described below are particularly dependent on the points not being set too far apart. The modulation of magneto-electrical fields is seen to be therapeutically effective in the spacing specified. It is hypothesized that this

spacing reflects underlying granularity in the of the vascular and nervous systems, i.e. the first level of organization of capillaries and nerve endings. It is further hypothesized that the variations of stimuli at this scale-as seen in the present invention-are related in magnitude to the scale of biochemical and bioelectrical processes in living tissues. Finally, it is hypothesized that this scale is consonant with the thickness of dermal layers, the skin, sometimes referred to as "the body's largest organ"

[0143] By using a flexible support in a planar-like array, the points can be quite sharp and yet not break the subject's skin because skin is elastic and properly supported point arrays, flexing under subject pressure, distribute the pressure evenly. The gentle, non-injurious irritation by these points, at least some of which are set apart as specified, affects dermal structures which have granularity at magnitudes of scale similar to the point spacings and to the depth of electromagnetic field deformations induced through the points.

[0144] This effect of scale is most evident with the use of metal points so connected (**FIG. 04-08**) as to permit application of electrical current or potential, enhancing therapeutic benefits in an unexpected manner and degree, therapeutic effects comparable to electro-acupuncture in their immediacy, intensity and benefit, even though they are not to be confused with acupuncture itself.

[0145] The flexible support is a synthetic, rubbery "magnetophore" material which is permanently magnetized by added ferromagnetic ingredients, similar to refrigerator magnets. This provides benefits of a magnetic field as a therapeutic stimulus.

[0146] Further developments incorporate the galvanic response of a subject's skin to adjacent ferromagnetic and diamagnetic metal points (**FIG. 09,11, 13-15, 28-30**) which create micro voltages and currents when connected due to the moist, saline, conductive character of human skin between them. This phenomenon yields unexpected benefits to broad local regions of a subject differing from those derived from direct stimulation by applying electric current or fields. The inventor has discovered useful coordination of acupuncture treatments and applications of his invention in its passive, galvanic mode that are dramatically effective, e.g. placing the point array in the mid-lumbar region to augment "Kidney Meridian" tonification, and, in another type of acute illness, lower-thoracic placement to augment healing of acute bronchial conditions by means of classic Traditional Chinese acupuncture techniques.

[0147] A further unexpected and novel effect of the mixed ferromagnetic and diamagnetic points is seen in the modulation of the magnetic field arising from the magnetophore base which varies in relative polarity and intensity as it passes from point to point.

[0148] One arrangement of diamagnetic (e.g., brass or copper) and ferromagnetic (e.g., iron or steel) points, the arrangement used in the preferred embodiment of this invention, is in alternating rows, connected within themselves by a conductor and the rows connected with each other by wire leads (**FIG. 07, 08**). Checkered and hexagonal patterns are subjects of further inquiry for continuing developments of the present invention.

[0149] It is hypothesized that this device marks a such novel, enhanced effects over or alongside other electrical and magnetic stimulation therapies because the assembled arrays of points create both an effect of a single large field and, simultaneously, the numerous pairs of electrode points create myriad small field changes. The unexpected effect is dramatically enhanced effectiveness of healing responses in a manner quite distinct from other therapies and also capable of beneficially augmenting those therapies. about 3 mm to 6 mm apart), show enhanced effects with all types of points and stimuli. Higher point densities have little or no effect ("like lying on a rug"); lower point array densities, a la Kuznetsov's IPLIKATOR, exhibit little or no effect.

[0150] Rectangular arrangements of points are practical to assemble but further research may uncover advantages for hexagonal or other arrays not further described in this document.

[0151] Current research indicates that the points should be sharp, or nearly so, to most effectively induce and modulate electromagnetic fields. In practice this device has not caused problems in which sharp points puncture, lacerate or abrade a subject's skin. Transient minor discomfort, a sensation of 'roughness,' is common. Flushing, i.e. localized redness and warm sensation characteristic of increased blood flow, accompanying and following treatment is seen as a practical indicator of effectiveness.

[0152] An advance in the development of this device incorporated magnetized material into the point block supports (**FIG. 02, 03, 09-15, 27-30**). The combination of an array of points with a broad magnetic field potentiates the magnetic forces much as with electrical fields. On one hand, the point arrays create a wide active field and on the other, they create alternating gradients of field strength and field orientation between adjacent points.

[0153] This important combination of a magnetized support and arrays of alternating diamagnetic and ferromagnetic metal points is referred to as the unit point block assembly (**FIG. 11-15, 28-30**) shown in the preferred embodiment of the present invention.

[0154] Assembling these unit blocks into arbitrarily larger arrays is easily accomplished with fasteners that allow flexibility across the whole device (**FIG. 13, 16**). Operational Assemblies (Ref. **172, 174, 176**) incorporate these combined units with a flexible base, wiring, connectors, and attachment points (**FIG. 17-20**) for power supplies, other components, and accessory layers (**FIG. 23-25**). Easily-layered accessory components (Ref. **180**) such as heating pads, and enhanced magnetic field sources can be used ad hoc (**FIG. 20-22**).

Description—Operational Modules

[0155] Therapeutic devices in common use apply up to 10 volts DC to a subject. Galvanically induced micro currents and their potentiation by the point arrays present the other extreme of intensity useful in this device, a very wide range. Many different forms of electrical current and electromagnetic fields are known to be useful or possibly useful.

[0156] Accordingly, it is important to accomodate the optional use of differing source modules (**FIG. 18-21, 23-26**) and the use of none. The adapter modules in both embodiments of this invention attach to any of the source modules (**FIG. 18-21, 23-26**) and to the built-in wiring

harness of the point block arrays, switching between optional source modules and local galvanic effects in a variety of combinations.

[0157] For safety and reliablility, all circuitry must be designed to isolate users from any possible harmful electrical currents, and unwanted electromagnetic frequencies. A combination of isolation circuitry and fault-responsive circuitry is incorporated accordingly and to be maintained at appropriate industrial, consumer, and medical safey standards.

Description—Adapter Modules

[0158] The electromechanical adapter module (**FIG. 18-21**, **23-25**; Ref. **160**) is electromechanical in operation and permits manual switching of individual point block assemblies in the array between up to two source modules, galvanically-induced currents, or open (no current flow). Unit blocks function in parallel when connected to a source module, including galvanically- and environmentally-induced loads unless serialized by a suitably configured Source Module. Blocks switched to "self" (the middle throw of the three position switch), each has its own separate galvanically- and environmentally-induced current.

[0159] A data and real time adapter module (**FIG. 26**; Ref. **162**) permits external devices to simultaneously monitor, drive or control each point block assembly. This direct or indirect data and control interface ennables one or multiple analog circuits through the multi-circuit analog Port (Ref. **228**) or digital data via integrated digital controllers through input/output Ports (Ref. **226**). It employs commercially-available integrated circuits, controller boards, and operating systems. The arbitrary number of circuits available to each point block is limited only by practical considerations.

Description—Source Modules

[0160] Source modules (Ref. **168**, **170**) can function self-contained or powered by battery, piezomechanically, or otherwise externally powered. The source can provide current flows or static potentials. These can be of direct or alternating polarities, continuous or discontinuous, uninterrupted or interrupted, unmodulated, frequency modulated, or amplitude modulated, unvaried, randomly, or regularly varied-as possible and as suitable. Variants may be manually, programmatically, limit, or feedback controlled and incorporate appropriate sensors.

[0161] The parallel-circuit source modules are designed to operate on unit blocks as proposed in the preferred and alternative embodiments.

[0162] Addressable-control source modules (**FIG. 26**; Ref. **170**) are used with the data and real-time adapter modules (Ref. **162**). The circuitry of each addressable control source module communicates with, controls or is controlled by external controllers through input-output ports (Ref. **226**), the data and real time adapter module to source module connector (Ref. **164**). Embodiments of this invention may employ very fine degrees of control and monitoring down to the individual point level through appropriately wired unit assemblies.

[0163] Self-metering or externally-controlled sources can maintain continuous or programmatically defined levels of stimuli based on simultaneous monitoring of the point arrays themselves.

Description—Attachable Accessories

[0164] Accessory attachments (**FIG. 20-22**) outwardly resemble one another except for attachments and connectors such as electrical wires or tubes and varying thicknesses of the completed assemblies. One or more accessories (Ref. **180**) can be layered between the operational assembly (Ref. **172**, **174**, **176**) and the visco-elastic pad (Ref. **178**) to provide supplementary stimuli, including electrical or magnetic fields, physical vibration, and heat or cold.

[0165] Attachment points are holes or integrated fasteners (Ref. **148**) which align the layers. Grommets or other reinforcements (Ref. **152**) may strengthen the attachment points.

Description of the Alternative [Clinical] Embodiment

[0166] The alternative [clinical] embodiment differs from the preferred [portable] embodiment in one respect. Each unit block is fitted (**FIG. 27-30**) with a clinical accessory mount designed to securely hold devices such as hypodermic needles, topical applicators, accupuncture needles, or sensors connected through a tubing or wiring harness to external device[s]. In the case of hypodermic or topical injectors, the external device may be standard medical drip bags or pumps. Devices such as acupuncture needles would be connected as needed to standard power sources now in common use by practitioners in the field.

[0167] Accessory components of the system incorporate openings (**FIG. 20, 22**; Ref. **150**) allowing access to the clinical accessory mount on each unit point block of the alternative embodiment. The components within each accessory are arranged with gaps (**FIG. 22**; Ref. **186**) that permit tubing and wiring harnesses to run unimpeded and be well-protected. Simple grommets or specially-purposed fasteners (Ref. **150**) may be used to reinforce and/or align these openings.

Advantages

[0168] From the description above, a number of advantages of my device become evident:

[0169] Novel and unexpected therapeutic benefits arise when point arrays in the specified range of spacings apply physical stimuli to areas of a subject's body, especially in flexible, planar arrangements of ferromagnetic and diamagnetic points in magnetized supports alone and with optional field sources as seen in the preferred embodiment of this invention.

[0170] Because the assemblies are relatively thin, they permit application of a wide variety of stimuli and intensities, singly or in arbitrary combinations, through accessory attachments.

[0171] The flexible and modular design of this invention accommodates needs for portability and simplicity of operation in the field in the preferred embodiment. It accommodates intensive use of invasive procedures, bulkier accessories, and complex control systems in clinical settings in the alternative embodiment. Finally, ongoing clinical and scientific research into phenomena related to this invention's use and novel effectiveness are facilitated by easy integration of monitoring, sensor, and control systems.

[0172] This invention offers therapeutic opportunities that relate to an unprecedented range of healing arts traditions and and medical disciplines including allopathic medicine, physical therapy, sports medicine, therapeutic massage, Traditional Chinese Medicine, folkloric medicine, naturopathies, herbalism, and others.

Operation—Preferred [Portable] Embodiment (**FIG. 19, 20, 23-26**)

[0173] Operation of this invention is typically by application of the active side to a surface of a subject's body. This is commonly achieved by first assembling (**FIG. 20, 21**) an operational assembly (Ref. **172**, **174**, **176**)—including an adapter module (Ref. **160**, **162**) and one, two, or no source modules (Ref. **168**, **170**)—with optional accessories (Ref. **180**) and the visco-elastic pad attachment (Ref. **178**). This combination is placed on a firm surface such as a massage table. The subject then lies upon or reclines against the active side of the device.

[0174] The point arrays and the subject's surface are deformed by their mutual contact so as to exert a relatively uniform pressure over the area of contact. The elasticity of human skin ensures that even very sharp points (Ref. **100**, **104**, **110**, **112**, **114**, **116**, **122**, **124**, **130**, **132**) do not puncture it. Subjects report little or no discomfort from the contact.

[0175] An adapter module (Ref. **160**, **162**) is required for operation of the preferred and alternative embodiments described in this application. The electromechanical adapter module (Ref. **160**) permits each unit block to be switched to a closed circuit condition permitting electrical potential or current flow from galvanic action induced by the adjacent ferromagnetic and diamagnetic points contacting the subject's skin.

[0176] The adapter modules further allow each unit block to be switched to one of two circuits which can be open (no current flow) or closed by an attached parallel source module (Ref. **168**). The source modules may induce electrical currents or potentials of any physical nature possible. They may provide simultaneous metering of electrical conditions between the two sets of connected points in the connected blocks, or they may allow simultaneous metering of those conditions as responsive changes are created in the subject.

[0177] The electromechanical adapter module (Ref. **160**) has source on-off-option switches (Ref. **210**) with 9 poles and three states. The states set the connected blocks open (no current), closed to themselves (galvanic effects in parallel) or connected to the source module plugged in to its connector (Ref. **214**). More elaborate versions of the electromechanical on-off-option source switches (Ref. **210**) accommodate differing combinations of effects and metering through multiple circuits and switch states.

[0178] The data and real-time adapter module (Ref. **162**) provides digital (Ref. **226**) and analog (Ref. **228**) interfaces to the unit blocks and controllers built in to the adapters themselves. With these adapters, computer-based, algorithmic or automated controls may be designed and built as needed for therapeutic or research goals. Displays (Ref. **222**), e.g. LED readouts, can optionally provide direct information apart from attached computers or other devices regarding the state[s] of elements within, attached to, or affected by the adapter module.

[0179] Addressable control source modules (Ref. **170**) may be used with the data and real-time adapter modules (Ref. **162**). The circuitry of each addressable control source module communicates with, controls, or is controlled by internal components, adapter module controls or external devices. They may generate, monitor, or modulate electromagnetic forces severally and in combination, limited only by the granularity of the connections to the point arrays and circuitry connecting them with those points.

[0180] Once the subject and the device have been placed in contact, the switch settings on the adapter modules (Ref. **160**, **162**) are set in accordance with the effects or monitoring desired.

[0181] Setting source selector switches (Ref. **208**) on the electromechanical adapter (Ref. **160**) to the center position allows galvanically-induced micro-currents to flow within each unit block. Setting some number of the source selector switches to one of the source on-off-option switches allows those blocks to be disconnected (open circuit), their galvanically induced micro-currents to flow in parallel as one circuit, or connected to an attached source module. That source module can then provide some induced effect, monitor electromagnetic conditions, or both.

[0182] Settings are revised as desired during a course of treatment or observation.

Operation—Alternative [Clinical] Embodiment (**FIG. 20, 21, 27-30**)

[0183] The single difference between the preferred (portable) and alternative (clinical) embodiments of this invention is the incorporation of a clinical accessory mount (Ref. **128**) in each unit block. This mount securely latches the injector, applicator, or sensor in place.

[0184] The additional step of attaching devices to the clinical accessory mounts (Ref. **128**) precedes assembly of the operational assembly with its attachments (**FIG. 20, 21**). This present invention allows for their use during the subsequent course of treatment or observation.

CONCLUSION, RAMIFICATIONS, AND SCOPE

[0185] Accordingly, the reader will see that this invention incorporates new and novel technologies for therapy and biomedical research.

[0186] First its use of point arrays of specified densities offers a broad subject area, non-invasive and gentle therapeutic stimulus that functions in novel and unexpected properties in comparison with point arrays at lesser densities.

[0187] Further, metal points mixing ferromagnetic and diamagnetic materials create galvanic micro current therapeutic stimuli.

[0188] Further, mixing ferromagnetic and diamagnetic materials in point arrays greatly potentiates the effectiveness of magnetic field stimuli.

[0189] Further the point arrays similarly potentiate applied electromagnetic stimuli in ways not observed by the single point sources employed in other therapeutic devices.

[0190] Further, heretofore separate modes of therapy are combined in a practical, expeditious, and unprecedented manner.

[0191] Further, the modular and extensible design is adaptable to portable field use and to intensive clinical use. Its extensibility accommodates heretofore unexplored subjects of quantifiable scientific research through sensors and control systems already developed and yet to be developed.

[0192] Embodiments not herein illustrated may incorporate more complex and detailed circuitry to extend their functionality, For example, the source modules, adapter modules, and the arrangement of connections between points can each vary from embodiments that affect all points together (in parallel) to the other extreme of separately monitoring and controlling arbitrary groups of individual points severally or together for forces, sensors and controllers of arbitrary degrees of complexity. It is anticipated that this characteristic architecture will permit research and therapies unprecedented in their scope.

[0193] Digital technology permits active addressing, control, and monitoring of any arbitrary groups of points, sources and conditions, limited only by the physical construction of the point arrays and circuitry. The element of change over time, especially changes responsive to a subject's conditions, is another ramification implicit in this present invention's architecture.

[0194] An alternative, simpler, embodiment of this invention, not illustrated, is possible in which the alternating point rows in each unit block are directly connected ("shorted"). This embodiment would permit always-on galvanically-induced micro-current flows. An alternative, low-cost adapter module that sets this always-on condition in the proposed embodiments is comprised of a connector plug closing each unit block's circuit at the jack.

[0195] Three types of accessory heat sources envisioned (not illustrated) are (a) a convenient electrical pad connected to household power, (b) a portable, liquid-filled, stoppered bladder suitable for chemical reaction heating [or cooling], and (c) a pressurized liquid system utilizing a separate heater and pump to circulating temperature-controlled substances through a tubes-and-bladder system. The electrical heating pad and portable bladder types are appropriate for portable uses. Pressurized accessory heaters are suitable in a clinical setting.

[0196] Accessory magnetic field boosters covering localized or wide areas may utilize permanent magnets (**FIG. 21**) or electromagnets driven by external power supplies.

[0197] The types of arrays of points vary within the scope of this invention. Arrangements of points may be non-planar, non uniformly sharp or dull, or randomized by material or location. Points may non-parallel to each other. Points may not hold fixed positions with respect to each other. Points may be moved separately or in groups.

[0198] The materials of the point arrays and supports will vary as further research uncovers phenomena of interest arising from or responsive to differences in those materials.

[0199] Although the description above contains many specificities, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. For example, the density, sharpness, type of electrical conductors or semiconductors connecting the points, constituent materials and arrangement of the points can assume all physically possible variations, and it is expected that, with further research, more novel and unexpected benefits will be discovered in other combinations of this basic combination of elements.

[0200] Thus the scope of the invention should be determined by the appended claims and their legal equivalents, rather than by the examples given.

What I claim as my invention is:

1. A therapeutic device comprised of

a. an array of points, and

b. said array protruding from a supporting material or structure, and

c. at least some of said points approximately 3-6 mm apart.

2. The device of claim 1 wherein said support is flexible.

3. The device of claim 1 wherein said support is magnetized.

4. The device of claim 1 wherein said points are made with metal.

5. The device of claim 4 wherein said points are of two classes:

diamagnetic and ferromagnetic.

6. The device of claim 5 wherein said classes of points are assembled in some alternating arrangement.

7. The device of claim 4 wherein said points are interconnected with electrical conductors comprising:

a. interconnections within some classes of points, and

b. controllable connections between classes of points.

8. The device of claim 7 wherein points or classes of points may be selectively and separably monitored.

9. The device of claim 7 wherein signals or forces applied to points or classes of points may be selectively and separably controlled.

10. The device of claim 4 wherein provisions are made to apply, allow, or monitor electromagnetic forces through the points.

11. The device of claim 10 including:

a. power, force, and signal sources,

b. sensors,

c. controls and access for said sources and sensors.

12. The device of claim 11 wherein said controls and sensors operate:

a. manually by direct settings, or

b. by the device itself through feedback loops, or

c. algorythmically or programmatically.

13. The device of claim 12 wherein monitoring information is derived from external sources.

14. The device of claim 10 wherein forces affecting points may be monitored concurrently with application of forces to the points themselves or other points.

15. The device of claim 1 wherein said device physically accommodates optional accessories to be layered with it in use.

16. The device of claim 15 wherein there is an accessory source of heat or cold.

17. The device of claim 1 wherein the points of said device exert uniform pressure on the subject by means of padding.

18. The device of claim 1 wherein said device accommodates physical access to the subject by other devices, instruments, monitors, sensors, or therapies.

19. The device of claim 18 with provision to attach one or more hypodermic needles and tubing reliably and safely.

20. The device of claim 18 wherein said accessories provide means of application or monitoring of other therapies singly or in combination including, but not limited to, electromagnetic forces, acupuncture needles, vibration, distension and pressure.

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