

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To: Daryl Richardson
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Date of mailing
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FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/IB19/51005

International filing date (day/month/year)

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IPC - A61N 1/04, 1/32, 1/36 (2019)

CPC - A61N 1/04, 1/323, 1/36014

Applicant

PANACEA QUANTUM LEAP TECHNOLOGY LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

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Date of completion of this opinion

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IB19/51005

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

- a. ☐ forming part of the international application as filed:
- ☐ in the form of an Annex C/ST.25 text file.
- ☐ on paper or in the form of an image file.
- b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
- c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
- ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).
- ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IB19/51005

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement		
1.	Statement		
	Novelty (N)	Claims	NONE 1-19
			YES NO
	Inventive step (IS)	Claims	NONE 1-19
			YES NO
	Industrial applicability (IA)	Claims	1-19 NONE
			YES NO
2.	Citations and explanations:		
	Claims 1-19 lack novelty under PCT Article 33(2) as being anticipated by US 2010/0152817 A1 to Gillbe, S (hereinafter 'Gillbe'). As for claim 1, Gillbe discloses a method for electromagnetic stimulation of a tissue (a stimulator using an array of electrodes to stimulate tissue, for example a limb 08 with arrays 06 and 07 which surround the limb; figures 1- 3; paragraphs [0113, 0115, 0116]), the method comprising the steps of: a) disposing an arrangement of electromagnetic transducers encompassing a volume containing a tissue (a stimulator using an array of electrodes to stimulate tissue, for example a limb 08 with electrode arrays 06 and 07 which surround the limb; figures 1- 3; paragraphs [0113, 0115, 0116]); and b) applying an electromagnetic field stimulus to a tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time (a composite waveform 01 is created to effect the excitable tissue, the waveform being created by series of component waveforms A-E between pairs of electrode A1, A2,-E2 according to the pattern of fig. 1; figures 1-3; paragraphs [0114-0116]); wherein the activation pattern makes it possible to vary the intensity and direction of an electromagnetic field vector produced by the arrangement of electromagnetic transducers (the voltage applied to opposing electrodes creates a field according to the vector plot of fig. 17 where the direction and magnitude of the field at any point resulting from the magnitude and current provided to each electrode, with resulting field from a combination of pairs being formed from a matrix; figures 1-3 and 17A-17B; paragraphs [0177-0181]). As for claim 2, Gillbe discloses the method of Claim 1, wherein, after step (b), is a step of changing the activation pattern and returning to step (b) (current control can be done on a pulse-by-pulse by pulse basis to change the pattern of the electrodes based on changes of impedance; figures 1 and 18; paragraphs [0080, 0211]). As for claim 3, Gillbe discloses the method of Claim 2, wherein, changing the activation pattern is executed on the basis of a measurement of intensity of the electromagnetic field produced by the arrangement of electromagnetic transducers, on a tissue impedance response feedback or a combination of these (current control can be done on a pulse-by-pulse by pulse basis to change the pattern of the electrodes based on changes of impedance; figures 1 and 18; paragraphs [0080, 0211]). As for claim 4, Gillbe discloses the method of Claim 1, wherein, at step (a), the arrangement of electromagnetic transducers is a unitary arrangement of magnetic field transducers (the stimulator may use magnetic energy and be in a single simulator case 120; figures 18 and 20a; paragraphs [0200, 0242]). As for claim 5, Gillbe discloses the method of Claim 1, wherein, at step (a), the arrangement of electromagnetic transducers has two electrical field transducers (a composite waveform 01 is created to effect the excitable tissue, the waveform being created by series of component waveforms A-E between pairs of electrode A1, A2,-E2 according to the pattern of fig. 1; figures 1-3; paragraphs [0114-0116]). As for claim 6, Gillbe discloses the method of Claim 1, wherein, at step (a), in the arrangement of electromagnetic transducers, the electromagnetic transducers are selected from a group consisting of engines, electrodes, photoelectric transducers, induction actuators, resistors, coils that generate magnetic fields for induction, antennas, parallel plate conductor materials, and combinations of these (a composite waveform 01 is created to effect the excitable tissue, the waveform being created by series of component waveforms A-E between pairs of electrode A1, A2,-E2 according to the pattern of fig. 1; figures 1-3; paragraphs [0114-0116]). As for claim 7, Gillbe discloses the method of Claim 1, wherein, at step (a), the arrangement of electromagnetic transducers is disposed over a frame encompassing the volume (a stimulator using an array of skin contact electrodes 03 on an insulating sheet 04 to stimulate tissue, for example a limb 08 with electrode arrays 06 and 07 which surround the limb; figures 1- 3; paragraphs [0113, 0115, 0116]). As for claim 8, Gillbe discloses the method of Claim 1, wherein, at step (a), the active face of each electromagnetic transducer of the arrangement of electromagnetic transducers is in contact with the external surface of the tissue (a stimulator using an array of skin contact electrodes 03 on an insulating sheet 04 to stimulate tissue, for example a limb 08 with electrode arrays 06 and 07 which surround the limb; figures 1- 3; paragraphs [0113, 0115, 0116]). As for claim 9, Gillbe discloses the method of Claim 1, wherein, at step (a), the active face of each electromagnetic transducer of the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue (the array may be part of an enclosure 19 which is implanted within a patient and thus spaced from the external surface of the tissue; figure 8-9B; paragraphs [0133, 0134]). ***-Continued Within the Next Supplemental Box-***		

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IB19/51005

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 15 and 18 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 15 and 18 are indefinite for the following reason(s):

Claim 15 lacks antecedent basis for "the de switching circuit". For the purposes of this examination, "the de switching circuit" is interpreted as "the switching circuit"

Claim 18 includes numbered elements without antecedent basis. For the purposes of this examination, the numbers have been removed from claim 18, and OSC has been interpreted as oscillator.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IB19/51005

Supplemental Box

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Continuation of:

-Continued from Box V: Citations and Explanations-

As for claim 10, Gillbe discloses the method of Claim 1, wherein, at: step (a), the active face of one of the electromagnetic transducers in the arrangement of electromagnetic transducers is spaced apart from the external surface of the tissue (the array may be part of an enclosure 19 which is implanted within a patient and thus spaced from the external surface of the tissue; figure 8-9B; paragraphs [0133, 0134]).

As for claim 11, Gillbe discloses the method of Claim 1, wherein, at step (a), a portion of an area of the active face of the electromagnetic transducers in the arrangement of electromagnetic transducers is in contact with the external surface of the tissue (a stimulator using an array of skin contact electrodes 03 on an insulating sheet 04 to stimulate tissue, for example a limb 08 with electrode arrays 06 and 07 which surround the limb; figures 1- 3; paragraphs [0113, 0115, 0116]).

As for claim 12, Gillbe discloses the method of Claim 5, wherein, step (b) is executed in a computing unit and the activation pattern follows the steps of: A) defining an electrical field transducers index with an initial value and a maximum number of pairs of electrical field transducers in the computing unit (the number of active electrode pairs and the simulation point can be controlled via the interface using sliders 16; figures 16; paragraphs [0167, 0169]); B) selecting a pair of electrical field transducers from the arrangement of electromagnetic transducers simultaneously in a position defined for the electrical field transducers index of step (A) (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform; figures 1 and 11-13; paragraphs [0148, 0150-0154]); C) activating the pair of electrical field transducers selected in step (B) with a determined polarity such that an electrical field transducer of said pair has positive electrical potential in relation to the other electric field transducer of said pair, during a determined period of time (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform, shown to be a uni-directional positive waveform; figures 1 and 11-13; paragraphs [0148, 0150-0154]); E) deactivating the pair of electrical field transducers selected in step (B) (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform before switching off for the next pair; figures 1 and 11-13; paragraphs [0148, 0150-0154]); F) increasing an index for electrical field transducers and comparing the electrical field transducers index with the maximum number of pairs of electrical field transducers (the next pair of electrodes of the composite waveform is selected is selected to be added; figures 1 and 11-13; paragraphs [0148, 0150-0154]); - if the electrical field transducers index is greater than the maximum number of pairs of electrical field transducers, making the index for the electrical field transducers equal to the value defined in step (A) and returning to step (B) (when each of the selected electrode pairs have pulsed, the next cycle begins, going back to the first pair; figures 1 and 11-13; paragraphs [0148, 0150-0154]); - if the index of the electrical field transducers is less than or equal to the maximum number of pairs of electrical field transducers, return to step (B) (the next pair of electrodes of the composite waveform generates their pulse; figures 1 and 11-13; paragraphs [0148, 0150-0154]); wherein the electrical field transducers index is less than the maximum number of pairs of electrical field transducers (the number of active electrode pairs and the simulation point can be controlled via the interface using sliders 16, with the demonstrating patterns using less than the total number of electrodes; figures 11-13 and 16; paragraphs [0148, 0150-0154, 0167, 0169]), and the arrangement of electromagnetic transducers has "n" pairs of electrical field transducers with "n" being a natural number greater than two (multiple pairs of electrodes, for example 8 pairs; figures 1 and 11-13; paragraphs [0148, 0150-0154]).

As for claim 13, Gillbe discloses the method of Claim 12, wherein, after step (C), there is a step (D) in which the polarity of the pair of electrical field transducers selected in step (B) is inverted in relation to the polarity of step (C) (the electrodes may use a bi-directional balanced waveform switching between forward and reverse pulses; figures 1 and 6; paragraphs [0149]).

As for claim 14, Gillbe discloses the method of Claim 1, wherein step (b) is executed in a computing unit and the activation pattern follows the steps of: A) defining a magnetic transducers index and a maximum number of magnetic transducers (the number of active electrode pairs and the simulation point can be controlled via the interface using sliders 16, and the simulators may use magnetic energy; figures 16; paragraphs [0167, 0169, 0200, 0242]); B) selecting a magnetic field transducer from the arrangement of electromagnetic transducers simultaneously in a position defined for the magnetic field transducers index of step (A) (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform; figures 1 and 11-13; paragraphs [0148, 0150-0154]); C) activating the magnetic transducer selected in step (B) for a determined period of time and going to step (D) (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform, shown to be a uni-directional positive waveform; figures 1 and 11-13; paragraphs [0148, 0150-0154]); D) deactivating the magnetic transducer selected in step (B) and going to step (E) (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform before switching off for the next pair; figures 1 and 11-13; paragraphs [0148, 0150-0154]); E) increasing a magnetic transducers index and comparing the magnetic transducers index with the maximum number of magnetic transducers (the next pair of electrodes of the composite waveform is selected is selected to be added; figures 1 and 11-13; paragraphs [0148, 0150-0154]); - if the magnetic transducers index is greater than the maximum number of magnetic transducers, make the magnetic transducers index equal to the value defined in step (A) and returning to step (B) (the next pair of electrodes of the composite waveform generates their pulse; figures 1 and 11-13; paragraphs [0148, 0150-0154]); - if the magnetic transducers index is less than or equal to the maximum number of magnetic transducers, return to step (B) (the number of active electrode pairs and the simulation point can be controlled via the interface using sliders 16, with the demonstrating patterns using less than the total number of electrodes; figures 11-13 and 16; paragraphs [0148, 0150-0154, 0167, 0169]); wherein the magnetic transducers index is less than the maximum number of magnetic transducers (multiple pairs of electrodes, for example 8 pairs; figures 1 and 11-13; paragraphs [0148, 0150-0154]).

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IB19/51005

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

-Continued from Box V: Citations and Explanations-

As for claim 15, Gillbe discloses a device for stimulating a tissue, with electromagnetic fields (a stimulator using an array of electrodes to stimulate tissue, for example a limb 08 with arrays 06 and 07 which surround the limb; figures 1- 3; paragraphs [0113, 0115, 0116]), the device comprising: - a computing unit (microprocessor 90; figure 18; paragraph [0187]); - an external power source connected to the computing unit (the battery 108 may be charged by an external charging unit and feeds the microprocessor 108; figure 18; paragraphs [0200]); - a decoupling circuit connected to the external power source and to the computing unit (charging and battery control 99; figure 18; paragraphs [0200]); - a switching circuit connected to the external power source, to the decoupling circuit and to the computing unit (switching elements connect each of the outputs to the power supply, battery, and microprocessor; figure 18; paragraphs [0187-0191]); and - an arrangement of electromagnetic transducers connected to the computing unit and to the switching circuit (the electrodes are connected to each of the outputs which connect to switching to connect to the power supply, battery, and microprocessor; figure 18; paragraphs [0187-0191]); wherein the computing unit implements a method for electromagnetic stimulation of a tissue (a stimulator using an array of electrodes to stimulate tissue, for example a limb 08 with arrays 06 and 07 which surround the limb; figures 1- 3; paragraphs [0113, 0115, 0116]), the method comprising the steps of: a) disposing an arrangement of electromagnetic transducers encompassing a volume containing a tissue (a stimulator using an array of electrodes to stimulate tissue, for example a limb 08 with electrode arrays 06 and 07 which surround the limb; figures 1- 3; paragraphs [0113, 0115, 0116]); and b) applying an electromagnetic field stimulus to a tissue through the arrangement of electromagnetic transducers according to an activation pattern for a determined period of time (a composite waveform 01 is created to effect the excitable tissue, the waveform being created by series of component waveforms A-E between pairs of electrode A1, A2,-E2 according to the pattern of fig. 1; figures 1-3; paragraphs [0114-0116]); wherein the activation pattern makes it possible to vary the intensity and direction of an electromagnetic field vector produced by the arrangement of electromagnetic transducers (the voltage applied to opposing electrodes creates a field according to the vector plot of fig. 17 where the direction and magnitude of the field at any point resulting from the magnitude and current provided to each electrode, with resulting field from a combination of pairs being formed from a matrix; figures 1-3 and 17A-17B; paragraphs [0177-0181]).

As for claim 16, Gillbe discloses the device of Claim 15, wherein step (b) is executed in a computing unit and the activation pattern follows the steps of: A) defining an electrical field transducers index with an initial value and a maximum number of pairs of electrical field transducers in the computing unit (the number of active electrode pairs and the simulation point can be controlled via the interface using sliders 16; figures 16; paragraphs [0167, 0169]); B) selecting a pair of electrical field transducers from the arrangement of electromagnetic transducers simultaneously in a position defined for the electrical field transducers index of step (A) (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform; figures 1 and 11-13; paragraphs [0148, 0150-0154]); C) activating the pair of electrical field transducers selected in step (B) with a determined polarity such that an electrical field transducer of said pair has positive electrical potential in relation to the other electric field transducer of said pair, during a determined period of time (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform, shown to be a uni-directional positive waveform; figures 1 and 11-13; paragraphs [0148, 0150-0154]); E) deactivating the pair of electrical field transducers selected in step (B) (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform before switching off for the next pair; figures 1 and 11-13; paragraphs [0148, 0150-0154]); F) increasing an index for electrical field transducers and comparing the electrical field transducers index with the maximum number of pairs of electrical field transducers (the next pair of electrodes of the composite waveform is selected to be added; figures 1 and 11-13; paragraphs [0148, 0150-0154]), - if the electrical field transducers index is greater than the maximum number of pairs of electrical field transducers, making the index for the electrical field transducers equal to the value defined in step (A) and returning to step (B) (when each of the selected electrode pairs have pulsed, the next cycle begins, going back to the first pair; figures 1 and 11-13; paragraphs [0148, 0150-0154]); - if the index of the electrical field transducers is less than or equal to the maximum number of pairs of electrical field transducers, return to step (B) (the next pair of electrodes of the composite waveform generates their pulse; figures 1 and 11-13; paragraphs [0148, 0150-0154]); wherein the electrical field transducers index is less than the maximum number of pairs of electrical field transducers (the number of active electrode pairs and the simulation point can be controlled via the interface using sliders 16, with the demonstrating patterns using less than the total number of electrodes; figures 11-13 and 16; paragraphs [0148, 0150-0154, 0167, 0169]), and the arrangement of electromagnetic transducers has "n" pairs of electrical field transducers with "n" being a natural number greater than two (multiple pairs of electrodes, for example 8 pairs; figures 1 and 11-13; paragraphs [0148, 0150-0154]).

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IB19/51005

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

-Continued from Box V: Citations and Explanations-

As for claim 17, Gillbe discloses the device of Claim 15, wherein step (b) is executed in a computing unit and the activation pattern follows the steps of: A) defining an electrical field transducers index with an initial value and a maximum number of pairs of electrical field transducers in the computing unit (the number of active electrode pairs and the simulation point can be controlled via the interface using sliders 16; figures 16; paragraphs [0167, 0169]); B) selecting a pair of electrical field transducers from the arrangement of electromagnetic transducers simultaneously in a position defined for the electrical field transducers index of step (A) (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform; figures 1 and 11-13; paragraphs [0148, 0150-0154]); C) activating the pair of electrical field transducers selected in step (B) with a determined polarity such that an electrical field transducer of said pair has positive electrical potential in relation to the other electric field transducer of said pair, during a determined period of time (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform, shown to be a uni-directional positive waveform; figures 1 and 11-13; paragraphs [0148, 0150-0154]); E) deactivating the pair of electrical field transducers selected in step (B) (a pair of electrodes may be combined to produce a single component waveform at a single time, where multiple pairs of electrodes are combined over multiple time periods with each pair switching on to create a given composite waveform before switching off for the next pair; figures 1 and 11-13; paragraphs [0148, 0150-0154]); F) increasing an index for electrical field transducers and comparing the electrical field transducers index with the maximum number of pairs of electrical field transducers (the next pair of electrodes of the composite waveform is selected to be added; figures 1 and 11-13; paragraphs [0148, 0150-0154]); - if the electrical field transducers index is greater than the maximum number of pairs of electrical field transducers, making the index for the electrical field transducers equal to the value defined in step (A) and returning to step (B) (when each of the selected electrode pairs have pulsed, the next cycle begins, going back to the first pair; figures 1 and 11-13; paragraphs [0148, 0150-0154]); - if the index of the electrical field transducers is less than or equal to the maximum number of pairs of electrical field transducers, return to step (B) (the next pair of electrodes of the composite waveform generates their pulse; figures 1 and 11-13; paragraphs [0148, 0150-0154]); wherein the electrical field transducers index is less than the maximum number of pairs of electrical field transducers (the number of active electrode pairs and the simulation point can be controlled via the interface using sliders 16, with the demonstrating patterns using less than the total number of electrodes; figures 11-13 and 16; paragraphs [0148, 0150-0154, 0167, 0169]), and the arrangement of electromagnetic transducers has "n" pairs of electrical field transducers with "n" being a natural number greater than two (multiple pairs of electrodes, for example 8 pairs; figures 1 and 11-13; paragraphs [0148, 0150-0154]).

As for claim 18, Gillbe discloses the device of Claim 15, wherein the computing unit is a special purpose computing unit comprising a central processor unit (CPU) connect to the oscillators from a first oscillator, a second oscillator to an oscillator "N" each oscillator having an activation signal output (the microprocessor 90 connects to a number of output stages 91-93 which form the component pulses of the electrodes, of which up to 16 outputs are provided; figures 18; paragraphs [0188]); wherein "N" is a natural number equal or greater than zero (the microprocessor 90 connects to a number of output stages 91-93 which form the component pulses of the electrodes, of which up to 16 outputs are provided; figures 18; paragraphs [0188]).

As for claim 19, Gillbe discloses the device of Claim 15, wherein the central processor unit is also connected to a peripheral device selected among others, from storage devices such as a memory unit, a database and a hard drive, input devices such as a keyboard, a camera, a touchscreen display, and a scanner, output devices such as a display, and a printer (microprocessor 90 connects to the patient controller 87 with program storage 103, an LCD and keypad 100 and configuration system 88 which is a pc based system 106; figures 18; paragraphs [0187, 0201, 0202]).

Claims 1-19 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.