

CLEARWATER CLINICAL LIMITED

The DizzyFIX:

Maneuver Training Device for Vertigo and Dizziness



Instruction Manual

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Revised: Nov/03/2014

Product Overview

The DizzyFIX is an effective and intuitive device that assists anybody in completing a particle repositioning maneuver that is often used in the treatment of BPPV.

Whether being used at home, by a doctor or health professional, this device helps the user in performing the crucial particle repositioning maneuvers that are used in treating benign paroxysmal positional vertigo (BPPV) and dizziness.

The DizzyFIX guides individuals with a diagnosis of BPPV through a series of special head and body positions that ultimately guide loose vertigo causing particles out of the inner ear and into non-reactive areas.

With the DizzyFIX, people can repeat the necessary maneuver at home with confidence, even in the case of highly recurrent cases of BPPV.

Caution: This device is not a substitute for medical advice or the attention of a physician. This version of the DizzyFIX is not intended as a medical device or as a treatment in and of itself but as an educational tool. Before using the DizzyFIX it is important that a physician be consulted about all possible causes of vertigo and dizziness and any potential risks associated with the use of this device.

<http://www.dizzyfix.com>

Legal Disclaimer

This booklet is intended to assist in the use of the DizzyFIX device. It is not a substitute for medical advice or the attention of a physician. Dizziness can be a debilitating condition with many different causes. Before using the DizzyFIX it is important that a physician be consulted about all possible causes of vertigo and dizziness.

While the information offered here is intended to be of help to the user, these instructions in no way establish a doctor-patient relationship between the user and Clearwater Clinical Ltd. or any Clearwater Clinical Ltd. employee or representative.

The use of this device should not preclude the customer from seeking medical advice or diagnosis from a health care professional as the device does not rule out other pathology. Customers experiencing other symptoms not described in this manual may have another underlying disease process. If this is the case you should seek medical attention.

Caution: Anyone who has limited range of motion of the neck should consult with his or her physician before performing this maneuver. Other conditions which should be evaluated by a physician prior to the use of this device include but are not limited to; degenerative or unstable neck disease, carotid artery stenosis, stroke, cognitive or mental illness, detached retina and vertebrovascular insufficiency.

The particle repositioning maneuver should always be performed with care and in the presence of another person and the device should be used only as directed.

The DizzyFIX is shatter resistant and the fluid is non-toxic but not designed for consumption.

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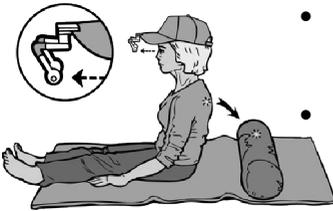
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Language: Versions of this manual are available in other languages on-line. Navigate to www.dizzyfix.com/instructions. Select your language of preference and download. All files are in PDF format.

Quick Start Guide

To use the Quick Start Guide you must first decide which side of your head you want to perform the maneuver, and find a friend to help you. Most people can tell which side causes the symptoms; use the DizzyFIX on this side first. If you are not sure which side causes the problem please review the rest of this manual for more details. Give the quick reference card to a friend who can help you.

Set up the device



- To perform a **LEFT** sided maneuver: While holding the device in your hand, maneuver the particle into the left (Yellow/Square) end of the tube.
- To perform a **RIGHT** sided maneuver: While holding the device in your hand, maneuver the particle into the right (Blue/Round) end of the tube.

Move the particle

1. Clip the device on to the center of the brim of the included hat then put the hat on your head, tighten the chinstrap and sit on the floor.
2. Move the particle from one end of the tube to the other end by adjusting your head and body (to do this you will need to roll on to your shoulder).
3. See the appropriate side, “left/yellow” or “right/blue”, of the Quick Reference card for help with this maneuver.

IMPORTANT-Watch the instructions online and use the ‘Quick Start Card’

This maneuver may not be easy to perform correctly. The DizzyFIX device is intended to assist you in performing the particle repositioning maneuver. However, for your safety and for the successful operation of the device, it is important that you first review this manual and watch the instructions online (www.dizzyfix.com/instructions) to increase your success.

Introduction

Why am I dizzy?

Balance is achieved by the combination of four main systems. Your vision allows you to keep an eye on the horizon. Your nerves sense pressure on your feet and the motion of your body. The balance organ in your ear measures gravity and acceleration and finally your brain puts it all together into your sense of balance. Problems in any of these systems will cause the sensation of dizziness.



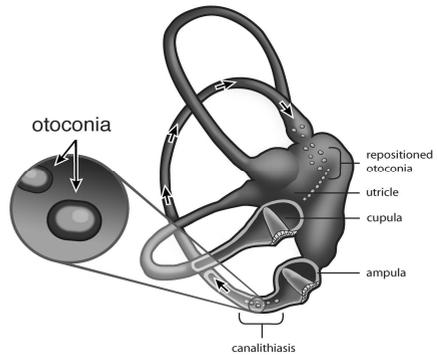
There are five main causes of dizziness. These can be located in the Head, Heart, Nerve, Eye and Ear. Having a problem with your head or brain can cause a variety of symptoms related to dizziness. Similarly a problem with your heart rate can cause light-headedness. A problem with the nerves in your body can also make you feel off-balance. Finally, a problem in the ear can often produce many of these symptoms.

What is Dizziness?

Dizziness is a non-specific symptom and is not a diagnosis. Dizziness encompasses at least three other medical terms for similar symptoms. “Vertigo” is described as a sensation of having your body or the room spin. “Pre-syncope” is the sensation of light-headedness just before fainting and “disequilibrium” is the sensation of being off balance without spinning, or light-headedness.

What is BPPV?

The most common cause of vertigo caused by the inner ear is a disease called Benign Positional Vertigo (BPV) or Benign Paroxysmal Positional Vertigo (BPPV). In this



condition the organ of balance in the inner ear malfunctions. The ear normally uses small crystals called “otoconia” to determine the direction of gravity. When the ear is sick these crystals come loose and float around inside the inner ear and form canalithiasis. These crystals bump into the walls of the inner ear and cause a sudden spinning sensation. There are many other causes of dizziness aside from BPPV. The DizzyFIX can assist anyone in performing the particle repositioning maneuvers that are used to treat BPPV.

How to detect BPPV?

The easiest way to determine if BPPV is present is to review the following symptoms.

A) These symptoms are present:

- Dizziness when lying down, rolling over or moving the head in certain ways
- The sensation lasts only for a few minutes, but the nausea can last longer

B) These symptoms are not often present:

- Dizziness when standing up too fast
- Dizziness that lasts continuously all day and night
- Hearing loss and noise in the ears when dizzy
- Muscle weakness, numbness, confusion and problems speaking when dizzy

If the primary symptoms are listed in section B then BPPV may not be present and further investigation by a physician should be undertaken.

How to determine the side of BPPV?

Since you have two ears, it is possible to have BPPV on either or both of the left side and right sides. Most people are aware which side is causing problems because they get dizzy when they lie down on a certain side. If it is unclear which side is the problem then try this simple test. This test is best performed using the DizzyFIX device but can be done without.

With the DizzyFIX:

1. While holding the device in your hand, move the particle to the left/yellow/square end of the tube.
2. Clip the device on to the brim of the enclosed hat.
3. Put the hat on and tighten the chinstrap.
4. Lie down fast and turn your head to the left, at least 45°. If possible hang your head over the edge of the bed until the particle begins to move.
5. When the particle enters the red zone on the tube you might experience dizziness. If this is the case you have a problem with your left ear.
6. If this does not cause dizziness then try starting with the particle in the right/blue/round side and turning your head to the right when lying down.

Without using the DizzyFIX:

1. Sit on your bed and turn your head to the left.
2. Lie down as fast as you can, and keep your head turned to the left. If possible, hang your head over the edge of the bed.
3. Wait for 30 seconds.
4. If you get spinning dizziness your affected ear is the left ear.
5. If this does not cause dizziness then try the same maneuver but turn your head to the right side when lying down.

How is BPPV treated?

Medical

Many people initially take various kinds of medication such as sedatives, antihistamines and anti-nausea drugs to help with their symptoms. Most people have tried at least 4 medications prior to seeking specialist medical attention. However, medications cannot cure BPPV and only mask the symptoms.

Particle Repositioning

The only non-surgical cure for BPPV is a “Particle Repositioning Maneuver”. This is a specific sequence of rolling movements of the head and body that guide the loose particles through the inner ear and out into a safe area. One version of the treatment maneuver was developed in 1992 by Epley and has undergone rigorous scientific study.

Surgery

Very few people with BPPV are ever treated surgically. However, a number of options are available. Some of these operations carry the risk of deafness and injury to the vestibular balance system. Surgical treatment is reserved for people with highly recurrent and symptomatic disease.

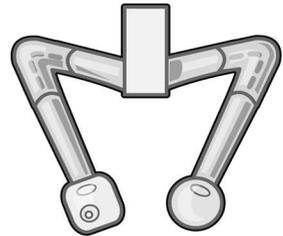
How do I use the DizzyFIX?

The following instructions are also described in the online video (www.dizzyfix.com/instructions). Give the enclosed quick reference card to a friend or family member so they can help you along during the maneuver. The general objective of the device is to guide you through the particle repositioning maneuver. **We recommend using the DizzyFIX once per day for one week or until the symptoms resolve. If symptoms persist despite this, seek further medical attention.** BPPV can recur at any time so it is important to keep the device as you may need it again. The device should be used at room temperature.

To perform a LEFT maneuver

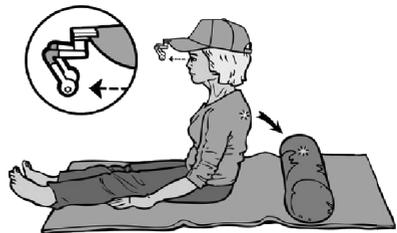
Set up the device

LEFT EAR: While holding the device in your hand maneuver the particle into the left (yellow) end of the tube.



Get Ready

1. Clip the device to the middle of the brim of a snugly fitting hat. Put the hat on your head so that it is level with the floor. Sit down on the floor.
2. Position a pillow on the floor behind you so that if you were to lie flat, the pillow would be under your shoulders and not your head.



Notes:

Move the particle (*Left Sided*)

Get the particle from the yellow (square) end of the tube to the blue (round) end by moving your head and body around.

1. Lie flat on your back over the pillow and turn your head 45° to the left. This will move the particle from the yellow end to the red zone. In this area you may experience dizziness. You should stay in this position for 10-30 seconds until the particle stops moving or until the dizziness settles down.



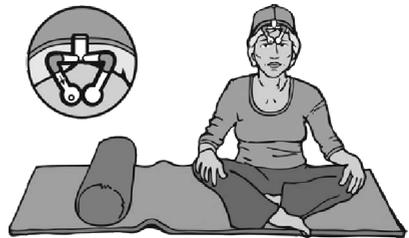
2. Turn your head 45° to the right and watch the particle move along the tube. You should stay in this position for 10-30 seconds or until the particle stops moving.



3. Roll on to your right shoulder and look towards the floor at 45° . This will move the particle from the middle of the tube to the opposite red zone. You should stay in this position for 10-30 seconds or until the particle stops moving.



4. Without turning your head, sit up sideways and watch the particle drop into the blue (round) end of the tube.



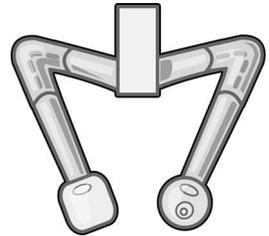
Review your progress

1. If the particle made it from the yellow (square) end of the tube to the blue (round) end of the tube then you have successfully completed the maneuver. We suggest repeating the maneuver daily for one week or until the symptoms resolve.
2. If the particle did not complete the journey to the blue end of the tube then please review the instructions and video again and repeat the maneuver until you successfully guide the particle through the tube.
3. Under rare circumstances, it is possible to have BPPV on both sides and you may need to use the DizzyFIX to perform the maneuver on the other ear for complete relief. In this case we suggest concentrating the maneuvers to one ear for a period of one week and then the other ear.

To perform a RIGHT maneuver

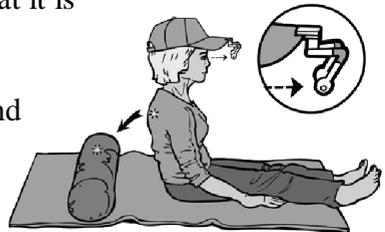
Set up the device

RIGHT EAR: While holding the device in your hand maneuver the particle into the right (blue/round) end of the tube.



Get Ready

1. Clip the device on to the middle of the brim of a snugly fitting hat. Put the hat on your head so that it is level with the floor. Sit down.
2. Position a pillow on the floor behind you so that if you were to lie flat, the pillow would be under your shoulders and not your head.



Notes:

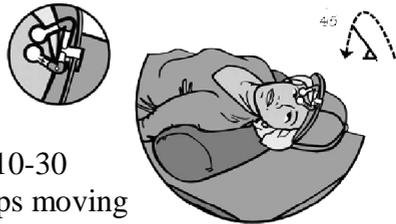
Move the particle (Right Sided)

Get the particle from the blue (round) end of the tube to the yellow (square) end by moving your head and body around.

1. Lie flat on your back over the pillow and turn your head 45° to the right. This will move the particle from the blue end to the red zone. In this area you may experience dizziness. You should stay in this position for 10-30 seconds until the particle stops moving or until the dizziness settles down.



2. Turn your head 45° to the left and watch the particle move along the tube. You should stay in this position for 10-30 seconds or until the particle stops moving



3. Roll on to your left shoulder and look towards the floor at 45°. This will move the particle from the middle of the tube to the opposite red zone. You should stay in this position for 10-30 seconds or until the particle stops moving



4. Without turning your head, sit up sideways and watch the particle drop into the yellow (square) end of the tube



Review your progress

1. If the particle made it from the blue (round) end of the tube to the yellow (square) end of the tube then you have successfully completed the maneuver. We suggest repeating the maneuver daily for one week or until the symptoms resolve.
2. If the particle did not complete the journey to the yellow (square) end of the tube then please review the instructions and video again and repeat the maneuver until you successfully guide the particle through the tube.
3. Under rare circumstances, it is possible to have BPPV on both sides and you may need to perform the maneuvers using the DizzyFIX on the other ear for complete relief. In this case we suggest treating one ear for a period of one week and then the other ear.

Final Comments

In the event that you are unable to complete the maneuver please consult the frequently asked questions and troubleshooting sections of this manual. Further assistance is also available. BPPV in particular is a highly recurrent form of dizziness. While it may be successfully treated by performing the particle repositioning maneuvers, it can recur in the future. We suggest keeping the device to assist you in performing the particle repositioning maneuvers correctly when necessary.

Vertigo and dizziness are complex problems which can have many factors associated with them. Some underlying causes of vertigo and dizziness are very serious and require immediate medical attention. This manual and this device are only intended to assist the user in performing the particle repositioning maneuvers correctly. Neither the DizzyFIX, nor this manual, are a replacement for a visit to a physician. Please also refer to the legal disclaimer section of this manual for further details.

FAQ

1. How did I get BPPV?

There are three main reasons for BPPV

- a. Increasing age predisposes you to get loose particles in the inner ear.
- b. Infections of the ear often cause these particles to come loose.
- c. Head trauma and car accidents are the main cause of BPPV in young people.

2. How long will episodes of BPPV last?

The episodes themselves can last up to several minutes each over a period of several months. Most people get better spontaneously after months or years. However, people who have a single episode of BPPV will likely have further episodes in their lifetime

3. How can I do the maneuver when I get dizzy doing it?

The dizziness associated with BPPV lasts only a few seconds to minutes. Most people can perform the maneuver despite their symptoms by waiting for the dizziness to pass before continuing on to the next step. In order for the maneuver to work the steps have to be followed carefully. If you get dizzy during the maneuver, remain motionless until the vertigo passes, and then continue.

4. Is this very common?

Yes. BPPV is the most common cause of dizziness related to the ear. Approximately 3 million new people are diagnosed with BPPV per year in the United States.

5. Will it come back?

Unfortunately this is very likely. The recurrence rate is somewhere between 20% and 60%. Fortunately a good treatment exists.

6. Why does BPPV recur?

The maneuvers to treat BPPV do not permanently remove the particles that cause dizziness. These maneuvers simply relocate the particles to an area of the inner ear that does not cause vertigo. However, after several months or years these particles can find their way back into areas of the inner ear that are problematic.

7. How can I reduce the chance of having it again?

There is very little which affects the recurrence rate of BPPV

8. Is there anything that makes BPPV worse or better?

Yes. Stress and lack of sleep both make the symptoms worse. Some people think a poor diet and alcohol intake also make the symptoms worse.

9. What are the crystals in the inner ear made of?

The “otoconia” crystals are primarily made up of calcium. Although they are a normal part of the inner ear, they are not supposed to be free floating.

10. How often can I use the device?

It is not necessary to use the device if symptoms are not present, but it is not harmful either. Most people use the device twice a day for several days or until the symptoms of BPPV stop. If your symptoms do not stop or other symptoms occur please check with your doctor.

11. What else can I do?

Medications like sedatives, antihistamines and anti-nauseants do help to a certain degree, but they will not cure your BPPV. Visit your family doctor to rule out other causes of dizziness. Time often helps people cope with dizziness. BPPV resolves spontaneously in most people after a period of between 3 months to 2 years. There is a surgical procedure for BPPV called “Posterior Semi-circular Canal Occlusion” but it involves drilling into the mastoid bone, which is the very thick bone behind the ear. It has certain risks associated with it and should be considered akin to brain surgery. Unless the symptoms are very severe this is not a reasonable option for most people. Acupuncture, Chiropractic and Naturopathic treatments may have benefit but this has yet to be quantified scientifically.

More answers at www.dizzyfix.com

Troubleshooting

1. I can't get the particle to move from one end of the DizzyFIX all the way to the other end.

People rarely have difficulty completing the maneuver because of physical limitations. This can be due to back, neck or weight problems. It is always best to complete this maneuver with a friend or family member. They may be able to help you complete the maneuver.

Please also ensure that the hat is situated on your head parallel to the ground and that the device is in the middle of the brim and pointing directly forwards.

If you still cannot successfully complete the maneuver, please contact your family physician.

2. The particle doesn't move.

This may have occurred during shipping. Loosen the particle with a quick and gentle tap of your finger on the device

3. The hat falls off.

The baseball cap that may have come with your device has a chin strap that secures your hat in place while you complete the maneuver. If you need to use another hat, make sure the fit is snug and secure.

4. I can't see the particle.

The particle is made from a highly reflective material and glows in UV light. If you are having trouble seeing it, make sure to wear your reading glasses during the maneuver. If you still can't see it, have a friend guide you using the device. If you still have problems, take the device to your physician.

5. I am still dizzy or worse after completing the maneuver.

There are several possible reasons for this outcome

- a. You have BPPV that is resistant to the maneuver. In this case it may be worth repeating the maneuver several times and consulting a medical professional.
- b. You have BPPV in both ears. In this case complete the maneuver for the opposite side as well, after waiting one week from the first side.
- c. Although you may have treated BPPV successfully, you may have had a recurrence since the initial treatment. This is quite common and you need only to repeat the maneuver.
- d. You have a rare subtype of BPPV that cannot be treated by this maneuver. Seek medical attention.
- e. You do not have BPPV. There are many other causes of dizziness. If your symptoms persist please consult with a physician or go to the emergency room.

Where to go for Further Assistance

DizzyFIX Website <http://www.DizzyFIX.com>

DizzyFIX Customer Help Line 1-877-349-9934

E-mail help@DizzyFIX.com

Family Physician (Contact Number) () _____ - _____

Local Emergency room () _____ - _____

Product Registration

Clearwater Clinical Ltd. is committed to excellence in customer service. We also endeavor to conduct ongoing research in the clinical sciences.

You can help by registering as a DizzyFIX user at www.dizzyfix.com. You will be sent a short online questionnaire about the DizzyFIX. These clinical surveys will help in the development of future versions of this and other products.

You can also register by mailing your contact information and symptom log to:

Product Registration
Clearwater Clinical Limited
1-877-349-9934
Suite 300, 1306 Wellington St W
Ottawa, Ontario, K1Y 3B2
CANADA

Guarantee and Warranty

The DizzyFIX comes with a 30 days customer satisfaction guarantee. If for any reason you are unhappy with the device, please return it in its original packaging with the original receipt and a description of the problem **to the original place of purchase**. See <http://www.dizzyfix.com/terms.asp> for details. If purchased from www.dizzyfix.com customers must contact info@dizzyfix.com to obtain an RMA authorization number prior to mailing and then return the entire device as directed by customer service.

Please note:

Clearwater Clinical is proud to provide a Limited one-year warranty period on manufacturing and workmanship defects. This excludes damage through misuse or mistreatment or any other causes of device failure except manufacturing and workmanship defects.

The warrantor will, at its discretion, provide you with a replacement or refurbished device, at no cost, once the original device is returned within the one-year warranty period with the original receipt.

This warranty applies to the original owner only. No other express or implied warranties exist except as listed above.

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CANADA

Dizziness and Symptom Log

Symptoms

Date

Physician Labeling

Etiology: BPPV is the most common cause of peripheral vertigo and affects up to 9% of the population over 60 years of age. BPPV may be due to age, infection or trauma.

Natural history: BPPV may resolve spontaneously in about 15% of cases by 1 week. BPPV can be highly recurrent in up to 50% of patients.

Indications: The DizzyFIX may be used, as an instructional guide, by adults who carry a diagnosis of posterior canal BPPV.

Contraindications: Care should be taken in patients with limited range of motion of the neck, unstable neck disease, carotid artery stenosis, stroke, cognitive or mental illness, detached retina and vertebrovascular insufficiency.

Diagnosis: Specific signs and symptoms associated with this condition include:

1. Paroxysmal onset with position change
2. Vertigo
3. Symptoms lasting only minutes
4. Rotatory Nystagmus in the Dix-Hallpike position

Treatment: Effective treatment can be achieved by performing the particle repositioning maneuver. The DizzyFIX assists in the performance of this maneuver by providing training and instruction.

Complications: Expected complications include nausea and dizziness. In some cases vomiting associated with the nausea may occur. Infrequent conversion of posterior canal BPPV to horizontal canal BPPV may occur.