



(51) International Patent Classification:
A61B 5/16 (2006.01)

(21) International Application Number:

PCT/US2019/066900

(22) International Filing Date:

17 December 2019 (17.12.2019)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/780,430

17 December 2018 (17.12.2018) US

(71) Applicant: **KING-DEVICK TEST, INC.** [US/US]; 2001
Butterfield Road, Suite 1025, Downers Grove, Illinois
60515 (US).

(72) Inventor: **DEVICK, Steven**; c/o King-Devick Test, LLC,
Two Mid America Plaza, Suite 110, Oakbrook Terrace, IL
60181 (US).

(74) Agent: **KENNY, Stephen, J.** et al.; Foley Hoag LLP, 155
Seaport Boulevard, Boston, MA 02210-2600 (US).

(81) Designated States (*unless otherwise indicated, for every
kind of national protection available*): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP,
KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(54) Title: METHODS AND SYSTEMS OF PREDICTIVE SCREENING AND MONITORING MIGRAINE ATTACKS USING
THE KING-DEVICK TEST

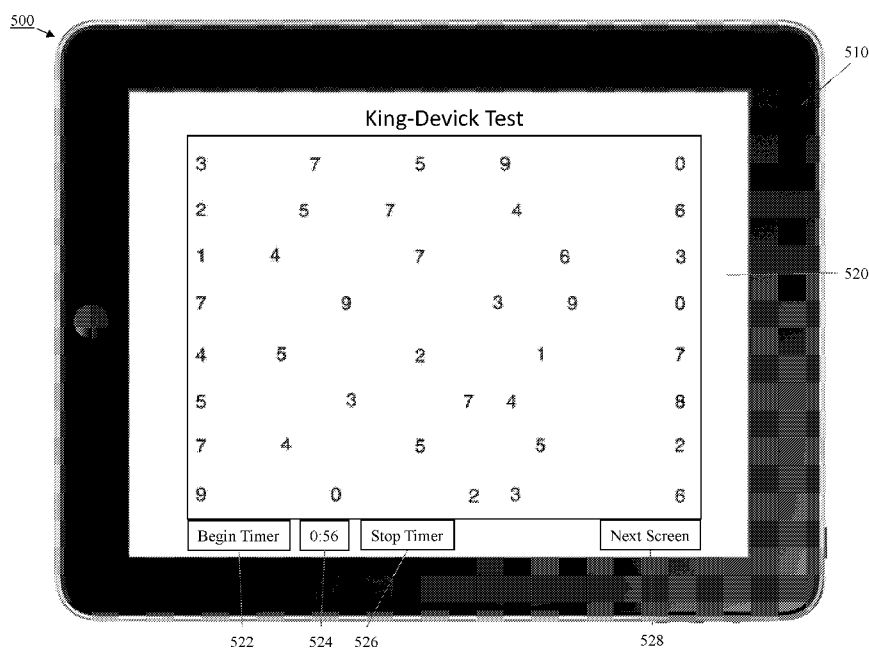


FIG. 5A

(57) Abstract: Methods, computer program products, and systems of screening and/or monitoring a person for Migraine attack using the King-Devick Test are provided. In various embodiments, the method includes providing a display and a timing device, generating, for display, a plurality of alphanumeric symbols, the plurality of alphanumeric symbols having a non-uniform spacing between adjacent alphanumeric symbols, providing an indication to the person to begin reading aloud the plurality of alphanumeric symbols, determining, with the timing device, a completion time to read the plurality of alphanumeric symbols, determining a difference between the completion time and a baseline time, and when the difference is greater than a predetermined threshold, providing an indication that the person has Migraine attack.



(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

METHODS AND SYSTEMS OF PREDICTIVE SCREENING AND MONITORING MIGRAINE ATTACKS USING THE KING-DEVICK TEST

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 62/780,430, filed December 17, 2018, which is hereby incorporated by reference in its entirety.

BACKGROUND

[0002] The present disclosure relates generally to techniques for predictive screening and monitoring migraine attacks. In particular, the present disclosure relates to the use of the King-Devick Test (“K-D Test” or the “Test”), an evidence-based tool for the assessment and monitoring of eye movement (oculomotor) disorders such as saccadic dysfunction, for predictive screening and monitoring of migraine attacks.

BRIEF SUMMARY

[0003] According to embodiments of the present disclosure, systems for, methods for, and computer program products for screening a person for Migraine attack using the King-Devick Test. In various embodiments, a method includes providing a display and a timing device. The method includes generating, for display, a plurality of alphanumeric symbols. The plurality of alphanumeric symbols have a non-uniform spacing between adjacent alphanumeric symbols. The method further includes providing an indication to the person to begin reading aloud the plurality of alphanumeric symbols, determining, with the timing device, a completion

time to read the plurality of alphanumeric symbols, determining a difference between the completion time and a baseline time, and when the difference is greater than a predetermined threshold, providing an indication that the person has Migraine attack.

[0004] In various embodiments, the plurality of alphanumeric symbols includes randomly- or pseudo-randomly generated numbers. In various embodiments, the plurality of alphanumeric symbols includes colors or pictures. In various embodiments, the method further includes displaying a plurality of screens, where each of the plurality of screens have a plurality of alphanumeric symbols. In various embodiments, the plurality of screens are arranged in order of increasing difficulty. In various embodiments, the baseline time corresponds to one or more previously recorded completion times for the person. In various embodiments, the method further includes adjusting the baseline time for the age of the person. In various embodiments, the baseline time is determined based on normative values. In various embodiments, the display screen is provided via a computer screen of a computing device. In various embodiments, the timing device is a timer on the computer. In various embodiments, determining a completion time includes detecting when the person begins recitation of the plurality of alphanumeric symbols and detecting when the person recites a final symbol of the plurality of alphanumeric symbols.

[0005] In various embodiments, the method further includes recording the number of errors by the person made while reading the plurality of alphanumeric symbols, determining an error rate by comparing the number of errors with a baseline number of errors, and when the error rate is greater than a predetermined error rate, providing an indication that the person has Migraine attack or may be having a Migraine soon. In various embodiments, the baseline number of errors corresponds to a previously recorded number of errors made by the person. In various embodiments, the baseline number of errors corresponds to normative values.

[0006] In various embodiments, the method further includes the step of, when the difference is greater than the predetermined threshold, administering a treatment to the person for Migraine attack. In various embodiments, administering the treatment includes recommending the person undergo additional testing. In various embodiments, administering the treatment includes administering a pharmaceutical composition. In various embodiments, administering

the treatment includes physically isolating (e.g. neck brace; positioning in a recumbent or prostrate position; etc.) the person's head and neck from additional trauma. In various embodiments, administering the treatment occurs immediately after the indication of Migraine attack is provided. In various embodiments, administering the treatment occurs before any other signs or symptoms of Migraine attack are observed. In various embodiments, the method includes repeating testing periodically to observe changes in completion time and number of errors made over time.

[0007] In various embodiments, a computer program product is provided for screening a person for Migraine attack using the King-Devick Test. The computer program product includes a computer readable storage medium having program instructions embodied therewith and the program instructions are executable by a processor to cause the processor to perform a method including generating, for display, a plurality of alphanumeric symbols. The plurality of alphanumeric symbols have a non-uniform spacing between adjacent alphanumeric symbols. The method further includes providing an indication to the person to begin reading aloud the plurality of alphanumeric symbols, determining, with the timing device, a completion time to read the plurality of alphanumeric symbols, determining a difference between the completion time and a baseline time, and when the difference is greater than a predetermined threshold, providing an indication that the person has Migraine attack.

[0008] In various embodiments, the plurality of alphanumeric symbols includes randomly- or pseudo-randomly generated numbers. In various embodiments, the plurality of alphanumeric symbols includes colors or pictures. In various embodiments, the method further includes displaying a plurality of screens, where each of the plurality of screens have a plurality of alphanumeric symbols. In various embodiments, the plurality of screens are arranged in order of increasing difficulty. In various embodiments, the baseline time corresponds to one or more previously recorded completion times for the person. In various embodiments, the method further includes adjusting the baseline time for the age of the person. In various embodiments, the baseline time is determined based on normative values. In various embodiments, the plurality of alphanumeric symbols are displayed on a computer screen of a computing device. In various embodiments, determining a completion time includes detecting when the person begins

recitation of the plurality of alphanumeric symbols and detecting when the person recites a final symbol of the plurality of alphanumeric symbols.

[0009] In various embodiments, the method further includes recording the number of errors by the person made while reading the plurality of alphanumeric symbols, determining an error rate by comparing the number of errors with a baseline number of errors, and when the error rate is greater than a predetermined error rate, providing an indication that the person has a Migraine attack or may be having a Migraine soon. In various embodiments, the baseline number of errors corresponds to a previously recorded number of errors made by the person. In various embodiments, the baseline number of errors corresponds to normative values.

[0010] In various embodiments, a system includes a display, a timing device, and a computing node comprising a computer readable storage medium having program instructions embodied therewith. The program instructions are executable by a processor of the computing node to cause the processor to perform a method including generating, for display, a plurality of alphanumeric symbols. The plurality of alphanumeric symbols have a non-uniform spacing between adjacent alphanumeric symbols. The method further includes providing an indication to the person to begin reading aloud the plurality of alphanumeric symbols, determining, with the timing device, a completion time to read the plurality of alphanumeric symbols, determining a difference between the completion time and a baseline time, and when the difference is greater than a predetermined threshold, providing an indication that the person is currently having a Migraine attack or an impending Migraine attack.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] The foregoing and other objects, features and advantages of the devices, systems, and methods described herein will be apparent from the following description of particular embodiments thereof, as illustrated in the accompanying drawings. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the devices, systems, and methods described herein.

[0012] FIGS. 1-4 depict exemplary test screens as displayed in a K-D Test according to embodiments of the present disclosure.

[0013] FIGS. 5A-5B depict a system for screening patients for migraine attacks according to embodiments of the present disclosure.

[0014] FIG. 6 depicts an exemplary computing node according to embodiments of the present disclosure.

DETAILED DESCRIPTION

[0015] Migraine is a highly prevalent neurological disease, affecting about 1 in 7 people. (Steiner TJ *et al.*, “Migraine: the seventh disabler,” *The Journal of Headache and Pain* 2013, 14:1; GBD 2015. *Lancet*. 2016; 388:1545-1602; Steiner TJ, *et al.* *J Headache Pain*. 2018;19(1):17.) A migraine can cause severe throbbing pain or a pulsing sensation, usually on one side of the head. It is often accompanied by nausea, vomiting, extreme sensitivity to light and sound, and in some instances, a visual aura in the form of a scintillating scotoma. Migraine attacks can cause significant pain for hours to days and can be so severe that the pain is disabling. (Dodick DW. Migraine. *Lancet* 2018; 391:1315–30.) Migraine is the single most disabling medical illness in adults between the ages of 15-49. Migraine patients visit the hospital emergency department at a rate of 1.2 million times per year in the U.S. alone. (GBD 2015. *Lancet*. 2016; 388:1545-1602; Steiner TJ, *et al.* *J Headache Pain*. 2018; 19(1):17.)

[0016] Migraine attacks may progress through several stages: prodrome, aura, headache, and postdrome. The timing and progression of the stages varies significantly from subject to subject, and from attack to attack. (Dodick DW. A Phase-by-Phase Review of Migraine Pathophysiology. *Headache*. 2018 May; 58 Suppl 1:4-16. doi: 10.1111/head.13300.)

[0017] One or two days before the headache phase of migraine, subjects may experience symptoms that signal an imminent headache phase, and in some, a neurological (aura) phase. The symptoms of the prodromal phase include difficulty concentrating or cognitive changes, mood changes, food cravings or loss of appetite, muscle stiffness (especially in the neck),

increased thirst and urination, and/or frequent yawning. While up to 70% of patients experience prodromal symptoms, the majority do not recognize these symptoms as the beginning of the Migraine attack.

[0018] Aura may occur before the headache phase but can also overlap with the later headache phase. Aura refers to reversible neurological symptoms that evolve over at least 5 minutes and resolve within 60 minutes, although approximately 20% of patients experience aura symptoms lasting longer than 60 minutes. Symptoms of aura may include visual, sensory, language, motor symptoms or symptoms that reflect brainstem dysfunction. Only about 20-30% of patients experience aura symptoms and the vast majority of patients who experience aura symptoms, also experience migraine attacks without aura. It is rare for patients with migraine with aura to have aura symptoms with every attack, and only two attacks associated with aura are required to render a diagnosis of “migraine with aura.”

[0019] The headache phase is invariably the most disabling portion of the migraine attack and usually lasts from four (4) to seventy-two (72) hours. During the headache phase, a subject may experience moderate to severe pain on one side or both sides of the head. The pain typically feels throbbing or pulsating. Additional symptoms almost always include sensitivity to light, sound, and sometimes sensitivity to odor and/or touch, nausea and/or vomiting, neck pain/stiffness, blurred vision; vertigo and/or dizziness. The headache phase invariably begins with mild pain and patients are often not able to distinguish between a tension-type headache and migraine and this leads to a delay in the administration of acute treatment, progression of an attack, and suboptimal acute treatment efficacy.

[0020] The postdromal phase follows the headache phase and may last up to 48 hours. It typically includes the type of symptoms experienced in the prodromal phase.

[0021] Migraine treatments fall into two broad categories: (1) treatment (pain-relieving) medications taken during migraine attacks and designed to reduce the intensity or stop symptoms, and (2) preventive medications taken on a predetermined basis (*e.g.*, regularly, often on a daily basis), or injected on a predetermined (*e.g.*, quarterly) basis, to reduce the severity or frequency of migraine attacks. Physicians typically prescribe treatment based on the frequency and severity of attacks, the degree of disability, and/or other medical conditions.

[0022] Pain-relieving medications and/or pharmaceutical compounds may be taken as soon as a subject experiences signs or symptoms of a migraine attack. Aspirin, ibuprofen, and/or acetaminophen may help relieve mild migraine in some people. However, these medications are typically not effective alone for moderate and/or severe migraine attacks, and if taken too often or for long periods of time, can lead to gastric ulcer, gastrointestinal bleeding, hepatic or kidney toxicity, myocardial infarction (NSAIDS), and medication-overuse headache. Triptans may effectively relieve the pain and other symptoms that are associated with migraine in about two-thirds of patients. However, only about 30% achieve complete relief of pain within 2 hours, and only 1 in 5 patients experience complete and sustained relief of pain over the ensuing 24 hours. Only about 15% of patients in the United States currently use triptans, largely due to lack of efficacy or intolerable side effects. Side effects of triptans include nausea, dizziness, drowsiness chest tightness, paresthesias, lightheadedness, limb heaviness, and weakness. Triptans are not recommended for people with established cardiovascular, cerebrovascular, or peripheral vascular disease, severe hypertension, or other significant risk factors for cardiovascular disease. Triptans are also not recommended for use in women who are pregnant. Ergots, such as dihydroergotamine ergotamine tartrate and caffeine combination drugs, are also contraindicated in patients with vascular disease because of the potential for vasoconstriction like triptans, and are seldom used and generally not as effective as triptans when administered orally due to poor absorption and low bioavailability. Ergots, like triptans and analgesics used for migraine, are most effective when taken soon after migraine symptoms start when pain intensity is mild. Ergotamine may worsen nausea and vomiting, and may also lead to medication-overuse headache. Opioid medications are sometimes used to treat migraine pain for people who cannot take triptans or ergots. Opioid medications, even when taken about once per week on average, can lead to medication overuse headache, and are prone to habituation, dependence, addiction, and accidental overdose. They are generally not recommended for use in patients with migraine.

[0023] Preventive medications may be prescribed for subjects having four (4) or more migraine attacks a month; in patients for whom acute treatment is contraindicated, not tolerated, not effective, or in patients with a history of or predisposition to medication overuse; for patients who experienced complications of migraine such as migrainous infarction; or for patients with

severe prolonged aura symptoms, migraine with brainstem aura, or hemiplegic migraine- regardless of frequency. In some patients, preventive medications can reduce the frequency, severity and length of migraine attacks and may increase the effectiveness of symptom-relieving medicines used during migraine attacks. However, only about 50% of patients respond (experience a 50% or greater reduction in migraine attacks or days with migraine) in the first 3-6 months after initiation, and only 15-20% can adhere to oral preventive medications one year after starting the drug. Most patients discontinue currently available oral preventive medications due to lack of efficacy or more often, the occurrence of intolerable side effects.

[0024] In view of the fact that acute treatment efficacy is most effective when treatment is administered early in the course of an attack while pain intensity is mild; suboptimal acute treatment efficacy is a significant and independent risk factor for migraine progression from an episodic to chronic disease state; prodromal symptoms are often not recognized; and the mild pain phase makes the distinction between tension-type headache and a migraine attack often difficult for patients, there is a need for a sensitive, easily-administered and interpretable tool or marker that can accurately detect a migraine attack in its early stages and facilitate the early administration of acute treatment which could prevent the progression of and reduce the severity and disability of an attack.

[0025] The embodiments will now be described more fully hereinafter with reference to the accompanying figures, in which exemplary embodiments are shown. The foregoing may, however, be embodied in many different forms and should not be construed as limited to the illustrated embodiments set forth herein.

[0026] The K-D Test is generally administered by providing a display and a timing device (*e.g.*, a computing device). On the display, one or more arrangements of objects and/or alphanumeric symbols may be presented to a subject being evaluated. Throughout the specification, the terms “arrangement of symbols,” “test card(s),” and “test screen(s)” may be used interchangeably. In some embodiments, the display includes a deck of cards, and each arrangement of symbols is provided on a card. In other embodiments, the display is a screen, such as an LCD/LED/OLED screen, of a general purpose computing device, computer, mobile

device, smartphone, or tablet, and each arrangement of symbols is displayed on the screen of the device.

[0027] The K-D Test typically includes arrangements of symbols on one or more (*e.g.*, four) screens, as illustrated in FIGS. 1-4. Each arrangement on a screen may include a series of alphanumeric symbols arranged in rows, with a staggered or irregular spacing between adjacent alphanumeric symbols in each row. Any suitable number of rows of alphanumeric symbols may be provided (*e.g.*, one, two, five, ten, fifteen, twenty, *etc.*). A demonstration screen or arrangement of symbols may be displayed first. The demonstration screen includes lead-lines to assist the subject in reading the arrangement of numbers in the pattern shown, *i.e.*, horizontally across a row and proceeding from the right-most side of the top row to the left-most side of the next row until the bottom row is completed. In various embodiments, the direction of the lead lines may be reversed. For example, the lead-lines may instruct the subject to read right-to-left and/or bottom-to-top. In some embodiments, each of the subsequent screens of the K-D Test follows the same arrangement as the demonstration screen. Each subsequent test screen may be progressively harder to read than the previous test screen. For example, the first test screen may include horizontal lead-lines that connect the alphanumeric symbols within individual rows, but may not include lines connecting the rows as in the demonstration card. The second test screen omits the lead-lines connecting the alphanumeric symbols within each row and may include wide spacing of alphanumeric characters within the horizontal rows. The third test screen may be more difficult than the previous test screens where, for example, the alphanumeric symbols within each row are closer together (*i.e.*, have reduced vertical spacing) which creates visual crowding. In various embodiments, the horizontal spacing between the alphanumeric symbols in each row may be reduced to create visual crowding and/or additional alphanumeric symbols may be included to thereby create visual crowding.

[0028] During the K-D Test, the subject is instructed to read one or more screens successively, *e.g.*, beginning with a Demonstration screen, followed by Test screen I (FIG. 2), optionally followed by Test screen II (FIG. 3), and optionally followed by Test screen III (FIG. 4). One or more additional test screens may follow in various embodiments. For certain subjects, *e.g.*, those having more advanced Migraine, a single test screen may be used. For example, a single screen may include one test card labelled as Test I. In various embodiments,

the demonstration card may be included. As a part of the instructions, the subject is instructed to read aloud the alphanumeric symbols provided on the display in a specified order, and to read such symbols as quickly and as accurately as possible. In various embodiments, the subject can be directed not to move their head during the Test. Instructions may be displayed any time prior to the commencement of the Test (*i.e.*, prior to the demonstration card being displayed). A timer may be used to measure the amount of time needed by the subject to complete the Test. Errors committed in the naming sequence (*e.g.*, additions, omissions, reversals, *etc.*) are tallied and recorded.

[0029] The K-D Test, widely recognized as a tool to evaluate saccadic eye movements, is ideally suited for use as a rapid, easy-to-administer screening tool to evaluate individuals having, suspected of having, or at risk for developing Migraine attack. Under normal conditions, the K-D Test is administered, and an objective conclusion is reached, as fast as about one minute for adults. The K-D Test can therefore be used in a variety of situations in which rapid, easy-to-administer Migraine attack screening is beneficial, such as during an examination by a medical professional or as part of a home- or self-examination program designed for people having, suspected of having, or at risk for developing Migraine attacks.

[0030] In various embodiment, the K-D Test is administered as part of general screening examinations to healthy patient populations in order to provide a rapid, objective, and easy-to-administer screen for Migraine attacks or other causes of suboptimal nervous system function.

[0031] In another embodiment, the K-D Test is administered to persons having Migraine attacks, suspected of having Migraine attacks, or at risk for developing Migraine attacks as a method for early detection of Migraine attacks, or as a method to monitor progression of Migraine attacks and/or quality of life. Because oculomotor dysfunctions are a common early biomarker of Migraine attacks, the K-D Test is particularly useful as an objective method to screen for Migraine attacks. In this scenario, the K-D Test is administered soon after the patient or a person observing the patient first notices any subtle Migraine symptoms and/or signs, and the result informs the patient whether or not he or she should seek medical treatment for Migraine. Moreover, due to its high level of sensitivity, the K-D Test is also administered to patients at risk for developing Migraine attacks (*e.g.*, family history of migraine) before the onset

of any perceivable Migraine attack symptoms, regardless of how subtle, providing a very early method of detection. Subjects could self-administer the K-D Test (or have it administered to them, *e.g.*, in the presence of a health care provider) every day, regardless of whether they feel well, as an easy way to detect minute changes in Migraine attack status. Those results could be electronically transmitted to the person's doctor if there is a reduction in performance time or errors in order to help the doctor make treatment decisions.

[0032] Fig. 1 illustrates an arrangement of alphanumeric symbols on a demonstration card of the K-D Test. The arrangement includes a series of numbers arranged horizontally in five (5) rows, with lead-lines to assist the person to read the arrangement of number in the pattern shown, *i.e.*, from left to right and from top to bottom. During the K-D Test, the subject receives instructions to read aloud symbols provided on the display in a specified order. The instructions may be provided visually through, *e.g.*, text, and/or audibly through, *e.g.*, voice. The subject may be directed not to move their head during the K-D Test. These instructions may be displayed prior to the commencement of the K-D Test. A timer (*e.g.*, integrated software timer) may be used to measure the amount of time needed by the person to complete the K-D Test. In some embodiments, the K-D Test uses three (3) test screens display sequentially to the subject via, for example, a tablet.

[0033] In various embodiments, as described above, each subsequent test screen may be progressively harder to read than the previous test screen. For example, as illustrated in FIG. 2, the first test screen has horizontal lines that connect the alphanumeric symbols within individual rows, but does not include lines connecting the rows as in the demonstration card of FIG. 1. In another example, as illustrated in FIG. 3, the second test screen omits the lines connecting the symbols within each row. In yet another example, as illustrated in FIG. 4, the third test screen is more difficult than the previous two screens because the rows of alphanumeric symbols are closer together (*i.e.*, have reduced vertical spacing) which creates visual crowding. During the K-D Test, the person is instructed to read several arrangements of symbols, *e.g.*, Test screen I (FIG. 2), followed by Test screen II (FIG. 3), and followed by Test screen III (FIG. 4). For certain test subjects, only a single test screen is used, *e.g.*, for subjects with more advanced Migraine.

[0034] In various embodiments, subsequent test screens may be easier in reading difficulty, the same reading difficulty, or harder in reading difficulty as the previous screen. In various embodiments, an adaptive module may detect the accuracy and/or time to completion of a test screen and adjust the difficulty of subsequent screens of the K-D Test. Each individual screen may have a predetermined time and/or predetermined acceptable number of errors (which may be represented by a mistake percentage). In various embodiments, more difficult test screens (*e.g.*, Fig. 4) have a higher number of acceptable errors compared to the number of acceptable errors for easier test screens (*e.g.*, Fig. 2). In various embodiments, more difficult test screens (*e.g.*, Fig. 4) have the same number of acceptable errors compared to the number of acceptable errors for easier test screens (*e.g.*, Fig. 2). In various embodiments, later test screens (*e.g.*, Fig. 4) have a lower number of acceptable errors compared to the number of acceptable errors for earlier test screens (*e.g.*, Fig. 2).

[0035] In various embodiments, the alphanumeric symbols displayed on each test screen may be randomly generated for each test screen. In various embodiments, each test screen may be different from other test screens. In various embodiments, a predetermined set of alphanumeric symbols may be generated, and the same predetermined set may be randomly arranged on one or more of the test screens (*e.g.*, each test screen). In various embodiments, the K-D Test may use any suitable visual cue, such as, for example, shapes (*e.g.*, square, triangle, circle, and/or octagon), objects (*e.g.*, apple, phone, lightbulb), and/or colors (*e.g.*, red, blue, green, and/or yellow) in the test screens for the subject to identify in a particular order as described above.

[0036] In various embodiments, the time to complete the K-D Test is compared to baseline data. In various embodiments, the baseline data may be determined from one or more previously recorded completion times of the K-D Test. Alternatively, the baseline data may be for a particular person's performance on the Test. In this case, baseline measurements may be made for the person, during, for example, routine medical examinations or at some other time. In various embodiments, the individual's baseline data would include the total time to take the Test and the number of errors made while taking the Test as well as the symbol type used (*e.g.*, alphanumerics, pictures, objects, greek letters, *etc.*). In various embodiments, if multiple K-D Tests were taken, the baseline time and number of errors could be averages. In various

embodiments, if there is an extended time period between tests, the baseline results may be adjusted to account for increasing age of the person being tested. For example, as a person ages, their baseline score may become slower. In another example, as a person ages, their baseline score may become faster. In various embodiments, those baseline results may be made available by way of the person's medical records or other method of recordation for purposes of comparison if needed.

[0037] In various embodiments, the baseline data may be determined from normative values *e.g.*, a statistical data for the person's age group, regarding the range of time necessary to complete the Test and the number of errors that a person of an age group can score and still have a "normal" Test result. In various embodiments, the normative values may be determined from large samples of subjects and may be found in published literature, such as academic journals. In various embodiments, the normative values may be adjusted based on age.

[0038] In various embodiments, the timer begins recording time once the first arrangement of symbols or test screen is displayed. In various embodiments, the touch-sensitive display is used by the person to advance from one test screen to the next test screen, and then to stop elapsed time when the final test screen is completed. In various embodiments, the timer can be paused between test screens. For example, the time is paused when "break" screens are displayed between successive test screens. In various embodiments, the timer may be visually displayed to the user. In various embodiments, the timer may be hidden from the user (*e.g.*, to prevent distractions). In various embodiments, the total time necessary for the person to complete all test screens is recorded as the completion time. In various embodiments, completion times are separately recorded for each individual test screen.

[0039] In some embodiments, the K-D Test is administered on a series of printed cards. In some embodiments, the timing device is a stopwatch.

[0040] In various embodiments, the timer may begin recording time once the subject begins reciting the alphanumeric symbols on the particular test screen. In various embodiments, the timer may begin recording time once a button (*e.g.*, one labelled "Record Time") is pressed on the display (*e.g.*, if a touch-screen display) or the computing device. In various embodiments, the timer may stop recording time once the subject finishes reciting the final alphanumeric

symbol on the particular test screen. In various embodiments, the timer may begin recording time once a button (*e.g.*, one labelled “Stop Timer”) is pressed on the display (if a touch-screen display) or the computing device.

[0041] A Test administrator can use on the timer to time the Test and follow along on an answer key. The answer key lists the correct sequence of symbols for each Test. The number of errors made during the Test is also recorded by a test administrator.

[0042] In various embodiments, the test data is compared to baseline data. In various embodiments, a result is considered “normal” if the completion time is the same or shorter than the baseline time and/or the total number of errors is below the baseline number of errors. In various embodiments, a result is considered “abnormal” if the total time is longer than the baseline time and/or the total number of errors is greater than the baseline number of errors. In various embodiments, a slight decline in performance as a person ages is normal. In various embodiments, a multiplier can be applied to a person’s baseline data to account for an anticipated decline in performance due to age.

[0043] In various embodiments, a determination about whether the completion time and number of errors is “normal” or “abnormal” may be made by comparison to a chart. In various embodiments, the chart may be uploaded onto the tablet or computer, and may include either the individualized baseline data, or generalized baseline data for the person’s demographic, *e.g.*, age. In some embodiments, the processor is able to provide a determination about whether a completion time is “normal” or “abnormal” by a comparison the completion time to the baseline time. In various embodiments, the data may be stored in an electronic health record (“EHR”).

[0044] In various embodiments, a determination about whether the completion time and number of errors is “normal” or “abnormal” may be made by computing a difference between the completion time and a previously recorded baseline and/or a normative value. In various embodiments, if the difference is greater than a predetermined value, the system may indicate to the subject and/or healthcare provider that the subject may be experiencing, has experienced, or may experience a Migraine attack. In various embodiments, the difference between the baseline and a recorded time for a subject experiencing the Migraine attack stage compared to interictal phase is 6.3 seconds or more. In various embodiments, for subjects that have migraine with aura,

the difference may be 5 seconds slower during migraine attacks compared to subjects with migraine without aura. In various embodiments, one skilled in the art will recognize that any difference between a completion time and a baseline time may be indicative of potential Migraine attack, depending on the particular subject.

[0045] In various embodiments, K-D Test results for a person testing “abnormal” would then serve as information that is submitted to the person’s physician and such person may be treated as if the person has Migraine attack, or is at risk for developing Migraine attack. In various embodiments, such treatment could include recommending the person undergo additional testing for Migraine attack, referring the person to a neurologist or other specialist for additional testing for Migraine attack, recommending the person be administered a treatment for Migraine attack, or administering the person a treatment (*e.g.*, a pharmaceutical composition) for treating Migraine attack, *etc.* In various embodiments, the K-D Test can be administered to the person periodically, *e.g.*, daily or weekly, to detect minute changes in the person’s Migraine attack status.

[0046] In various embodiments, for patients who take the Test regularly, or frequently enough that they might learn the number patterns and thereby misleadingly improve their scores (perhaps even as their saccadic eye movements degrade), a battery of K-D Tests can be used, in which the spacing of the alphanumeric symbols is preserved but the symbols themselves are changed randomly or pseudo-randomly. In various embodiments, administering the Test on computing device, such as on a suitably-sized tablet computer, can facilitate the use of a virtually limitless number and/or spacing variations. In various embodiments, the spacing of the alphanumeric symbols may be varied randomly or pseudo-randomly, while the symbols themselves are preserved.

[0047] FIGS. 5A-5B illustrate a system 500 for administering the King-Devick Test for screening for and/or monitoring migraine attacks. System 500, which includes a tablet 510 or other computer device having one or more physical processors configured by software which, when executed, perform the operations described herein. The tablet 510 has a user interface including a touch-sensitive display 520 and a timer (not shown, but integrated into the microprocessor of the tablet 510). The display 520 provides a series of screens or arrangement

of symbols that require the person to use saccadic eye movements in order to read aloud quickly and accurately. In some embodiments, the symbols are random numbers, letters, colors, or pictures. Reading aloud is understood to mean identifying the number or letter and/or orally naming the color or picture image, *e.g.*, “One,” “Red,” or “Apple.” The display 520 shown in FIG. 5A is currently displaying the test screen of FIG. 3.

[0048] The touch-sensitive display 520 further includes a button 522 having the label “Begin Timer.” Button 522 may provide the subject and/or a healthcare professional the ability to start the timer manually. The touch-sensitive display 520 further includes a button 524 for displaying the elapsed time. The touch-sensitive display 520 further includes a button 526 having the label “Stop Timer.” Button 526 may provide the subject and/or a healthcare professional the ability to stop the timer manually. The touch-sensitive display 520 further includes a button 528 having the label “Next Screen.” Button 528 may provide the subject and/or a healthcare professional the ability to proceed to the next test screen. In various embodiments, button 528 may be disabled (*e.g.*, “grayed out”) when the option to move to the next screen is not available, such as, when the subject has not finished the current test screen or if no additional test screens are available in the K-D Test.

[0049] FIG. 5B illustrates the system 500 displaying a results screen on the display 520. In particular, the results show the current completion time 530, the baseline completion time 532, a difference 534 between the completion time and baseline time, and an indication 536 that the subject seek additional testing and/or treatment for Migraine attack.

[0050] In various embodiments, the system 500 may include an automatic symbol randomization module. The automatic symbol randomization module may generate a plurality of random symbols for each individual test screen. During the automatic symbol randomization module, automatic speech recognition software is utilized to detect and estimate errors in the subject’s stated symbol sequence as compared to the randomly generated symbol sequence displayed as well as record the subject’s audio performance during the K-D Test. Following completion of the K-D Test, the user may replay the subject’s recorded performance and adjustments to the automatic speech recognition error estimate may be made.

[0051] In various embodiments, the system 500 may include voice recognition module that utilizes, for example, natural language processing as is known in the art. The voice recognition module may recognize input speech from a user and convert the input speech into text for processing. The text may be parsed and the parsed text compared to the correct answers to the alphanumeric symbols displayed on the system 500. In various embodiments, the voice recognition module may automatically begin the timer when the system determines that the subject begins the test by saying the first alphanumeric symbol. In various embodiments, the voice recognition module may stop the test when the system detects that the subject has said the last alphanumeric symbol on the test screen.

[0052] In various embodiments, an amount of time elapsed is recorded from when the first speech is detected by the voice recognition module to when the final alphanumeric symbol is detected by the voice recognition module.

[0053] In some embodiments, the system 500 includes a database (which may be stored locally or in the cloud) with which to compare the completion time with a baseline time to complete reading the one or more series of symbols. In some embodiments, the system 500 can make a determination whether the person has an “abnormal” result based on comparing the completion time with the baseline time.

[0054] The above systems, devices, methods, processes, and the like may be realized in hardware, software, or any combination of these suitable for an application. The hardware may include a general-purpose computer and/or dedicated computing device. This includes realization in one or more microprocessors, microcontrollers, embedded microcontrollers, programmable digital signal processors or other programmable devices or processing circuitry, along with internal and/or external memory. It will further be appreciated that a realization of the processes or devices described above may include computer-executable code created using a structured programming language that may be stored, compiled or interpreted to run on one of the above devices, as well as heterogeneous combinations of processors, processor architectures, or combinations of different hardware and software. In another aspect, the methods may be embodied in systems that perform the steps thereof, and may be distributed across devices in several ways. At the same time, processing may be distributed across devices such as the various

systems described above, or all the functionality may be integrated into a dedicated, standalone device or other hardware. In another aspect, means for performing the steps associated with the processes described above may include any of the hardware and/or software described above. All such permutations and combinations are intended to fall within the scope of the present disclosure.

[0055] Embodiments disclosed herein may include computer program products comprising computer-executable code or computer-usable code that, when executing on one or more computing devices, performs any and/or all the steps thereof. The code may be stored in a non-transitory fashion in a computer memory, which may be a memory from which the program executes (such as random access memory associated with a processor), or a storage device such as a disk drive, flash memory or any other optical, electromagnetic, magnetic, infrared or other device or combination of devices. In another aspect, any of the systems and methods described above may be embodied in any suitable transmission or propagation medium carrying computer-executable code and/or any inputs or outputs from same.

[0056] It will be appreciated that the devices, systems, and methods described above are set forth by way of example and not of limitation. Absent an explicit indication to the contrary, the disclosed steps may be modified, supplemented, omitted, and/or re-ordered without departing from the scope of this disclosure. Numerous variations, additions, omissions, and other modifications will be apparent to one of ordinary skill in the art. In addition, the order or presentation of method steps in the description and drawings above is not intended to require this order of performing the recited steps unless an order is expressly required or otherwise clear from the context. Thus, while particular embodiments have been shown and described, it will be apparent to those skilled in the art that various changes and modifications in form and details may be made therein without departing from the spirit and scope of this disclosure and are intended to form a part of the disclosure as defined by the following claims, which are to be interpreted in the broadest sense allowable by law.

[0057] The following abstract describes a study that demonstrated altered cerebral function during Migraine attacks that can be quantified using the King-Devick Test.

[0058] The King-Devick test (KDT) and visual contrast sensitivity test (VCS) in migraine: The effect of a migraine attack on saccadic eye movements and visual contrast sensitivity by Chia-Chun Chiang, MD, Amaal J. Starling, MD, Juliana VanderPluym, MD, David W. Dodick, MD.

[0059] OBJECTIVE

[0060] To detect an alteration in central nervous system function using KDT and VCS by demonstrating a difference during a migraine attack compared to the inter-ictal (between attack) phase. □

[0061] BACKGROUND

[0062] Migraine is characterized by head pain and other symptoms such as photophobia, cognitive dysfunction and alterations in visual contrast during attacks. The KDT is a timed rapid number naming test that evaluates saccadic eye movements, attention, information processing, and is highly sensitive to altered cerebral function. For VCS, participants are asked to read rows of letters of varying size on an iPad with low contrast level to the background. KDT and VCS have been shown to correlate with neurologic dysfunction in various neurological diseases.

[0063] DESIGN/METHODS

[0064] We included adult subjects with episodic or chronic migraine with or without aura (less than 25 headache days/month). We enrolled on-site Mayo employees, and the KDT and VCS were performed by the same examiner to minimize bias. For each participant, we performed KDT and VCS testing during headache phase of migraine attack, and inter-ictal non-headache phases. Power analysis suggests a sample size of 26 subjects is needed to detect an effect size of 0.8 for both KDT and VCS, with an 80% power and a significance level at 0.05. Subjects served as their own controls.

[0065] RESULTS

[0066] We collected data on 28 subjects. There was a statistically significant difference in the performance of KDT during a migraine attack compared to the interictal baseline. On

average, the KDT score was 6.3 seconds longer during the migraine attack compared to the interictal baseline performance. For VCS (both 100% and 2.5% contrast sensitivity), there was no significant difference between the migraine attack and the interictal baseline.

[0067] CONCLUSIONS

[0068] This study provides objective quantitative data demonstrating altered cerebral function during migraine attacks. Saccadic eye movements may serve as a biomarker for a migraine attack. The KDT could be an effective tool to understand migraine pathophysiology, document the true interictal state, as well as to characterize migraine associated disability during and between attacks.

[0069] With reference to **Fig. 6**, a schematic of an example of a computing node is shown. Computing node **10** is only one example of a suitable computing node and is not intended to suggest any limitation as to the scope of use or functionality of embodiments of the invention described herein. Regardless, computing node **10** is capable of being implemented and/or performing any of the functionality set forth hereinabove.

[0070] In computing node **10** there is a computer system/server **12**, which is operational with numerous other general purpose or special purpose computing system environments or configurations. Examples of well-known computing systems, environments, and/or configurations that may be suitable for use with computer system/server **12** include, but are not limited to, personal computer systems, server computer systems, thin clients, thick clients, handheld or laptop devices, multiprocessor systems, microprocessor-based systems, set top boxes, programmable consumer electronics, network PCs, minicomputer systems, mainframe computer systems, and distributed cloud computing environments that include any of the above systems or devices, and the like.

[0071] Computer system/server **12** may be described in the general context of computer system-executable instructions, such as program modules, being executed by a computer system. Generally, program modules may include routines, programs, objects, components, logic, data structures, and so on that perform particular tasks or implement particular abstract data types. Computer system/server **12** may be practiced in distributed cloud computing environments

where tasks are performed by remote processing devices that are linked through a communications network. In a distributed cloud computing environment, program modules may be located in both local and remote computer system storage media including memory storage devices.

[0072] As shown in **Fig. 6**, computer system/server **12** in computing node **10** is shown in the form of a general-purpose computing device. The components of computer system/server **12** may include, but are not limited to, one or more processors or processing units **16**, a system memory **28**, and a bus **18** that couples various system components including system memory **28** to processor **16**.

[0073] Bus **18** represents one or more of any of several types of bus structures, including a memory bus or memory controller, a peripheral bus, an accelerated graphics port, and a processor or local bus using any of a variety of bus architectures. By way of example, and not limitation, such architectures include Industry Standard Architecture (ISA) bus, Micro Channel Architecture (MCA) bus, Enhanced ISA (EISA) bus, Video Electronics Standards Association (VESA) local bus, and Peripheral Component Interconnect (PCI) bus.

[0074] Computer system/server **12** typically includes a variety of computer system readable media. Such media may be any available media that is accessible by computer system/server **12**, and it includes both volatile and non-volatile media, removable and non-removable media.

[0075] System memory **28** can include computer system readable media in the form of volatile memory, such as random access memory (RAM) **30** and/or cache memory **32**. Computer system/server **12** may further include other removable/non-removable, volatile/non-volatile computer system storage media. By way of example only, storage system **34** can be provided for reading from and writing to a non-removable, non-volatile magnetic media (not shown and typically called a "hard drive"). Although not shown, a magnetic disk drive for reading from and writing to a removable, non-volatile magnetic disk (*e.g.*, a "floppy disk"), and an optical disk drive for reading from or writing to a removable, non-volatile optical disk such as a CD-ROM, DVD-ROM or other optical media can be provided. In such instances, each can be connected to bus **18** by one or more data media interfaces. As will be further depicted and

described below, memory **28** may include at least one program product having a set (e.g., at least one) of program modules that are configured to carry out the functions of embodiments of the invention.

[0076] Program/utility **40**, having a set (at least one) of program modules **42**, may be stored in memory **28** by way of example, and not limitation, as well as an operating system, one or more application programs, other program modules, and program data. Each of the operating system, one or more application programs, other program modules, and program data or some combination thereof, may include an implementation of a networking environment. Program modules **42** generally carry out the functions and/or methodologies of embodiments of the invention as described herein.

[0077] Computer system/server **12** may also communicate with one or more external devices **14** such as a keyboard, a pointing device, a display **24**, etc.; one or more devices that enable a user to interact with computer system/server **12**; and/or any devices (e.g., network card, modem, etc.) that enable computer system/server **12** to communicate with one or more other computing devices. Such communication can occur via Input/Output (I/O) interfaces **22**. Still yet, computer system/server **12** can communicate with one or more networks such as a local area network (LAN), a general wide area network (WAN), and/or a public network (e.g., the Internet) via network adapter **20**. As depicted, network adapter **20** communicates with the other components of computer system/server **12** via bus **18**. It should be understood that although not shown, other hardware and/or software components could be used in conjunction with computer system/server **12**. Examples, include, but are not limited to: microcode, device drivers, redundant processing units, external disk drive arrays, RAID systems, tape drives, and data archival storage systems, etc.

[0078] The present disclosure may be embodied as a system, a method, and/or a computer program product. The computer program product may include a computer readable storage medium (or media) having computer readable program instructions thereon for causing a processor to carry out aspects of the present disclosure.

[0079] The computer readable storage medium can be a tangible device that can retain and store instructions for use by an instruction execution device. The computer readable storage

medium may be, for example, but is not limited to, an electronic storage device, a magnetic storage device, an optical storage device, an electromagnetic storage device, a semiconductor storage device, or any suitable combination of the foregoing. A non-exhaustive list of more specific examples of the computer readable storage medium includes the following: a portable computer diskette, a hard disk, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), a static random access memory (SRAM), a portable compact disc read-only memory (CD-ROM), a digital versatile disk (DVD), a memory stick, a floppy disk, a mechanically encoded device such as punch-cards or raised structures in a groove having instructions recorded thereon, and any suitable combination of the foregoing. A computer readable storage medium, as used herein, is not to be construed as being transitory signals per se, such as radio waves or other freely propagating electromagnetic waves, electromagnetic waves propagating through a waveguide or other transmission media (*e.g.*, light pulses passing through a fiber-optic cable), or electrical signals transmitted through a wire.

[0080] Computer readable program instructions described herein can be downloaded to respective computing/processing devices from a computer readable storage medium or to an external computer or external storage device via a network, for example, the Internet, a local area network, a wide area network and/or a wireless network. The network may comprise copper transmission cables, optical transmission fibers, wireless transmission, routers, firewalls, switches, gateway computers and/or edge servers. A network adapter card or network interface in each computing/processing device receives computer readable program instructions from the network and forwards the computer readable program instructions for storage in a computer readable storage medium within the respective computing/processing device.

[0081] Computer readable program instructions for carrying out operations of the present disclosure may be assembler instructions, instruction-set-architecture (ISA) instructions, machine instructions, machine dependent instructions, microcode, firmware instructions, state-setting data, or either source code or object code written in any combination of one or more programming languages, including an object oriented programming language such as Smalltalk, C++ or the like, and conventional procedural programming languages, such as the “C” programming language or similar programming languages. The computer readable program

instructions may execute entirely on the user's computer, partly on the user's computer, as a stand-alone software package, partly on the user's computer and partly on a remote computer or entirely on the remote computer or server. In the latter scenario, the remote computer may be connected to the user's computer through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be made to an external computer (for example, through the Internet using an Internet Service Provider). In some embodiments, electronic circuitry including, for example, programmable logic circuitry, field-programmable gate arrays (FPGA), or programmable logic arrays (PLA) may execute the computer readable program instructions by utilizing state information of the computer readable program instructions to personalize the electronic circuitry, in order to perform aspects of the present disclosure.

[0082] Aspects of the present disclosure are described herein with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems), and computer program products according to embodiments of the disclosure. It will be understood that each block of the flowchart illustrations and/or block diagrams, and combinations of blocks in the flowchart illustrations and/or block diagrams, can be implemented by computer readable program instructions.

[0083] These computer readable program instructions may be provided to a processor of a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions, which execute via the processor of the computer or other programmable data processing apparatus, create means for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks. These computer readable program instructions may also be stored in a computer readable storage medium that can direct a computer, a programmable data processing apparatus, and/or other devices to function in a particular manner, such that the computer readable storage medium having instructions stored therein comprises an article of manufacture including instructions which implement aspects of the function/act specified in the flowchart and/or block diagram block or blocks.

[0084] The computer readable program instructions may also be loaded onto a computer, other programmable data processing apparatus, or other device to cause a series of operational

steps to be performed on the computer, other programmable apparatus or other device to produce a computer implemented process, such that the instructions which execute on the computer, other programmable apparatus, or other device implement the functions/acts specified in the flowchart and/or block diagram block or blocks.

[0085] The descriptions of the various embodiments of the present disclosure have been presented for purposes of illustration, but are not intended to be exhaustive or limited to the embodiments disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art without departing from the scope and spirit of the described embodiments. The terminology used herein was chosen to best explain the principles of the embodiments, the practical application or technical improvement over technologies found in the marketplace, or to enable others of ordinary skill in the art to understand the embodiments disclosed herein.

WHAT IS CLAIMED IS:

1. A method of screening a person for Migraine attack using the King-Devick Test, comprising:
 - providing a display and a timing device;
 - generating, for display, a plurality of alphanumeric symbols, the plurality of alphanumeric symbols having a non-uniform spacing between adjacent alphanumeric symbols;
 - providing an indication to the person to begin reading aloud the plurality of alphanumeric symbols;
 - determining, with the timing device, a completion time to read the plurality of alphanumeric symbols;
 - determining a difference between the completion time and a baseline time; and
 - when the difference is greater than a predetermined threshold, providing an indication that the person has Migraine attack.
2. The method of claim 1, wherein the plurality of alphanumeric symbols comprises randomly- or pseudo-randomly generated numbers.
3. The method of claim 1, wherein the plurality of alphanumeric symbols comprises colors or pictures.
4. The method of claim 1, further comprising displaying a plurality of screens, each of the plurality of screens having a plurality of alphanumeric symbols, the plurality of screens arranged in order of increasing difficulty.
5. The method of claim 1, wherein the baseline time corresponds to previously recorded completion times for the person.
6. The method of claim 5, further comprising adjusting the baseline time for the age of the person.
7. The method of claim 1, wherein the baseline time is determined based on normative values.
8. The method of claim 1, further comprising:

- providing a computing device, wherein the visual display is a computer screen.
9. The method of claim 8, wherein the timing device is a timer on the computer.
 10. The method of claim 1, wherein determining a completion time comprises:
detecting when the person begins recitation of the plurality of alphanumeric symbols;
detecting when the person recites a final symbol of the plurality of alphanumeric symbols.
 11. The method of claim 1, further comprising:
recording the number of errors by the person made while reading the plurality of alphanumeric symbols;
determining an error rate by comparing the number of errors with a baseline number of errors; and
when the error rate is greater than a predetermined error rate, providing an indication that the person has Migraine attack or may be having a Migraine soon.
 12. The method of claim 11, wherein the baseline number of errors corresponds to a previously recorded number of errors made by the person.
 13. The method of claim 11, wherein the baseline number of errors corresponds to normative values.
 14. The method of claim 1, further comprising:
when the difference is greater than the predetermined threshold, administering a treatment to the person for Migraine attack.
 15. The method of claim 14, wherein administering the treatment comprises recommending the person undergo additional testing.
 16. The method of claim 14, wherein administering the treatment comprises administering a pharmaceutical composition.
 17. The method of claim 14, wherein administering the treatment occurs immediately after the indication of Migraine attack is provided.

18. The method of claim 14, wherein administering the treatment occurs before any other signs or symptoms of Migraine attack are observed.
19. The method of claim 11, comprising repeating testing periodically to observe changes in completion time and number of errors made over time.
20. A computer program product for screening a person for Migraine attack using the King-Devick Test, the computer program product comprising a computer readable storage medium having program instructions embodied therewith, the program instructions executable by a processor to cause the processor to perform a method comprising:
- generating, for display, a plurality of alphanumeric symbols, the plurality of alphanumeric symbols having a non-uniform spacing between adjacent alphanumeric symbols;
 - providing an indication to the person to begin reading aloud the plurality of alphanumeric symbols;
 - determining, with the timing device, a completion time to read the plurality of alphanumeric symbols;
 - determining a difference between the completion time and a baseline time; and
 - when the difference is greater than a predetermined threshold, providing an indication that the person has Migraine attack.
21. The computer program product of claim 20, wherein the plurality of alphanumeric symbols comprises randomly- or pseudo-randomly generated numbers.
22. The computer program product of claim 20, wherein the plurality of alphanumeric symbols comprises colors or pictures.
23. The computer program product of claim 20, wherein the baseline time corresponds to previously recorded completion times for the person.
24. The computer program product of claim 23, further comprising adjusting the baseline time for the age of the person.
25. The computer program product of claim 20, wherein the baseline time is determined based on normative values.

26. The computer program product of claim 20, further comprising displaying the plurality of alphanumeric symbols on a computer screen of a computing device.
27. The computer program product of claim 20, wherein determining a completion time includes detecting when the person begins recitation of the plurality of alphanumeric symbols and detecting when the person recites a final symbol of the plurality of alphanumeric symbols.
28. The computer program product of claim 20, further comprising
recording the number of errors by the person made while reading the plurality of alphanumeric symbols;
determining an error rate by comparing the number of errors with a baseline number of errors; and
when the error rate is greater than a predetermined error rate, providing an indication that the person has Migraine attack.
29. The computer program product of claim 28, wherein the baseline number of errors corresponds to a previously recorded number of errors made by the person
30. The computer program product of claim 28, wherein the baseline number of errors corresponds to normative values.
31. A system of screening a person for Migraine attack using the King-Devick Test, comprising
a display;
a timing device; and
a computing node comprising a computer readable storage medium having program instructions embodied therewith, the program instructions executable by a processor of the computing node to cause the processor to perform a method comprising:
generate, for display, a plurality of alphanumeric symbols, the plurality of alphanumeric symbols having a non-uniform spacing between adjacent alphanumeric symbols
provide an indication to the person to begin reading aloud the plurality of alphanumeric symbols;

determine, with the timing device, a completion time to read the plurality of alphanumeric symbols;

determining a difference between the completion time and a baseline time; and

when the difference is greater than a predetermined threshold, providing an indication that the person has Migraine attack.

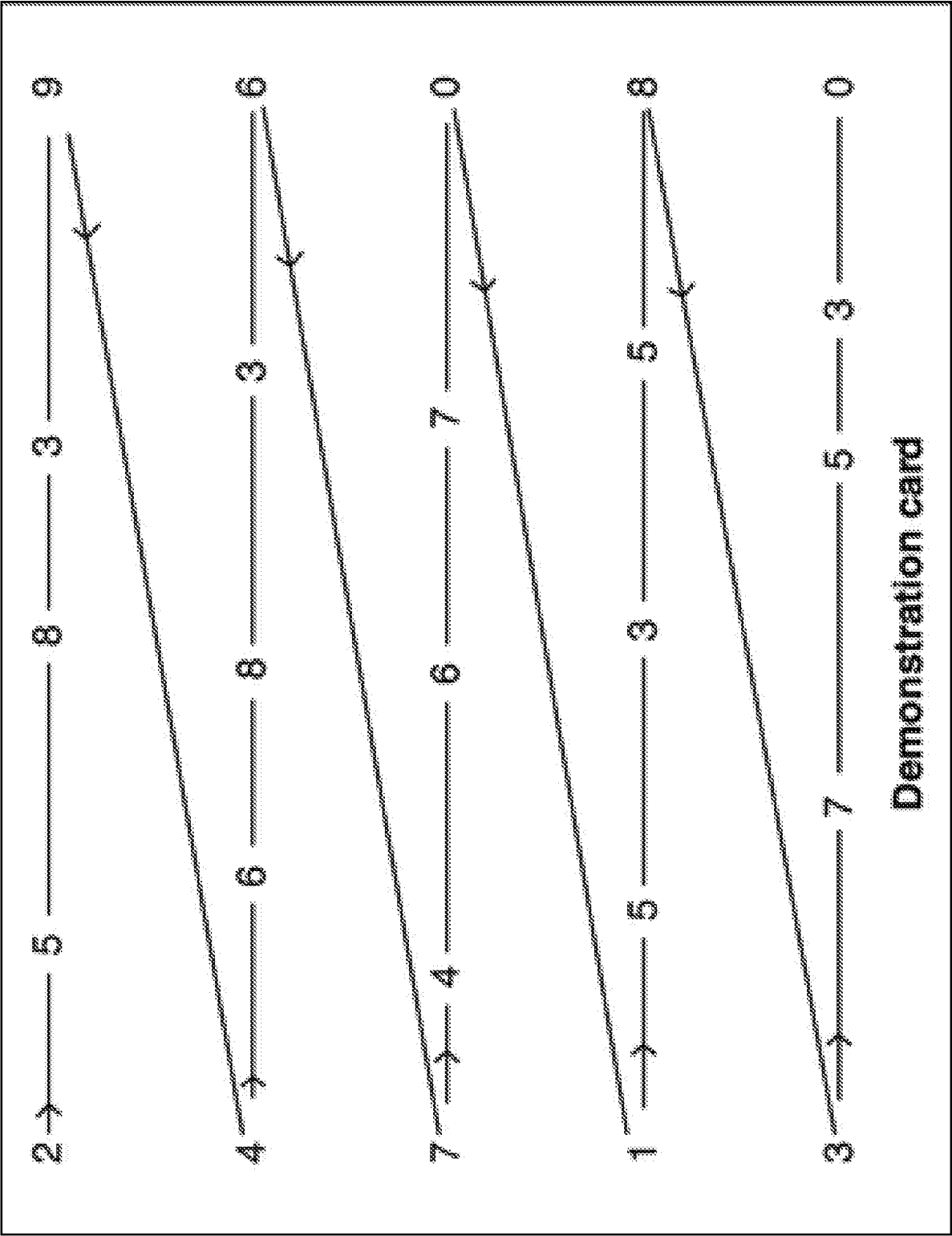


FIG. 1

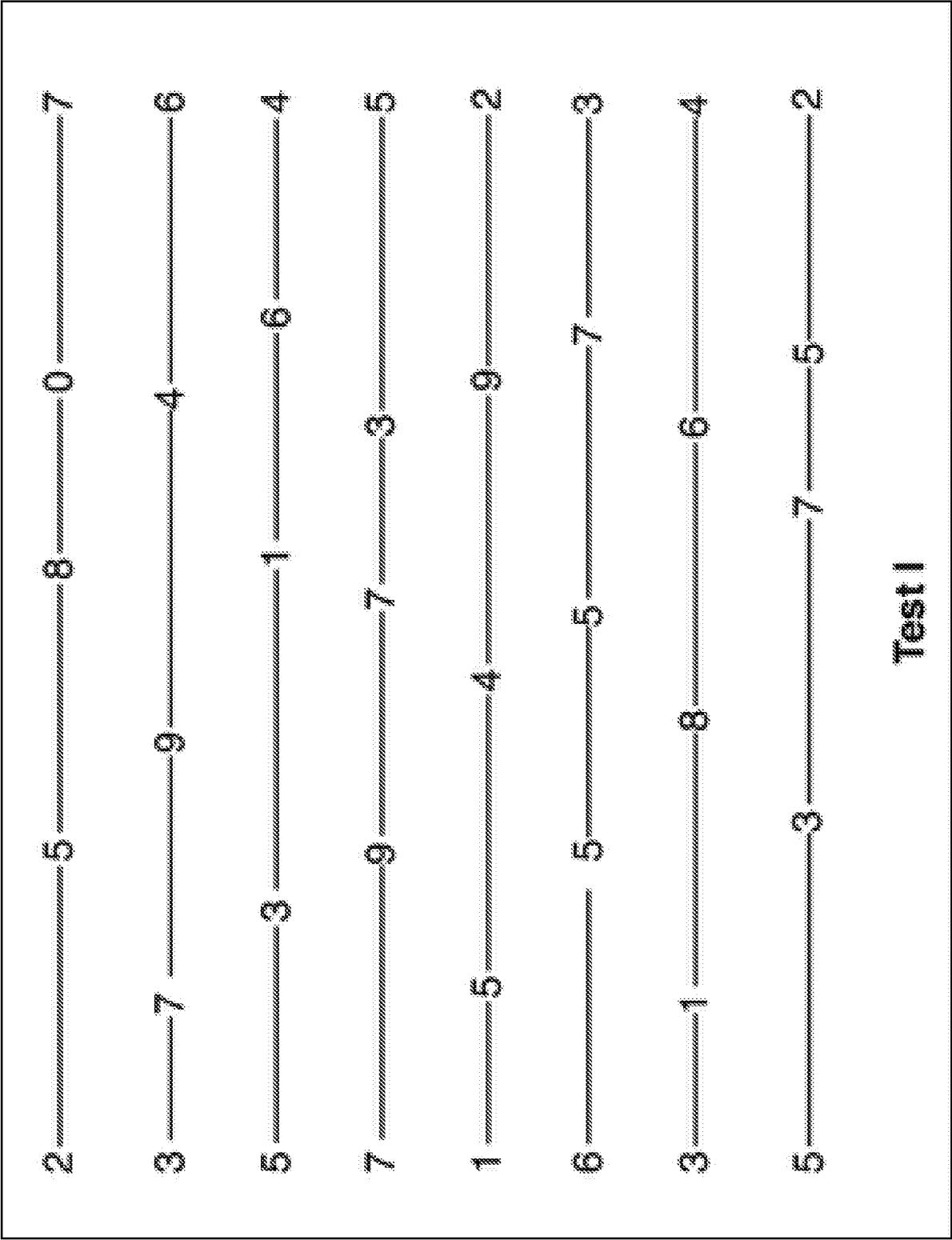


FIG. 2

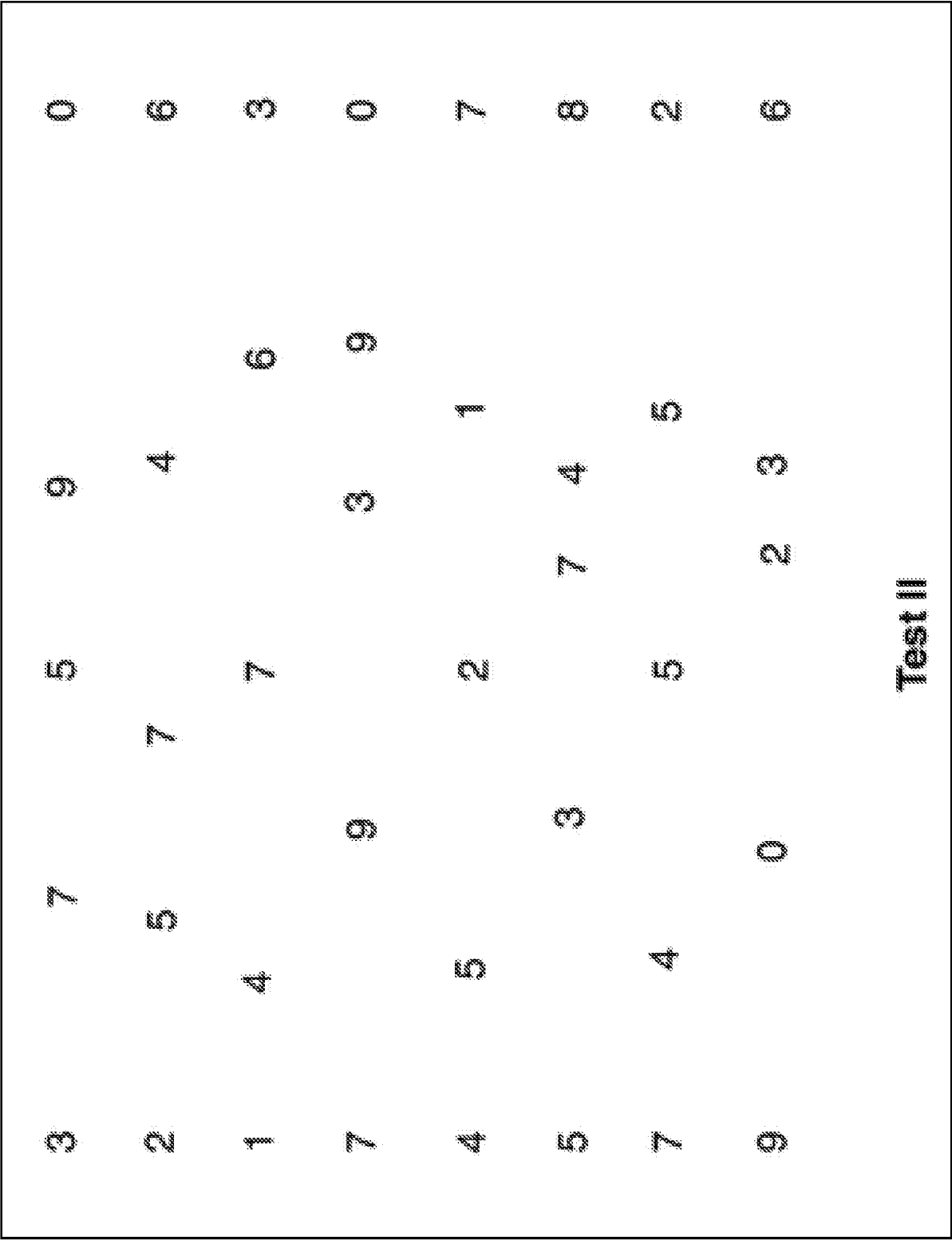


FIG. 3

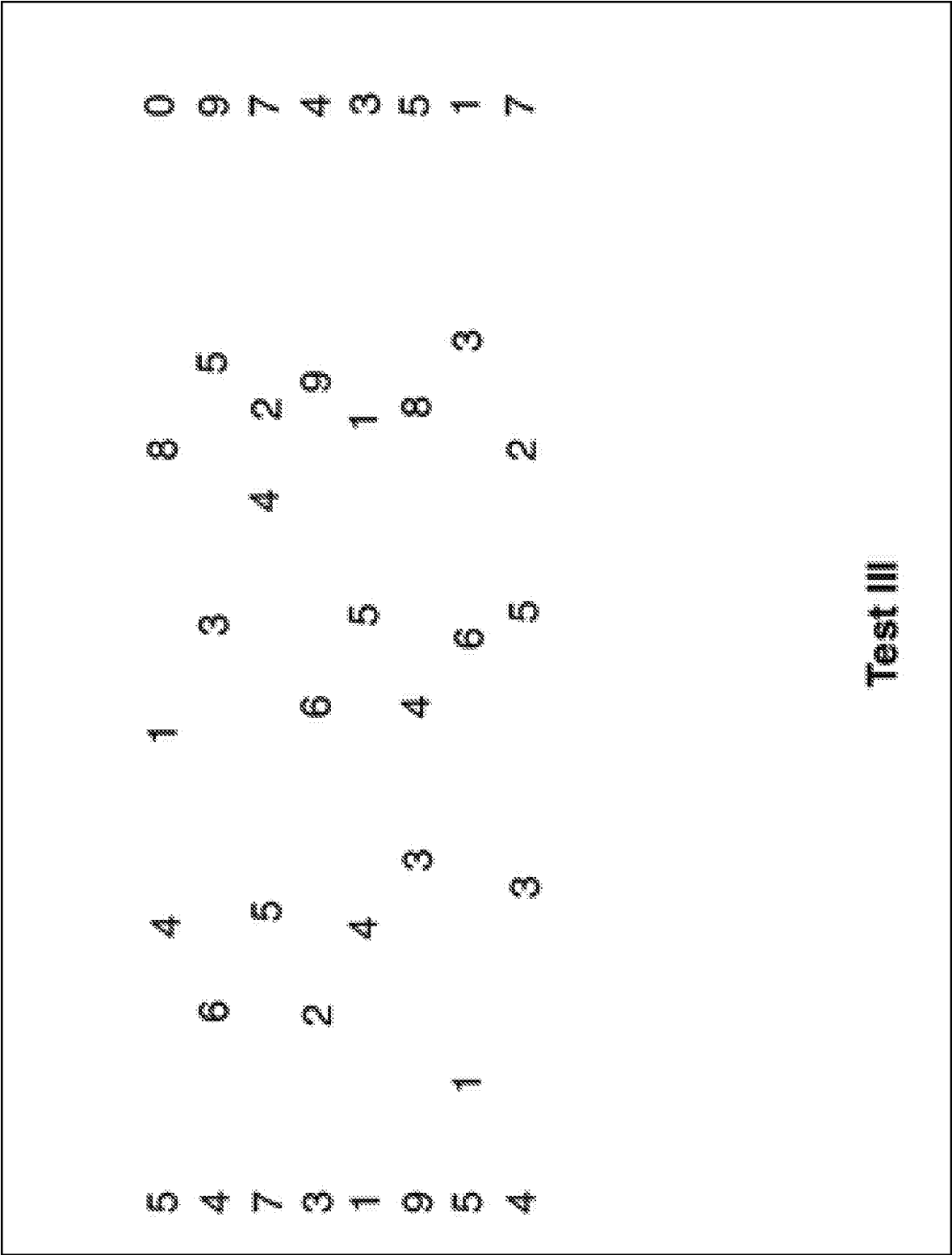


FIG. 4

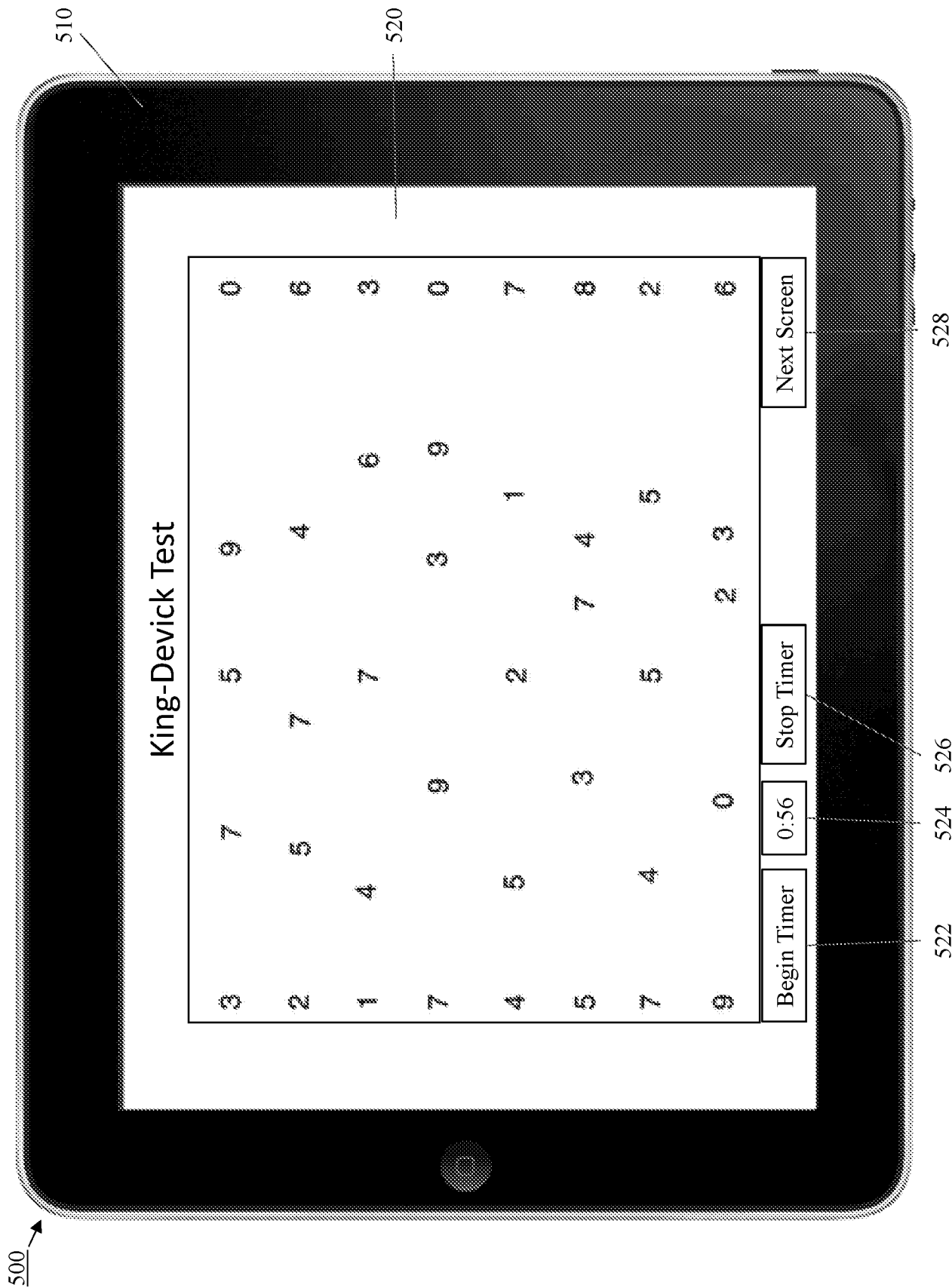


FIG. 5A

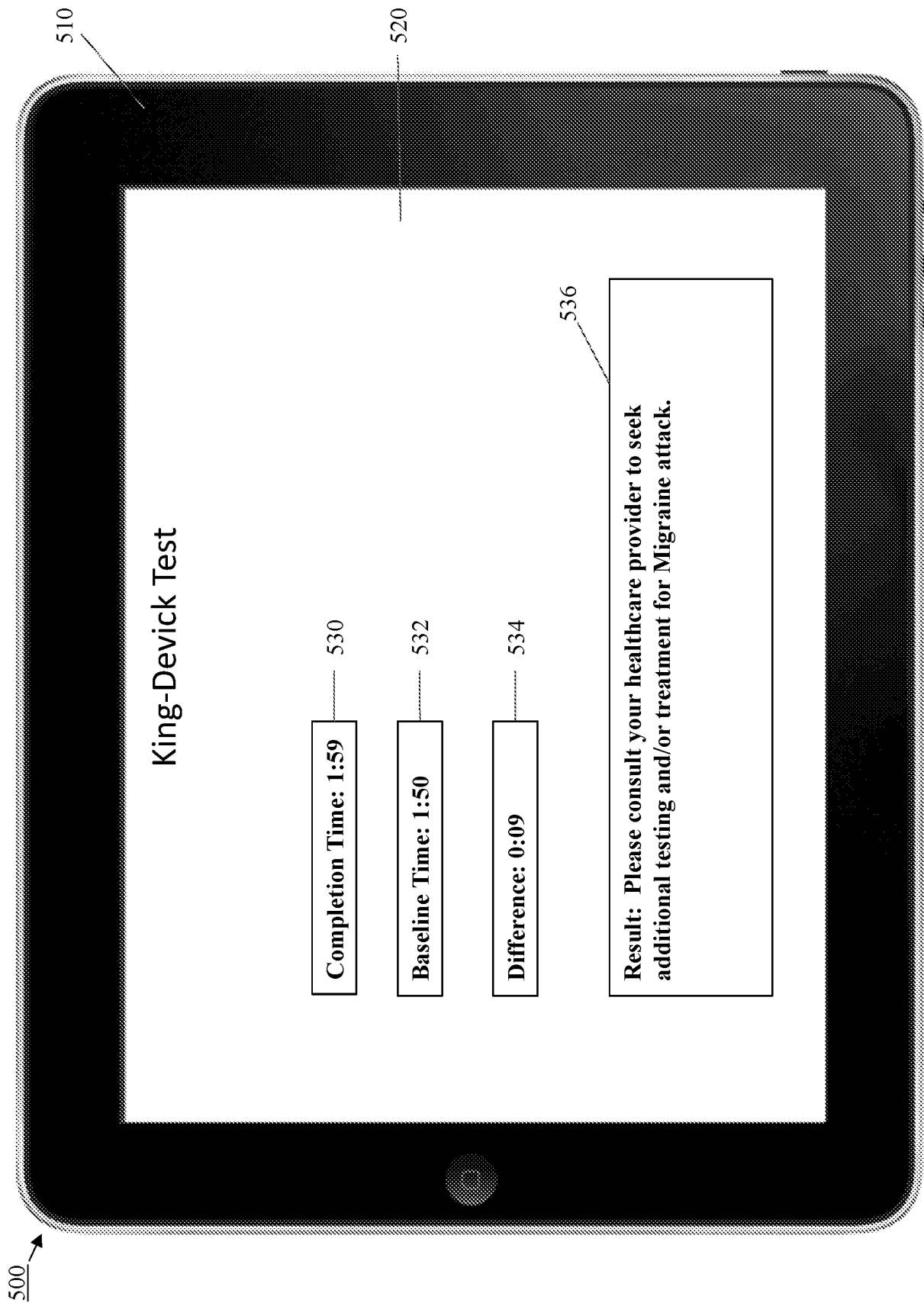


FIG. 5B

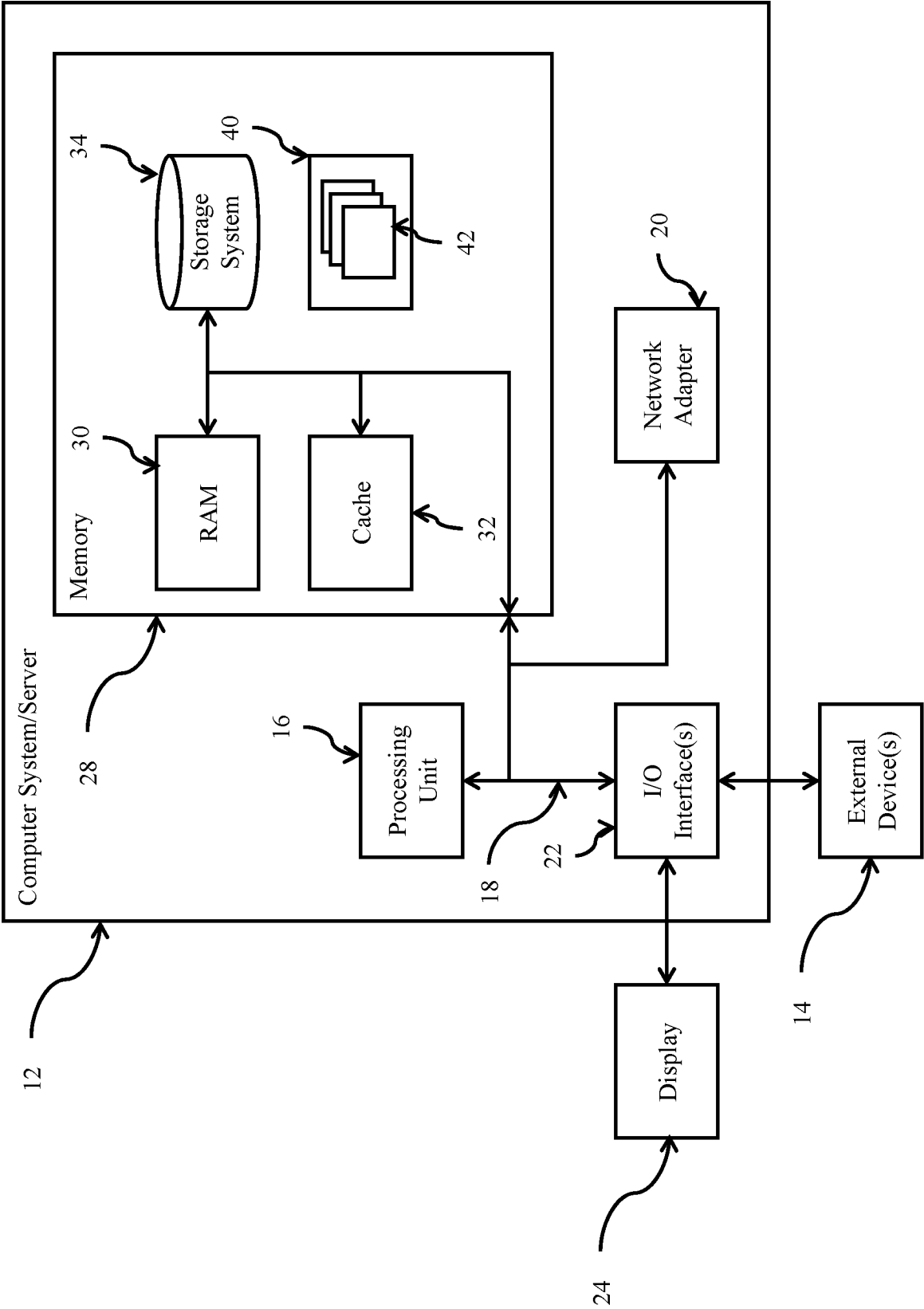


Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US19/66900

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 5/162 (2020.01)

CPC - A61B 5/162

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2004/0081945 A1 to REEVES, D. et al. 29 April 2004; entire document.	1-31
A	CHIANG et al. "The King-Devick Test (KDT) and Visual Contrast Sensitivity Test (VCS) in Migraine: the Effect of Migraine Attack on Rapid Eye Movements and Visual Contrast Sensitivity"; Headache, The Journal of Head and Face Pain; Publication [online]. 27 June 2018 [retrieved 13 February 2020]. Retrieved from the Internet: <URL: https://headachejournal.onlinelibrary.wiley.com/doi/full/10.1111/head.13306 >; pp 1-3.	1-31
A	WO 2018/106839 A2 (NOCIRA, LLC) 14 June 2018; entire document.	1-31

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"D" document cited by the applicant in the international application

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

13 February 2020 (13.02.2020)

Date of mailing of the international search report

03 MAR 2020

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-8300

Authorized officer

Shane Thomas

Telephone No. PCT Helpdesk: 571-272-4300