DIZZYDOCTOR™ SYSTEMS LLC

DizzyDoctor™ Systems LLC creates innovative products that allow user access to more accurate real-time diagnostic and treatment strategies for a variety of vestibular and balance disorders. These disorders can render an individual dysfunctional and unable to perform activities of daily living. The DizzyDoctor™ System with Vertigo Recording Goggles™ is a portable eye movement recording device system that can be worn like a pair of ski goggles and allow the use of a personal smartphone in the home setting to record abnormal eye movements during episodes of vertigo or disequilibrium. The recordings require health care provider review of eye movement recordings to support diagnoses of balance disorders.

User Assistance Information

Vertigo Recording Goggles Version 1.0

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1. GENERAL WARNINGS AND CAUTIONS

Read Instructions before Using
It is important to be sure you achieve the proper positions of your body and head during the video recording session. See Section 5 for Step-by-Step Instructions.

Check with Your Doctor First
Do not use The DizzyDoctor™ System until you have discussed your symptoms with your healthcare practitioner first and they have performed a thorough history and physical on you. Your healthcare practitioner will tell you if they feel it is safe to collect your eye movements at home during your “dizzy attacks”.

Do Not Use The DizzyDoctor™ System If You Have the Following
Do not use The DizzyDoctor™ System if you have had a recent surgery, are pregnant, or have a serious eye, heart, neck, or back condition.

Importance of Your Helper for Accurate Recordings
The DizzyDoctor™ System can be used in the home or medical office setting. In either setting, you will need a helper to ensure you can accurately record your eye movements. This is explained in Section 5 on Step-by-Step Instructions.

Use a Secure Computer System
The DizzyDoctor™ System recordings of your eye movements are Personal Health Information. Upload your eye movement recordings using only an established web service such as AOL, Comcast, Xfinity, or similar service.

We Are Not Responsible for iPhone Damage During Use of the DizzyDoctor System
The VRG is not a protective iPhone case. If you drop your iPhone and VRG while in use, your iPhone will likely be damaged.

Keep Out of the Reach of Children and Pets
Keep out of the reach of children and pets. While the Vertigo Recording Googles (VRG) are made of biocompatible materials and have durable strength, inappropriate play or chewing of the VRG may lead to maladjustment of parts and affect recordings.

Low Battery Warning
If the illumination light in the VRG is blinking, or does not switch on, it means the VRG system has determined the battery is too low to function effectively. The device is not broken. Follow the directions in Section 9 of this User Manual to troubleshoot and replace the battery.
Attention Healthcare Providers
As a healthcare provider, it is important to understand there are many causes for episodic dizziness. More benign cases include orthostatic hypotension, BPPV, Migraine, and Meniere's Disease. More worrisome causes can include intracranial mass/mass effect, vertebrobasilar insufficiency, and cardiac arrhythmias. It is important to rule out more worrisome causes of your patient’s dizziness prior to sending them home with The DizzyDoctor™ System to collect their own eye movements.

2. PURPOSE OF THE DEVICE (INDICATIONS OF USE)

The DizzyDoctor® System 1.0.0 Eye Movement Monitor is indicated for use in the medical office, and in the home setting for monitoring patients with a diagnosis of dizziness caused by peripheral vestibular disorders who are under the supervision of a physician. The device detects abnormal eye movements in response to standard positional maneuvers by recording, tracking, storing and displaying vertical, horizontal and torsional eye movements. This device provides no diagnosis and does not provide diagnostic recommendations.

Prior to obtaining an FDA indication for use as noted above, the original idea of the DizzyDoctor System was for use by the user’s healthcare practitioner in their battery of diagnostic tests to determine why a patient may be experiencing episodic vertigo or disequilibrium.

Dizziness and postural instability are common in patients in a standard Otolaryngology, Cardiology, or Neurology practice. It is also a common complaint in internal medicine and physical therapy practices. Accurate diagnosis and choice of treatment is hampered by difficulties in obtaining accurate diagnostic data when the patient is actually symptomatic. The DizzyDoctor™ System broadens physician access to video recordings of abnormal eye movements that may be present with multiple types of disorders including BPPV (benign paroxysmal positional vertigo), Meniere’s Disease, viral, inflammatory, or traumatic injuries to the inner ear, migraine vertigo, or cardiovascular causes. Each one of these disorders may present with “Dizziness” but also may present with a pattern of abnormal eye movements at the time of an “attack” of symptoms. Recordings may be obtained at any time the patients experience new or exacerbated episodes of dizziness in the home (non-office) setting.
3. DESCRIPTION OF THE DEVICE SYSTEM

The DizzyDoctor™ System allows the user the ability to perform self-testing to obtain video recordings of either normal or abnormal eye movements in response to standard head positions typically used for assessing balance disorders such as Benign Paroxysmal Positional Vertigo (BPPV). The DizzyDoctor™ System has seven components:

1. Vertigo Recording Goggles™
2. The DizzyDoctor™ System App
3. An iPhone supplied by the User
4. The User’s Helper
5. A Web Hosting Service Supplied by the User
6. The DizzyDoctor™ System Website
7. The User’s Physician and their Physician Portal

![Diagram of the DizzyDoctor™ System components and their connections.]
3.1 Vertigo Recording Goggles™ (VRG)

The VRG provides a secure docking station for the user’s iPhone which aligns with the user’s pupil of the eye for accurate video eye movement recordings. The VRG has no direct electrical connections with external devices or equipment, and uses light from two LEDs of the VRG Illumination System. The VRG uses an iPhone compatible macro lens to adjust the focal length of the iPhone camera lens. The VRG comfortably secures with a flexible and adjustable headband strap. The current version of the Vertigo Recording Goggles is 1.0.

3.2 The DizzyDoctor™ System Application (App)

The DizzyDoctor™ System App (“the App”) can be downloaded from the Apple Store accessible from your iPhone.

The App provides the following functions:

1. Fast recording of user’s real-time eye movements when the user’s head is placed in a series of four to seven different strategic positions in space. Recordings can be made conveniently whenever the user is feeling symptomatically dizzy, using their own smartphone device.

2. This device provides the opportunity to record eye movements in a series of accurately defined head positions, specifically the Dix-Hallpike test and supine positional test.

3. The App provides head stability data during the eye recording to the user’s physician or healthcare practitioner that helps validate either normal or pathologic nystagmus patterns.

4. This test can be performed in a clinical environment, or also remotely from the clinic where the patient is more likely to be experiencing episodic dizziness.

5. The user can upload the recorded smartphone videos to the DizzyDoctor website and access their account on the website at a later date to review the videos.

6. The App also provides the functions to: view, process, or delete recorded videos on the actual smart phone, access the contact information of different physicians worldwide that specialize in treating patients with vertigo, view educational information about diseases that cause vertigo including benign paroxysmal positional vertigo (BPPV), Meniere’s disease, vestibular neuronitis, and migraine vertigo, view the company focus, and provide user feedback to the company.

7. The App also provides instructional videos for proper device usage.
3.3 iPhone Supplied by the User

The DizzyDoctor™ System is compatible with the following iPhone models: iPhone 5, 5s, 6, 6 Plus, 6s, 6s Plus, 7, 7 Plus

3.4 The User’s Helper

Get a friend or family member by your side to aid in your recording session. This is to ensure user safety and to ensure optimal eye movement recordings. Ask your friend or family member to review the Step-by-Step instructions in Section 5 and Section 5.3 for Helper Instructions.

3.5 Web Hosting Service Supplied by the User

The user should use a Web Hosting Service which is password protected for uploading eye movement recordings to the DizzyDoctor™ System website. Such services are provided by carriers like AOL, Comcast, Xfinity and others. Web Hosting Services use webserver software that accepts videos from the DizzyDoctor™ App, and inputs the information from App to the database and server. All storage of encrypted user information is stored in this way. There is no local storage of user information, user data, or video files on the user’s smartphone. The encryption is completed immediately following the recording on the iPhone app. This means that after the recording the videos are completely encrypted before being uploaded to the server.

3.6 The DizzyDoctor™ System Website

The DizzyDoctor™ website is the interface between you and your physician. The website provides a secure environment for sharing Personal Health Information. The website processes and displays videos, data, and physician information. Users and their physicians register on the website or via the iPhone App. Password protected sign-in opportunities will allow the user and physician access to the website. The user may process, view, or delete their eye movement video data here. They may personally view their videos or share their videos with their treating physician or healthcare provider while following up in clinic.
The website communicates with the user’s smartphone. This allows comments to be entered on the user’s smartphone regarding a particular eye movement recording and automatically be updated to the website’s user portal. This instantly updates the comments associated with the user’s recorded videos.

The website also functions to: view, process, and delete recorded videos on the webserver; access contact information about different physicians worldwide that have a practice interest in treating vertigo; view educational information about diseases that cause vertigo including benign paroxysmal positional vertigo (BPPV), Meniere’s disease, vestibular neuronitis or labyrinthitis, and migraine vertigo.

The website provides instructional videos on proper device use as well as information on different types of typically observed abnormal and normal (physiologic) eye movements and how they may be used to help a healthcare practitioner understand the user’s disease process. They may also view the company focus, and provide user feedback to the company.

The DizzyDoctor™ website not only contains a user portal where patients/users may personally log in to review their uploaded eye movement videos, but also a physician portal. In the physician portal, the healthcare practitioner may log in and view their patients eye movement recordings after receiving the appropriate user login ID and password.

### 3.7 The User’s Physician

The user’s physician can register on the iPhone App or on their office computer. After the physician logs into their physician portal, they have the opportunity to view their patient’s eye movement data. The physician is required to have the patient’s permission to access their eye recordings that have been uploaded to the DizzyDoctor™ System website. The user’s health care provider may then use these eye movement recordings along with the battery of diagnostic testing already performed on the patient to help determine the etiology of their episodic vertigo.

The opportunity to record eye movements remotely, and/or in a physician’s office at the time the user is acutely vertiginous or “dizzy”, is extremely valuable as there are a variety of different disorders that could be causing the patients symptoms.
4. CONDITIONS THAT MAY AFFECT USE

Overall, the DizzyDoctor™ System is a robust platform that allows a patient to record real-time eye movements in a series of standard testing positions when a patient is removed from a clinic environment. This data can be later presented to their health care practitioner to aid in the diagnosis of episodic vertiginous complaints.

Conditions that may affect use include:

- Not following the step-by-step instructions to ensure proper body and head movements during the recording sessions. See Step-by-Step Instructions in Section 5. Users should view the Instructional Video provided on the iPhone app and the DizzyDoctor™ website before use. Users should also read the instructional pamphlet provided in the box containing the VRG.

- Using the VRG without a Helper. It is HIGHLY recommended all users have a helper to ensure the accuracy and safety of all testing protocols.

- Insufficient charge on your iPhone battery could interrupt recording. Check that your iPhone is charged before use.

- Not having your iPhone in the non-quiet mode and set at an appropriate volume level. Please make sure your iPhone is in the non-quiet mode and the volume is at maximum level so you and your helper can hear the verbal instructions provided by the DizzyDoctor™ program.

- Misalignment of the VRG on the user’s head. This is easy to adjust with your Helper who will ensure that your eye is centered in the video recording screen.

- Use of the VRG without the head strap. Always use the head strap for a secure fit of the VRG so it doesn’t slip on the head during the recording session.

- Use of a non-secure web hosting service. See section 3.5.

- A poorly charged VRG battery. It is expected that the VRG battery will provide 20 hours of power. A replacement 3V CR2 battery can be purchased at many retail locations and easily replaced. See section 9.

- Broken or misaligned LEDs that may result in poor quality eye recordings. This is unlikely, but if this occurs contact DizzyDoctor Systems LLC. See contact information on page 1 to return your VRG for possible replacement or repair.

- Not notifying your physician that you have uploaded new recordings to the DizzyDoctor™ website for physician review. Always notify your physician or health care practitioner when you have recorded and processed eye movement videos during your episodes of dizziness.
5. STEP-BY-STEP INSTRUCTIONS – SET-UP AND USE

5.1 Instructions for Users

See Section 5.3 for Instructions for Helpers.

1. Make sure you have purchased the correct DizzyDoctor™ System Vertigo Recording Goggle that corresponds with your smartphone version. (i.e. 5/5s/6/6s/6 plus/7/8).

2. If you currently have a smartphone holder/protector on your smartphone, you must remove your personal existing phone case/protector prior to inserting your smartphone into the Vertigo Recording Goggles™.

3. Read the Getting Started and Quick Start guide provided in the Vertigo Recording Goggle box.

4. Get a friend or family member by your side to aid in your recording session. It is highly recommended the user have a friend or family member assist in the recording session to ensure user safety and optimal eye movement recordings.
5. Download the App using your iPhone, go to the Apple App Store. Install and download the DizzyDoctor™ iPhone App.

6. Open the DizzyDoctor™ iPhone App. (see circle showing the App icon in iPhone screenshot)

7. Sign up. You may sign up on the App directly on your iPhone, or once you are on your computer or laptop, go to www.dizzydoctor.com.

8. Create a Patient Portal Account:

   **If creating an account on the DizzyDoctor™ website:**
   
   - Go to the “Patient Sign-up” page, create a user account with a username and password.
   
   - Then Click “Submit.” (Note, an account can also be made by using your iPhone.)

   **If creating an account on the DizzyDoctor™ iPhone App:**
   
   - Open the App and press the “Sign Up” button on the bottom left corner of the start screen.
   
   - Create a user account with a username and password
   
   - Then click “Continue”

9. Log-in to your account on the DizzyDoctor™ iPhone App. (See screenshot below)

10. Make sure your phone is in a non-quiet mode and at the maximum volume level, so that you can hear verbal instructions given by the eye movement recording app.
11. It is highly recommended the user have a friend or family member assist in the recording session to ensure user safety and optimal eye movement recordings.

12. Watch the instructional video titled “How to use DizzyDoctor”.

   After watching the instructional video, do a practice session with the VRG by performing the 4 positions shown in the diagrams below. This practice session is important, so that you and your helper can become aware of the correct testing positions to use should you actually experience a vertiginous episode at a later date. You may also perform 3 additional test positions in the Advanced Testing Section if asked by your physician.

13. Position yourself onto a table or bed so that you may comfortably perform all of the four to seven testing positions, as described in the “How to use DizzyDoctor” video and as shown below.

   Now practice each position with your Helper. The Helper should gently support the user’s head as the user reclines and rises from each position.
**POSITION 1**

Turn head right 45° then lay back flat with head slightly over the edge of the bed or table.

You must hold your head still while in this position to ensure an accurate recording. Keep your eyes open while recording!

**POSITION 2**

Sitting Back Up with your Head Neutral.

You must hold your head still while in this position to ensure an accurate recording. Keep your eyes open while recording!
POSITION 3
Turn head left 45° then lay back flat with head slightly over the edge of the bed or table.

You must hold your head still while in this position to ensure an accurate recording. Keep your eyes open while recording!

POSITION 4
Sitting Back up with your Head Neutral

You must hold your head still while in this position to ensure an accurate recording. Keep your eyes open while recording!
ADVANCED TESTING
POSITION 5
Supine Head Center
(elevated 30° on two pillows)

You must hold your head still while in this position to ensure an accurate recording. Keep your eyes open while recording!

ADVANCED TESTING
POSITION 6
With head elevated 30° on two pillows, turn head 45° to the right

You must hold your head still while in this position to ensure an accurate recording. Keep your eyes open while recording!
ADVANCED TESTING

POSITION 7
With head elevated 30° on two pillows, turn head 45° to the left

You must hold your head still while in this position to ensure an accurate recording. Keep your eyes open while recording!

14. Clip your smartphone in the front plate of the Vertigo Recording Goggles so that the smartphone is securely fastened to the front plate.
15. Start a recording by clicking the “STEP BY STEP” button.

16. Put the vertigo recording goggles over the user’s head. Make sure to adjust the head-strap so that they tightly fit the user’s face such that the goggles do not shift upwards or downwards easily while the user lies down and sits up.
17. Switch the illumination light ON by pressing the green button located on top of the goggle frame. (As shown in the picture below)

18. Follow the test set up instructions shown on the iPhone App. You will also be given verbal/audio instructions to properly perform the four Dix-Hallpike testing positions.

19. To ensure your eye is in the center of the recording screen, you may slightly adjust the goggle up or down and also left or right. After you are sure the eye is centered, click on the start button in the center of the screen.

20. There is a pupil detection component to the software to detect the user’s eye in the video before the software will typically proceed with the testing.

21. Follow the verbal and pictorial instructions on the iPhone App to perform your eye movement recording session.
22. Once the recording is complete, take the goggles off of the user. **Make sure you turn off your illumination light by pressing the green button on the top of the goggle frame so that your Lithium battery does not die.**

23. Review your recorded videos from the recording session in the video player area of the App. 

- If the videos seem to show good results, (eye is centered, wide open, in focus, and minimal blinking) continue to the next step, and process your videos for your physician to review when you schedule your next follow-up visit.

- If the videos are out of focus, not centered, or contain excessive blinking, then perform another recording.

- The blue dots next to the videos, in the video manager area, mean they have not been viewed by you yet.

- Remember to add notes about what symptoms you were experiencing or what triggered your vertigo to the notes section to help your healthcare provider! Your notes are automatically updated to your videos in your patient portal on the DizzyDoctor™ website.

24. If you want to process your videos, click the button below the notes section that says “Process Video” (processing your video will cost 1 credit). You may also delete any videos you do not like by pressing the “Delete Video” button.

25. After processing a video they are now available for viewing on your patient portal on www.dizzydoctor.com. You may also notify your physician that these eye movement videos have been recorded and they are available for viewing. This may be valuable data to your physician to better help them understand your “dizzy” episodes.
5.2 How to Purchase Credits:

1. Log into your DizzyDoctor™ profile, on the DizzyDoctor™ Website. After logging in you will be placed on the video manager page.

*Note* you automatically get logged out of your account after 10 minutes of inactivity. This helps insure privacy to your account data. Type in your username and password and click “LOGIN” to go back to your patient portal page.

2. Go to the “CREDITS” page on the top navigation bar.
3. Click the number of credits you would like to purchase and click “Purchase More Credits.”

4. Enter your payment info. Credit Card payments are processed through Stripe which is a secure payment platform.

5. **CONGRATULATIONS!** You have successfully purchased credits, you are now ready to process your videos.
5.3 Helper Instructions of Use

1. Thank you for helping out your friend or family member with their recording. Your main responsibility is to ensure that the patient is performing all the required positions safely and properly.

2. To begin, help the user open the app and login.

3. Make sure the user is sitting on a table or bed in a position where they can hang their head barely over the edge of the table or bed. This is EXTREMELY important that they are in the proper starting position before starting a recording session. See position below.

4. Help the user place the VRG goggles on their head. Make sure they are positioned properly and fit securely on the face similar to any standard swim or ski goggle. If the goggles are too loose, tighten the strap so the goggles do not slip during testing. It is EXTREMELY important the goggles fit snugly on the face to avoid slipping during the recording session.

5. Once the user is in the correct position, click “Step-By-Step” on the main screen, and follow the verbal and visual instructions.

6. The first screen is shown below. Make sure the phone is correctly in the goggle. Also make sure the goggles are securely fastened to the user’s head. Now, click next.
7. The next screen lets you see the position of the pupil, similar to the photos below. Your job is to center the pupil in the screen to optimize recording. You may move the goggle up or down and also left or right. After you are sure the eye is centered, tap on the start button.

8. Now make sure the user is sitting up straight and looking straight ahead. It is IMPORTANT to start the test with the user’s head looking straight ahead and not chin / nose up or down and not chin / nose right or left.

You can help position them HEAD CENTER by looking at the diagram on the screen or by looking at the 3D head on the top right of the video recording screen.

NOTE* The dot in the top left corner of the iPhone screen will be red if the patient is in the wrong position. Try your very best to keep the user in a position where the dot is green. This dot will appear in all positions for a guide.

There will also be verbal cues to confirm correction movements, such as: “Good, you are in the correct testing position.”

9. Now follow the verbal and visual instructions on the iPhone to perform the 4 different positions shown below for the standard Dix-Hallpike test or the 3 different position for the Advanced Supine Positional Test.

Make sure to stabilize the user’s head for more precise recordings. It is important to have the user hold their head still during the 4 to 7 recording positions.

The helper may assist by placing their hands on the user’s head to help hold it stable as shown below. If the user cannot get into the position correctly, click the stop button and press start again to perform a new recording session.
STARTING POSITION

Sitting Head Neutral
You must start sitting with your nose pointed directly in front of you. Not pointed up or down or to left or right.

POSITION 1

Turn head right 45° then lay back flat with head slightly over the edge of the bed or table

You must hold the user’s head still while in this position to ensure an accurate recording.
**POSITION 2**
Sitting Back Up with your Head Neutral

You **must** hold the user’s head still while in this position to ensure an accurate recording.

**POSITION 3**
Turn head left 45° then lay back flat with head slightly over the edge of the bed or table

You **must** hold the user’s head still while in this position to ensure an accurate recording.
POSITION 4
Sitting Back up with your Head Neutral

You must hold the user’s head still while in this position to ensure an accurate recording.

ADVANCED TESTING
POSITION 5
Supine Head Center (elevated 30° on two pillows)

You must hold the user’s head still while in this position to ensure an accurate recording.
ADVANCED TESTING
POSITION 6
With head elevated 30° on two pillows, turn head 45° to the right

You **must** hold the user’s head still while in this position to ensure an accurate recording.

ADVANCED TESTING
POSITION 7
With head elevated 30° on two pillows, turn head 45° to the left

You **must** hold the user’s head still while in this position to ensure an accurate recording.

10. Once the recording is finished help the user take off the VRG goggles, make sure the illumination switch is turned off, and review the videos together.
5.4 How to Process Videos – For Users and Helpers


2. Click on the specific video that you would like to process. The video list is on the right-hand side of the video player area. If you have recorded multiple videos, then use the scroll bar to see the date and time of the video you would like to view.

The selected video will be labeled as “Uploaded” or “Processed”. If it has been processed, then you may click on the specific date and time and view the eye movement videos, eye tracking nystagmograph, and gyroscopic head positioning graphs. These data sets are now available to show to your health care practitioner at your next follow up clinic visit. If your physician is logged into their physician portal, you may provide them with your username and log in to review your videos together. Tell them the symptoms you were experiencing at the time of your “dizzy episode” and what possibly triggered the attack and what made you feel better or worse. After reviewing your recordings, your physician will be able to print out a report that includes your nystagmographs for that recording session. Your physician will be automatically logged out of your session after 30 minutes of inactivity to help maintain your privacy.
5.5 Instructions for Physicians and Other Healthcare Providers

The following sections provide information on how to register, log-in, review video eye recordings, and counsel patients on The DizzyDoctor™ System.

5.5.1 Registration on DizzyDoctor™ Website

A Physician or Health Care Practitioner can sign up by clicking “Sign Up” in the top right corner of the home page. They will then click on “Physician Sign Up”. The application asks for in depth information about their practice, patient focus, and address.

Note* Once the Health Care Practitioner is done registering, their info will be sent to the DizzyDoctor™ team so that they can verify them. Approval can take anywhere from 1-6 business days. If you need to register faster, please give us a call and we will help you out.
5.5.2 Log-in to View Patient’s Video Eye Recordings

Once the physician is approved, they will receive an email or call from the DizzyDoctor team office notifying them that their profile is ready for use. Once logged in, the physician will land on the Profile page. Here the physician will see their profile exactly as a patient user will be viewing it. In addition, the Physician Portal page will ALSO HAVE a “Patient Login” button on the top right. This is where the physician will be logging their patients in so that they may view their eye movement data and print their interpretation and billing sheets.
When the physician clicks on the patient log in button, the following window will pop up. This is where the physician will have their patient enter their username and password to log into their portal.

![Login Window](image)

Once logged into the user's portal, the physician will be able to view their patient's videos. Processed videos will have eye movement/eye tracking tracings as well as head stability data to assist the physician in their diagnostic process. The graphs, or nystagmographs, titled “Eye Movement” depict the horizontal and vertical movement of the pupil that is being tracked by the eye tracking crosshair on the screen. The graph titled “Device Position” is depicting the smartphone’s horizontal and vertical positioning throughout the recording by using the smartphones internal 6 axis gyroscopic data. This validates the patient’s head stability during the recording sessions. These four graphs will allow a physician to determine whether a user’s eye movements are pathological or of the physiological type typically seen in a compensatory vestibular ocular reflex (VOR). A physiological nystagmus is the body's normal response to the head moving and is not necessarily caused by a disease process. The juxtaposition of the four graphs in the “Video” section helps to ensure accurate physician interpretation. There is the ability to click and view the list of processed videos in the date and time stamped list on the right of the profile page. Most processed videos will be available to view within minutes of recording on the user app as long as there is reliable cellular/WiFi connection. So, if a physician clicks on a patient’s Video Recording File, labeled “Uploaded”, a pop-up screen will be displayed asking if the patient would like to pay a credit to immediately process that video for viewing. If the “Yes” button is pressed, the videos will then be displayed with Analysis Data for viewing by the physician, who is typically present with the patient. If there are no credits available to process the video, then the patient must purchase a “Processing Credit”, in the credits area of the DizzyDoctor Website. A “Processing Credit” costs the patient approximately $19.99, and the payment is processed via Stripe, a secured payment platform.
Once the physician has viewed the whole patient Dix-Hallpike Test or Supine Positional/Gaze Evoked Test video they may now print the interpretation and billing sheet by pressing “Print Report and Billing Sheet” below the video player. The billing sheet contains printouts of both the “Eye Movement” and “Device Position” graphs. It also has a physician interpretation section, common ICD 10 diagnosis codes typically associated with the “Dizzy Patient”, and proper CPT billing codes for the professional component of interpreting Dix-Hallpike and Supine Positional/Gaze Evoked Testing. If the physician performs the Dix-Hallpike or Supine Positional/Gaze Evoked Testing in their office and also interprets the data, they may potentially bill for both the technical and professional component of the tests. DizzyDoctor Systems LLC does not guarantee a physician can bill for reimbursement from a particular insurance payer for their efforts evaluating their patients eye data.
5.5.3 Use of the DizzyDoctor System in the Physician Office

1. Go to www.DizzyDoctor.com and make a physician account.

2. Request us to send you some Vertigo Recording Goggle (VRG) units on the DizzyDoctor website.

3. When you get a DizzyDoctor system VRG, try to do a practice recording and view your video on the DizzyDoctor website so you understand how it all works.

4. Have your patient with complaints of brief episodic “Dizziness” purchase a DizzyDoctor system VRG from you and download and install the DizzyDoctor App on their smart phone.

5. Tell your patients to then perform a practice session recording their new DizzyDoctor system.

6. It will cost your patient $19.99 to upload and process their video recording, so you can view it in your Physician Portal. This small fee is not covered by their insurance company.

7. Tell your patient to perform another eye recording session the next time they are experiencing a brief episode of dizziness.

8. Have your patient come into the office to review their eye movement videos and nystagmograms with you during a follow up visit.

9. Log on to your physician portal and have your patient enter their username and password to allow you to view their videos, which will be time and date stamped. The patient’s data window will automatically log out of your physician portal after 30 minutes of inactivity to protect their privacy.

10. Click on the print interpretation and billing sheet button and fill out your interpretation of your patient’s data as well as your billing codes. This should take no more than 30 seconds.

11. Educate your patient that if they are experiencing any other symptoms suspicious for stroke such as difficulty speaking, weakness or loss of sensation in their arms or legs, or loss of vision, that they should call your office or 911.
The DizzyDoctor system was designed as a powerful tool in the healthcare practitioners’ battery of tests to aid in the diagnosis of the vertiginous patient. The DizzyDoctor system does not provide a diagnosis. Most health care practitioners often find it difficult to provide their patient with an accurate diagnosis regarding complaints of episode vertigo as the events can often be brief and symptoms mimic multiple pathogenesis. For example, a typical Meniere’s patient may have superimposed BPPV. A given attack of vertiginous complaints may be secondary to either a Meniere’s hydrops or dislodged otolithic debris. If the patient can quickly present to their physician, then the exam may typically focus on a history of fluctuating tinnitus, aural fullness, or hearing changes and presence of nystagmus. If nystagmus is present, the patterns observed may direct the physician to move more in the direction of a Meniere’s hydrops attack if there is a sustained right/left beat or sustained torsional beat nystagmus present. Similarly, they may move in the direction of BPPV if there is a pattern of gravity dependent nystagmus present on Dix-Hallpike right/left testing or supine positional testing. A patient with a paroxysmal cardiac arrhythmia may consistently not have any associated patterns of nystagmus. Migraine or migraine associated vertigo may present with a sustained horizontal or vertical pattern that lasts hours and self-resolving. The most important point is that most attacks occur when the physician can’t get access to the exam. This is where the DizzyDoctor™ app will come in handy.

If the physician has already ruled out intracranial (i.e. brain, brain perfusion compromise) and retrocochlear (i.e. acoustic neuromas mass) pathologies yet still refining their differential diagnosis, then they may provide their patient access to the DizzyDoctor system. Then with the help of a friend or family member, they may record their eye movements during their brief episodes of vertigo or “dizziness”. Also instruct your patient to place comments in the video comments section at the time of the recording as to what triggered the event or associated symptoms with the event. The collected videos are automatically uploaded to the patient’s web server secure account within minutes of recording from their iPhone. The physician can instruct their patient to call them and let them know their videos are available for review or to make a clinic appointment for review and exam. The physician has their own login portal on the DizzyDoctor website. After logging in with the ID and password provided by the patient, the physician may click on the videos of interest and view the entire video and displayed eye tracking and nystagmographs. The physician and patient may also discuss notes regarding triggers or symptoms that were entered in the notes section associated with the time and dated videos. This data can be used in the physician’s battery of tests to help provide a more refined diagnosis of the patient’s symptoms. The DizzyDoctor system obviously does not provide a diagnosis. When the physician is done reviewing the data, they may print out an interpretation and billing sheet for that encounter. If warranted, the physician should tell their patient to go home and collect more eye movement data, or educate them on better use of the system. The physician may also use the DizzyDoctor system in their office. They may instruct the patient to bring in their personal VRG and iPhone to perform a recording in the presence of their physician.
5.5.4 Counseling Points for Patients Using the DizzyDoctor System

• Tell your patient to practice using their Dizzy Doctor Vertigo Recording Goggles and iPhone app at home when they are symptom-free.

• Tell your patient they should also practice viewing their recorded eye movement videos on their iPhone as well as on their DizzyDoctor.com patient portal. Tell them this will ensure that their videos were correctly uploaded to the server and can be later viewed by you, the physician, when you see them back in clinic.

• Tell your patient to try their best to hold their head still and try to not blink often while performing the eye recording. Tell them this is because the whole idea of the recording is to look at how their eyes move or “jerk” during testing at the time they are having a Dizzy attack. If they are blinkign often then you can’t see their eyes.

• Tell your patient it is very important they have a friend or family member help them get into the positions during the test with the Vertigo Recording Goggles. This will ensure the patient remains safe while lying down and sitting up. Also, their helper can make sure to hold their head still while they are in the recording positions by placing their hands on the sides of the patient’s head.

• Tell your patient to type a comment in the “notes” section below the video player describing what symptoms they were experiencing when they become dizzy or what triggered the episode. Ask them to note if they had fullness, tinnitus, or hearing loss in a particular ear at the time they were feeling dizzy. Did they get dizzy lying down in bed? Rolling over? How long did it last?

• Very few things in life are free. it will cost your patient $19.99 to upload and process their videos they collect when they are experiencing dizziness. This will allow them to present their videos to you in a format that allows you to better interpret the data. This fee is not covered by insurance companies. However the small fee is better than showing up to your office with no data.
6. CLEANING & MAINTENANCE

The Vertigo Recording Goggle Frame is made of durable plastic material, the foam head cushion, and silicon head strap are designed for long wear. The electronic illumination system has been tested for shock-resistance and durability. Within reasonable limits of use as intended by the labeling, the VRG is essentially maintenance free. The VRG is not guaranteed to protect the iPhone from damage if dropped to the ground while the iPhone is clipped into the VRG face plate.

The CR2 battery has a self-life of 3 years and two years of intermittent use. Please make sure to properly recycle the battery. See Section 9 for changing the battery.

Mild household cleaners for glass may be used to clean the surface of the VRG. Avoid getting water in the housing containing the illumination system and battery. If accidentally submerged or exposed to liquids that may have entered the housing of the illumination system, do not use the VRG. Open the housing, remove the battery and use a hair dryer on low to medium setting to dry the interior. Test the illumination system before putting on the VRG for self-testing.

7. STORAGE

Store the VRG in the original carton box or in the microfiber optics bag provided. Store the VRG in a dry area at temperatures between 37 degrees Fahrenheit and 98 degrees Fahrenheit. Do not expose your VRG to prolonged direct sunlight such as inside a vehicle.

8. TROUBLESHOOTING/FAQS

1. What if the LED light starts to flash?
   – Pull the front plate off and Change the battery see section 9 for further instructions.

2. What if the strap is too loose?
   – Pull on the end of the strap to tighten it so that it fits snug on the user’s head. See section 5.1 number 16.
3. What if the strap breaks?
   – Do not use the VRG and contact the DizzyDoctor team for a possible replacement strap.

4. What if the foam pad peels off?
   – Do not use the VRG as it can cause injury and contact the DizzyDoctor team for a possible replacement foam pad.

5. What if there is a blurry image on the videos?
   – Remove your iPhone and carefully clean the lens with standard glass cleaner the dry with a microfiber towel.

6. What if a LED board breaks off/or does not light up?
   – Do not use the VRG and contact the DizzyDoctor team immediately for support

7. What is the DizzyDoctor System?
   – The DizzyDoctor System is composed of three parts. It includes the Vertigo Recording Goggles, the DizzyDoctor iPhone Application, and the DizzyDoctor Website Patient/Physician Portal.

8. What are the Vertigo Recording Goggles?
   – The Vertigo Recording Goggles (VRG) are the specially designed goggles that allow a patient to attach their iPhone so that they may obtain video eye movement recordings in the Dix- Hallpike testing positions. The Vertigo Recording Goggles hold the iPhone in the proper placement over the patient’s eyes.

9. How do I order the DizzyDoctor System?
   – The DizzyDoctor System is comprised of an iPhone App, the Vertigo Recording Goggles as well as the online profile. To order the system simply sign up and make a profile then obtain a set of goggles from a registered physician’s office that correspond with your iPhone version. Then download the free application that is available on the Apple iTunes store on your iPhone.

10. How do I order the Vertigo Recording Goggles?
    – You can order the Vertigo Recording Goggles through a registered physician at their clinic or you can go to www.DizzyDoctor.com to find physicians near you that are interested in treating vertigo and are signed up on the DizzyDoctor website.

11. How much does the Vertigo Recording Goggles cost?
    – The Vertigo Recording Goggles are available from your health care provider who will charge you usually $100 for the teaching/tutorial aspects associated with getting you set up to use the system. Again, the $100 when obtained from your physician covers the brief tutorial/training required to properly operate your DizzyDoctor™ System.
12. When will I get my Vertigo Recording Goggles?

Go to the DizzyDoctor website. In the Doctors area, find a Doc to get your goggles from. If a physician is signed up as an authorized distributor, they will have the Vertigo Recording Goggles in their office available for purchase. These can be obtained for a training fee of $100. The $100 price from your physician or healthcare provider covers the training program for how to use the DizzyDoctor™ System correctly and safely in how they want to personally manage your data collection process.

13. Is there a warranty?

- DizzyDoctor products are warrantied against all manufacturer defects for 6 months. DizzyDoctor does not warranty against lost items or lenses against scratching. Warranty is valid only if obtained through an authorized Physician distributor.

14. How do I file a warranty claim?

- Return your product in a cardboard box not an envelope, via UPS or registered mail to guarantee their safe arrival. Ship to: 7625 Mesa College Drive, Suite 200A San Diego, CA 92111 Attn: Warranty Department. Please include a letter concerning your claim, and a check or money order for $8 for return shipping and handling. Make sure to include your name, telephone number, and address. You can also file a warranty claim by emailing support@dizzydoctor.com.

15. Can I use the Vertigo Recording Goggles to monitor visual conditions?

- No, the Vertigo Recording Goggles are not permitted to monitor visual conditions.

16. What if I no longer have the same iPhone?

- If you happen to get a new version of iPhone you can obtain a new set of Vertigo Recording Goggles that correspond with your current version of iPhone.

17. Are the Vertigo Recording Goggles compatible with any smartphone?

- The Vertigo Recording Goggles are compatible with iPhone 5, 5s, 6, 6s, 7, 8.

18. How do I start?

- Start by obtaining the Vertigo Recording Goggles from the DizzyDoctor website or from a registered physician. Then, create a patient account at DizzyDoctor.com so that your video recordings may be viewed by you and your physician. Finally, download the DizzyDoctor App to your iPhone and log in with the same credentials as your DizzyDoctor Patient Portal. When experiencing an episode of dizziness, you may then use the DizzyDoctor App and the Vertigo Recording Goggles to obtain a video recording of your eye movements.
19. Can the recordings be performed on my own?
   - The DizzyDoctor System is designed to be used with the assistance of a family member or friend.

20. Do I need assistance performing the Dix-Hallpike testing?
   - Yes. To ensure safety, you should use the assistance of a family member or friend while using the DizzyDoctor System and Vertigo Recording Goggles.

21. How do I know if I got an acceptable video of my eye movement?
   - After each video recording session, you can view the raw, unprocessed footage on your iPhone before uploading it to the patient portal on the DizzyDoctor website. This allows you to ensure the video is clear and has obtained a good recording of your eye movements. This means the eye is somewhat centered on the screen and that you are not blinking excessively during the 20+ second recordings.

22. Will the video recordings be saved on my phone?
   - After a recording session is complete, the raw footage will automatically be stored in the DizzyDoctor Server for 30 days. It will also be automatically uploaded to the DizzyDoctor Patient Portal for further data processing and unlocked for viewing in more elegant detail for a processing fee (1 credit per video sequence). Standard data usage fees from your cellphone data plan may also apply if you are not using WiFi. DizzyDoctor™ is not responsible for those costs.

23. Do my videos upload to the DizzyDoctor Patient Portal automatically?
   - Every video will automatically attempt to upload to the DizzyDoctor Server and Patient Portal immediately after the recording process has ended. As long as your iPhone is in connection with your service plan or WiFi, you may also review the raw footage on your iPhone device. Once a video recording has been uploaded to the DizzyDoctor Patient Portal, they will be stored for 30 days. These videos will not be available to view until they have been unlocked and processed with credits (Credits cost about $19.99 each to upload a video sequence). Once they have been unlocked, the videos will stay on the Patient Portal for a period of up to 2 years.

24. What does it mean to process and unlock a video?
   - When a video has been unlocked with a purchased credit, it will then be automatically processed to provide an enhanced viewing experience for both the patient and the physician. Not only will the processing allow for sequential viewing of the four separate Dix- Hallpike or 3 different Supine Positional Positions, it will also allow viewing of the eye tracking data in nystagmograph form. There will also be a side-by-side display of horizontal and vertical gyroscopic data integral to the phone that will verify to the viewing physician that the patient was keeping their head still throughout the recording process. These pertinent pieces of information will allow for more accurate understanding and diagnosis of the patient’s condition.
25. What is a credit and how much do they cost?
   - Credits may be purchased in the DizzyDoctor Patient Portal. They allow you to unlock/process videos that have been uploaded from the DizzyDoctor iPhone App to the Patient Portal. Once a video has been unlocked with a credit, it will then automatically be processed and available for viewing by you and your physician. It costs one credit per video. The prices are as follows:
     
     | Credits | Cost     |
     |---------|----------|
     | 1       | $19.99   |
     | 4       | $74.99   |
     | 6       | $99.99   |

26. How long will the DizzyDoctor System keep my videos?
   - You will be able to view raw footage on the DizzyDoctor App for a period of 30 days. If they have not been unlocked and processed on the Patient Portal with a credit within 30 days, these videos will be deleted. Unlocked and processed videos will stay in the website Patient Portal for viewing for 2 years.

27. What happens if my iPhone memory is full?
   - An error message will appear in the DizzyDoctor App. Unused videos or photos on your phone will then need to be deleted prior to any further recordings. DizzyDoctor LLC is not responsible for any lost video eye recordings on your phone.

28. How can my physician or other health care provider see my video?
   - At your follow up office visit, your physician will be able to access the recorded videos that you have unlocked in your patient portal from the DizzyDoctor website. To view these videos, the physician will first log into THEIR DizzyDoctor physician portal account. The patient will then provide the physician with their patient log in credentials including their username and password. Once logged in, the physician will then have access to all of the unlocked, processed videos. The physician will not be able to see any videos that have NOT been unlocked from the DizzyDoctor iPhone Application. For the convenience of the physician, please unlock your videos prior to your appointment time if you want your physician to see them with you.

29. How does my physician sign up for the DizzyDoctor System so he or she can view my videos?
   - Your physician simply has to go to DizzyDoctor.com and create a physician portal account with a username and password. They will then be able to log into their portal and view your unlocked videos once you provide them with your log in information at your follow up appointment. Your physician will automatically be logged out of your account after 10 minutes to help protect your privacy. If the physician would like to distribute their own Vertigo Recording Goggles, they may
click on the “Request Goggles” tab

30. How do I find physicians who support the DizzyDoctor System?
   – To find physicians or distributors of the DizzyDoctor System, you will first need to make a profile. Once you have made a profile and signed in, simply click on the physician locator tab on the home page of your patient portal. A list of physicians will also be available in the DizzyDoctor iPhone App by clicking on the “DOCTORS” tab at the bottom of the screen.

31. What is DizzyDoctor System’s Privacy Policy?
   – The DizzyDoctor System follows the regulations of the Health Insurance Portability and Accountability Act (HIPAA). The full privacy policy is available to read from a link on DizzyDoctor.com or on the DizzyDoctor App.

32. Is any assembly required after I receive my Vertigo Recording Goggles?
   – No. The Vertigo Recording Goggles are fully assembled when shipped. When you want to start a video recording, you will have to attach your smart phone to the goggles and start the DizzyDoctor iPhone App.

33. Does the Vertigo Recording Goggles require batteries?
   – Yes, the Vertigo Recording Goggles require a single CR2 Battery.

34. How do I get the DizzyDoctor System App?
   – The DizzyDoctor System App can be downloaded from the iTunes App store.

35. How much does the DizzyDoctor System App cost?
   – The DizzyDoctor App is available for download for free from the iTunes App store.

36. How do I create an account to access the DizzyDoctor System App?
   – You will need to first create a Patient Portal account on the DizzyDoctor website including a username and password. Click on the “Sign-Up” link at the top right corner of the home screen or the bottom right of the Log-in page. You will also enter this same username and password when logging into the DizzyDoctor iPhone App. This will allow you to directly upload your videos from the DizzyDoctor iPhone App to the online Patient Portal.

37. What if I forgot my password?
   – At the bottom of the “Log-In” page, there will be a tab labeled “Forgot Password?” By clicking here and following the instructions, an email will be sent to your account so you may reset your password.
38. Do you offer free stickers?
   - Yes. We offer free DizzyDoctor logo stickers. For all sticker inquiries please send a self-addressed envelope with a stamp to the following address:

   DizzyDoctor Systems
   ATTN: Sticker Inquires
   7625 Mesa College Drive, Suite 200
   San Diego, California 92111

   For any other questions regarding the software or hardware refer to the FAQ’s on www.dizzydoctor.com.

9. CHANGING THE BATTERY

1. The battery is contained behind the front plate labeled “VRG”. The battery is a standard CR2 battery. To remove the Face Plate, hold onto the Goggle Frame and force the Face Plate to the LEFT as shown below.
2. Pull the face plate until it is completely free.

3. Once the face plate is free, remove the CR2 Battery

4. Carefully insert a new CR2 battery while making sure the + and – match the markings on the VRG goggles. CR2 batteries are available in almost any pharmacy or department store that sells camera batteries.
5. Next, slide the phone’s Face Plate back on. Being careful to slide from Right to Left until the locking clip snaps the Face Plate into place on the VRG Goggles.

6. Press the Green Illumination Switch, located on the upper right hand of the Goggles, to turn the illumination system on; and verify the lights on the Goggles turn on. If they do not, remove the face plate and verify the battery is properly placed in the battery holder.

7. Correctly dispose the old CR2 battery.

**IMPORTANT NOTE:** Lithium batteries (similar to most camera batteries) are best disposed of as a non-hazardous waste when fully or mostly charged. DO NOT INCINERATE or subject cells to temperatures in excess of 212°F.
10. SUMMARY

Our highly trained team comes from all over the world including Germany, India, China, and the United States. We come from different backgrounds which make us excel in bringing software engineering to the medical community. We are incorporated in San Diego, California to design and market medical devices related to a variety of vestibular and balance markets. Our goal is to create innovative products that allow patient access to remote diagnosis and treatment strategies for a variety of vestibular and balance disorders that render an individual unable to perform activities of daily living.

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Vertigo refers a sensation of movement and can be perceived as spinning, swaying, or tilting. It can either be subjective vertigo, in which people perceive self-motion, or objective vertigo, in which they perceive motion of the environment\textsuperscript{1}. Dizziness or vertigo is the third most common symptom complaint reported in general medical clinics\textsuperscript{2}. In addition, 3-5\% of visits across multiple clinical settings are due to concerns of dizziness\textsuperscript{3}. This translates to an estimated 25\% of emergency department visits\textsuperscript{3} and \textasciitilde{}10 million ambulatory visits per year in the US alone\textsuperscript{4}.

The goal of the DizzyDoctor System is to provide these dizzy or vertiginous patients with an accurate diagnosis for their symptoms. It allows a patient to obtain eye movement recordings in a remote, non-clinical environment while they are symptomatic. The DizzyDoctor System tests
patients in the four proper Dix-Hallpike positions while obtaining eye movement recordings and analyzing for the presence or absence of nystagmus. The DizzyDoctor System is composed of the Vertigo Recording Goggle (VRG) unit, the DizzyDoctor iPhone App, and the DizzyDoctor website. For a patient to collect eye movement data, they simply need to attach their iPhone to the VRG unit, open the DizzyDoctor App, obtain video recordings of their eye movements in the four proper Dix-Hallpike positions, and upload these videos to the DizzyDoctor website. These videos may then be viewed by their clinician for further analysis and diagnosis. With these crucial eye video recordings, the clinician can have a better understanding as to what may be causing the patients symptoms and therefore prescribe the proper treatment course.

Vertigo can arise from a variety of causes and is usually classified into two groups—peripheral vestibular disorders or central vestibular disorders. In a study published by Strupp and Brandt, the three most common peripheral vestibular disorders in order of frequency are benign paroxysmal positional vertigo (BPPV), Meniere’s disease, and vestibular neuronitis. Each of these disorders is caused by a different pathology affecting a part of inner ear, which is composed of the semicircular canals, the otolith (utricle and saccule), and the vestibular nerve. Central vestibular disorders are a more serious condition, particularly when caused by brainstem or cerebellar ischemic stroke. Recent prospective studies show that dizziness and vertigo are the most common symptoms reported in vertebrobasilar ischemic strokes, which encompass approximately 20% of all strokes.

There is growing evidence that the etiology of acute vertiginous syndrome is often misdiagnosed in many patients and that many clinicians are seeking better guidelines to aid them in their diagnosis. A common trend in differentiating between all of these disorders is the evaluation of eye movements or patterns of nystagmus. Nystagmus is defined as the repetitive and rhythmic oscillation of the eyes and can be vertical, horizontal, torsional, oblique, or any combination of these movements. Research has shown that stimulatory testing such as the Dix-Hallpike positional test is crucial in the evaluation of dizziness because it can reproduce the patient’s symptoms and elicit nystagmus patterns necessary for diagnosis. Other tests utilized at the bedside in a clinical setting include the head impulse test, ocular tilt reaction (including head tile, ocular torsion, and skew deviation), and tests of balance function.

In an emergency department setting, further imaging studies may be ordered to rule out stroke. However, there are multiple factors and studies that suggest bedside examination is superior to brain imaging in determining the diagnosis of an acute episode of vertigo. A study by Chalela et al. suggests the sensitivity of computed tomography scans in identifying stroke is as low as 26%. A second study estimated the sensitivity of CT scans for acute infarction of the posterior fossa to be even lower at 16%. While magnetic resonance imaging is more sensitive that computed tomography, sensitivity is lowest within 24 hours of onset (the most crucial clinical time period).
Sensitivity may even be lower in MR imaging for lesions involving the brainstem or cerebellum\textsuperscript{18-20}. Within the first 48 hours of symptom onset, initial diffusion-weighted MR imaging may reveal false negative results\textsuperscript{19,20,25} in 12-20\% of stroke patients\textsuperscript{21-22}. Results such as these can be detrimental to a patient and even fatal in some cases. It is important for a physician to also rely on the physical and bedside examination for his/her diagnosis.

One of the main examination findings a clinician will be evaluating for during his/her physical examination is nystagmus. Both positional and spontaneous nystagmus patterns are informative clues to the patient’s diagnosis\textsuperscript{23}. When looking at spontaneous nystagmus, it is important to evaluate the direction and effect of gaze on the intensity or direction of the nystagmus\textsuperscript{6}. In other cases, gaze-evoked nystagmus (GEN), or nystagmus that is developed when the eyes are in the most eccentric positions, may also be evaluated\textsuperscript{6}. Bedside maneuvers can induce nystagmus or modulate pre-existing spontaneous nystagmus\textsuperscript{6}, which is essential in revealing any underlying vestibular dysfunction\textsuperscript{26-27}. The Dix-Hallpike maneuver, utilized in the DizzyDoctor System, is one such bedside maneuver that allows for the evaluation of nystagmus patterns.

Each vestibular disorder may display a unique set of nystagmus patterns. The recognition of these types of nystagmus patterns is crucial to obtain the correct diagnosis of the patient’s vertigo/dizziness. The DizzyDoctor System will allow a vertiginous or dizzy patient to obtain recordings of their eye movements during a vertiginous event, remote from a clinical environment. These recordings may later be analyzing by a licensed physician to determine a proper diagnosis. By allowing the patient to obtain a recording while they are symptomatic, the DizzyDoctor System catches and records the nystagmus patterns while they are most prominent or severe. While the DizzyDoctor System was primarily designed for the diagnosis of BPPV, an accurate and well-versed knowledge of the different nystagmus patterns commonly seen in peripheral or central vestibulopathies may further aid a clinician’s diagnostic process.

**Benign Paroxysmal Positional Vertigo**

Benign paroxysmal positional vertigo (BPPV) is a common vestibular disorder caused by dislodged otoconia or otoliths in the semicircular canals of the inner ear. Otoconia are microscopic calcium carbonate particles that originate from the macule of the utricle\textsuperscript{40}. They are normally attached to strategically placed hair cell sensors in the maculae and they deflect those hair cells towards gravity in a linear fashion. Occasionally, these otoliths or “crystals” become dislodged by either idiopathic or disease processes and can migrate into the semicircular canals of the labyrinth. Gravitational movements of these otoconia within the semicircular canals cause positional related vertigo and other associated symptoms of nausea, vomiting, pallor, and sweating\textsuperscript{40}. During the episode of
vertigo, there is often an objectively observed pathological eye movement called nystagmus\textsuperscript{40}. Certain nystagmus patterns are indicative of the otolith debris in different areas of the semicircular canals.

The cause of BPPV has been studied by many and is most frequently reported to be idiopathic\textsuperscript{28}. 50-70\% of BPPV cases are reported as “primary” or “idiopathic” while 30-50\% are due to “secondary” causes\textsuperscript{28}. Secondary causes in order of most common are: head trauma (7-17\%), viral labyrinthitis (15\%), Meniere’s disease (5\%), migraine (<5\%), and inner ear surgery (<1\%)\textsuperscript{28,32,35}.

BPPV has been suggested to be the most common cause of peripheral vestibular disorders\textsuperscript{5,33}. In a study by Brevern et al. with a patient population of 4869 participants, the mean age of symptom onset was 49.4 (SD 13.8) years\textsuperscript{29}. Baloh et al. suggests BPPV is most commonly onset between the fifth and seventh decades of life\textsuperscript{32}. Brevern et al. also reported a lifetime prevalence of BPPV of 2.4\%, a one year prevalence of 1.6\%, and a 4 week prevalence of 0.7\%\textsuperscript{29}. A study conducted by Mizukoshi et al. in Japan suggested the estimated incidence of BPPV to be 10.7 to 17.3 per 100,000 per year\textsuperscript{34}. In the United States alone, there is an estimated incidence of 160,000 new cases per year\textsuperscript{39}. These reported occurrences are likely an underestimate as some cases of BPPV can resolve prior to evaluation and documentation. It is also believed that BPPV is more common in women than men\textsuperscript{29,38} with a female-to-male ratio of 2:1 to 3:1\textsuperscript{32}. BPPV has a large impact on the elderly population and they are thought to be at an increased risk\textsuperscript{28}. A study by Oghalai et al. studied a population of 100 elderly patients, ranging from 51-95 years of age, and found 9\% had undiagnosed BPPV\textsuperscript{31}. The patients in this study who were found to have undiagnosed BPPV also had a significantly lower “activities of daily living” (ADL) score\textsuperscript{31}, meaning their lifestyles were also impaired by their condition. The DizzyDoctor System can help both elderly and non-elderly patients obtain a diagnosis of BPPV and seek treatment for their condition.

During the Dix-Hallpike positional maneuvers, the DizzyDoctor System allows for accurate oculography recordings of nystagmus. There are many published studies detailing the different types of nystagmus patterns that may present depending on which semicircular canal is affected. 60-90\% of all BPPV cases are caused by loose otoliths within a posterior semicircular canal\textsuperscript{39}, making it the most common form of BPPV\textsuperscript{6}. Other studies report posterior semicircular canal BPPV occurring in as many as 85-95\% of cases\textsuperscript{38}.

According to the clinical practice guidelines set by Bhattacharyya et al., diagnosis of posterior semicircular canal BPPV is made when a patient 1) reports symptoms of vertigo provoked by changes in head position relative to gravity and 2) when, on physical examination, characteristic nystagmus is provoked by the Dix-Hallpike maneuver\textsuperscript{30}. In posterior canal BPPV (PC-BPPV), an upbeating and ipsiversive torsional nystagmus (top poles of the eye beating toward the downward
ear) should be evoked. This is a result of the otolith debris and endolymph flowing away from the cupula, therefore deflecting the cupula in an excitatory ampullofugal direction. When the patient sits up from the Dix-Hallpike supine position, the direction of the nystagmus will be reversed; leading to a compensatory downbeat and contraversive torsional nystagmus.

The DizzyDoctor System obtains eye movement recordings in both the supine and recumbent sitting position in order to assess both positional and compensatory nystagmus patterns. It is a unique system that allows a symptomatic patient to obtain eye movement data away from a clinical environment. BPPV episodes are brief, lasting only seconds, and brought on by head movements. Because BPPV episodes are so short-lived and usually occur without warning, it is often difficult for physicians to obtain a diagnosis for their patients. By the time the patient presents to the emergency department or clinic for evaluation, their symptoms may have resolved or nystagmus may not be present during the Dix-Hallpike maneuver due to repositioning of the loose otoliths over time. Therefore, it is useful for the patient to obtain eye movement recordings in the Dix-Hallpike positions as soon as they experience a vertiginous event. The DizzyDoctor System allows for a patient to obtain these recordings in any location. The patient may subsequently present their data to the clinician to aid in a more efficient and accurate diagnosis.

**Other Peripheral Vestibular Disorders**

Other peripheral vestibular disorders may also present with acute attacks of vertigo. Some of these disorders include Meniere’s syndrome, vestibular labyrinthitis/vestibular neuronitis, and migraine. Each of these disorders may also present with a unique pattern of nystagmus and symptoms. A unique feature of the DizzyDoctor system is the “Instant Video” recording option, which allows for recording in any position. Evaluation of spontaneous nystagmus, gaze-evoked nystagmus, and other various positional nystagmus may be observed in addition to Dix-Hallpike positioning.

**Meniere’s Disease**

Meniere’s Disease (MD), also known as endolymphatic hydrops, is another peripheral vestibular disorder that can present with acute attacks of episodic vertigo. During a Meniere’s attack, the vertigo is severe, lasting minutes to hours, and is usually accompanied by fluctuation in low-frequency sensorineural hearing, tinnitus, and aural fullness. Most patients will also have nausea, vomiting, and significant imbalance. MD is often hard to diagnose, however criteria has been established and published. According to the Research Committee of Japan, MD is diagnosed with, “1) two or more spontaneous episodes of vertigo lasting 20 minutes to 12 hours.”
2) audiometrically documented low- to medium- frequency sensorineural hearing loss\textsuperscript{46,47} in one ear, defining the affected ear on at least one occasion before, during, or after one of the episodes of vertigo\textsuperscript{48,49}, 3) fluctuating aural symptoms (hearing, tinnitus, or fullness) in the affected ear\textsuperscript{50}, and 4) symptoms not better accounted for by another vestibular diagnosis\textsuperscript{51,42}.

MD is believed to be caused by an excess of endolymphatic fluid pressure within the inner ear\textsuperscript{38}. The excess fluid builds due to a dysfunction in the production and absorption of endolymph, primarily the defective absorptive activity of the endolymphatic duct and sac\textsuperscript{1,52}. The cause of this dysfunction is unknown, however many factors have been identified and it is believed to be an interaction between both extrinsic and intrinsic factors\textsuperscript{1,42}. Some extrinsic factors that have already been identified as possible causes include: inflammation, trauma, otosclerosis, autoimmunity, and endocrine disorders\textsuperscript{1}. Intrinsic factors include congenital (genetic) or developmental predispositions\textsuperscript{1}.

In most MD cases, only one ear is affected\textsuperscript{1}. In about 15\% of patients, there is bilateral ear involvement\textsuperscript{1}. Most patients present with symptoms between 20 and 50 years of age\textsuperscript{1,38}. Both men and women are affected by the disease in equal numbers\textsuperscript{1}. The reported disease incidence rate ranges between 10 to 190 per 100,000 persons\textsuperscript{38,42,53-55}.

During an acute Meniere's attack, spontaneous nystagmus can be observed and used for further diagnostic purposes\textsuperscript{56}. The vertigo is often described by patients as a severe whirling sensation and is accompanied by a mixed type of spontaneous nystagmus\textsuperscript{42}. The most common type of spontaneous nystagmus observed includes a horizontal and torsional component\textsuperscript{42}. In some instances, the spontaneous nystagmus may also change its direction over time\textsuperscript{56,58}. The spontaneous nystagmus may first beat towards the affected ear (known as the irritative phase), but then reverse direction toward the unaffected ear (known as the paretic phase)\textsuperscript{56-59}. Finally, there may be a recovery phase, in which the spontaneous nystagmus returns to beating back towards the affected ear due to restoration of input from the peripheral vestibular apparatus as well as central compensation\textsuperscript{56,58,59}.

Recordings of these nystagmus patterns and phases may be crucial for diagnosis of this disease. With the DizzyDoctor System, a symptomatic patient can obtain instant eye oculography recordings throughout their vertigo attack. Being able to view and analyze a patient’s nystagmus patterns in combination with their comprehensive audiometric testing will allow a licensed clinician to make a more accurate diagnosis.
Vestibular labyrinthitis/neuronitis

Vestibular neuronitis is an acute peripheral vestibular disorder characterized by sudden onset of severe vertigo with associated nausea, vomiting, and imbalance\(^{38,41}\). It is most commonly caused by a viral pathology affecting the vestibular portion of the vestibulocochlear nerve (CN VIII)\(^{38}\). If the cochlear portion of the eighth cranial nerve is also affected, then the patient will have a change in hearing function and the syndrome is then called a vestibular labyrinthitis\(^{38}\). The affected individuals will likely experience symptoms of vertigo for days to weeks and some may experience a lingering disequilibrium. Studies have shown that most cases of vestibular labyrinthitis/neuronitis are caused by the reactivation of a latent herpes simplex virus type 1 (HSV-1) infection\(^{5}\).

On physical examination, a spontaneous horizontal rotary nystagmus toward the unaffected ear will be present\(^{1,5,6,41}\). This nystagmus can typically be suppressed by visual fixation\(^{5,6}\). If tasked with eccentric gaze, the nystagmus frequency will increase during gaze in the direction of the spontaneous nystagmus and decrease during gaze in the opposite direction (Alexander’s Law)\(^{6}\). In addition, the affected individual will display a position pathological head-impulse test and postural imbalance\(^{5,6}\). The DizzyDoctor System can be used to record these eye movements at acute onset of a viral labyrinthitis or neuronitis. An efficient diagnosis and quick initiation of treatment will help to prevent long term damage to the vestibulocochlear nerve. Therefore, these eye movement recordings can be crucial to a patient’s recovery and long term vestibular function.

Vestibular Migraine

Vestibular Migraine (VM) refers to recurrent attacks of vertigo caused by a migrainous process, in the absence of presence of headache symptoms\(^{1,60}\). Currently, the International Headache Society (IHS) does not recognize Vestibular Migraine as a separate classification of migraine, however other criteria have been researched and established\(^{62}\). According to Neuhauser et al., VM is diagnosed if a patient exhibits: 1) episodic vestibular symptoms of at least moderate severity (including rotational vertigo, positional vertigo, head motion sensitivity, or other illusionary self or object motion), 2) migraine according to the IHS criteria, 3) at least one of the following migrainous symptoms during at least two vertiginous attacks (these include: migraine headache, photophobia, phonophobia, visual or other aura), and 4) other causes have been rule out by appropriate investigation\(^{62-63}\).

In a population study conducted by T. Lempert and colleagues with 200 migraine patients, 9% had definite VM\(^{61}\). The lifetime prevalence of vestibular migraine was reported at 0.98%\(^{61}\). VM currently affects more than 1% of the general population\(^1\). Approximately 10% of patients presenting to
Dizziness clinics and 9% of patients presenting to migraine clinics receive this diagnosis. Migraine has classically been more prevalent in women and the same is true for VM with a reported female-to-male ratio between 1.5- and 5-to-1. Multiple studies have cited that VM occurs more often in patients who suffer from migraine without aura as opposed to those who have migraine with aura. The duration of vertigo differs in each patient and can last anywhere from a few seconds (10%) to minutes (30%), hours (30%), or even days (30%).

While the exact cause of vestibular symptoms in migraine is still debated, it has been suggested that neurotransmitters including calcitonin-gene-related peptide, serotonin, norepinephrine, and dopamine play a role in modulating the activities of the central and peripheral vestibular systems. When these neurotransmitters are released in a unilateral fashion—similar to the unilateral localization of hemiplegic migraines—it could cause a fixed vestibular imbalance resulting in rotational vertiginous symptoms. Bilateral release of these neurotransmitters may result in a state of vestibular excitability and sensitivity. During a vestibular migraine, patients may experience spontaneous vertigo, positional vertigo, or a combination of the two.

Like other peripheral vestibular disorders, VM may present with different patterns of nystagmus. A recent study suggested as many as 70% of VM migraine patients may exhibit either spontaneous or positional nystagmus during an acute vestibular migraine. In a study by Von Breven et al., 20 patients with acute VM were examined during a vestibular migraine episode with 3-D video oculography to assess the absence or presence of both spontaneous and positional nystagmus. In summary, six patients had isolated spontaneous nystagmus, five had isolated positional nystagmus, and three had a combination of both spontaneous and positional nystagmus. Unlike patients with BPPV, the positional nystagmus cases always revealed nystagmus that persisted as long as the patient was in position—unlike with BPPV where positional nystagmus typically fatigues over time. In addition, the direction of VM nystagmus did not usually beat in the plane of the position.

We believe that the DizzyDoctor System is an innovative product that will help clinicians analyze recordings of these nystagmus patterns. During a vestibular migraine, patients can record both instant videos to assess spontaneous nystagmus as well as positional recordings in the four Dix-Hallpike positions. A clinician may better understand the patient’s diagnosis by analyzing both the duration and directional pattern of nystagmus in each video oculography recording. While the diagnosis of Vestibular Migraine requires more details regarding the patient’s symptoms, obtaining a detailed collection of video oculography recordings taken during an acute vertiginous episode can provide more key diagnostic information.
REFERENCES

Documents used as reference for definition of the format and content of this specification.


