ZEHNIT®

VertiMobile® Eye Movement Recording System

Instruction For Use V1.1

Shanghai ZEHNIT Medical Technology Co., Ltd.

Contents

# 1. Product name, model number

Name: VertiMobile Recording Goggles

Model: ZT-VertiMobile -XXX

ZT – VertiMobile – XXX

Product Model

Product Name

Company Abbreviation
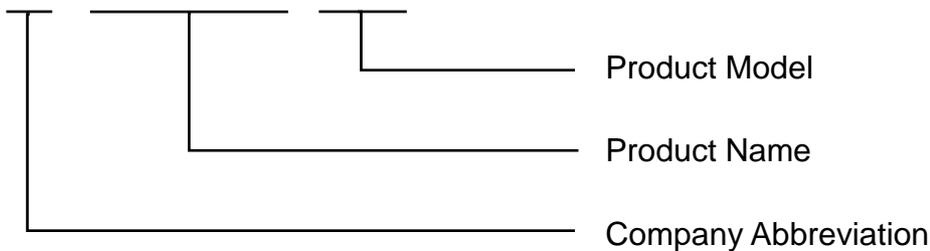
ZT-VertiMobile -iPhone 6/6s	Compatible with iPhone 6/6s
ZT-VertiMobile -iPhone 7/8	Compatible with iPhone 7/8
ZT-VertiMobile -iPhone X/Xs	Compatible with iPhone X/Xs

2. Company information

Manufacturer: Shanghai ZEHNIT Medical Technology Co., Ltd.

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Phone Number: 0086-21-58255835

Email: info@zehnit.cn

3. Intended use

VertiMobile Recording Goggles are intended for recording eye movements with a smartphone for the purpose of assisting a physician or other health-care practitioner in diagnosing and monitoring balance disorders.

VertiMobile Eye Movement Recording system is to be used by trained personnel only, such as audiologists, physical therapists, ENT surgeons, doctors, hearing health-care professionals or personnel with a similar level of qualifications.

The device should not be used by persons who lack the necessary knowledge and training to understand its use and to know how results should be interpreted.

4. Contraindications, warnings and precautions

4.1 Contraindications

(1) Blindness

(2) Broken nose or other face/head trauma

(3) Neck trauma

(4) Recent eye surgery

(5) Recent neck or spine surgery

(6) Ptosis

4.2 Warnings and precautions

	WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.
	CAUTION, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.
NOTICE	**NOTICE** is used to address practices not related to personal injury.

1. The system must not be used in the presence of explosive or flammable gases.

2. The goggles should not be worn by patients who have serious vision defects or who blink abnormally rarely.

Please consult a specialist before using the goggles on these types of patients.

3. No modification of this equipment is allowed without the prior authorization of ZEHNIT.

4. The instrument is not protected against harmful ingress of water or other liquids. If any spillage occurs, check the instrument carefully before use or return it for service.

5. Do not use the equipment if it is showing visible damage.

⚠

1. Use this device only as described in this manual.

2. Do not use the equipment if it is broken. Have the equipment repaired.

3. Proper use of this device depends on a careful reading of this manual and all additional instructions and labels.

4. Let the system reach room temperature before turning it on. Extra time for reaching room temperature may be needed to avoid condensation if the system has been moved from a very cold location to a warmer one.

5. The patients or test subjects should not wear any visual aids such as glasses.

6. The patients or test subjects should not wear makeup around the eyes.

NOTICE

1. To prevent system faults, take appropriate precautions to avoid PC viruses and similar.

2. Dropping and other undue impacts to this device should be avoided. If the device is dropped or otherwise damaged, return it to the manufacturer for repair. Do not use the device if any damage is suspected.

3. ZEHNIT is not responsible for the loss of any data which may occur while performing work on your smartphone and PC. You are responsible for backing up your own data.

Within the European Union it is illegal to dispose of electric and electronic waste as unsorted municipal waste. Electric and electronic waste may contain hazardous substances and therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin shown below. The cooperation of the user is important in order to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

5. Application instruction

5.1 VertiMobile Eye Movement Recording Goggles

VertiMobile Eye Movement Recording Goggles consist of following parts:

A: Phone Holder

B: Goggles Frame

C: Head Strap

D: Replaceable Face Cushion
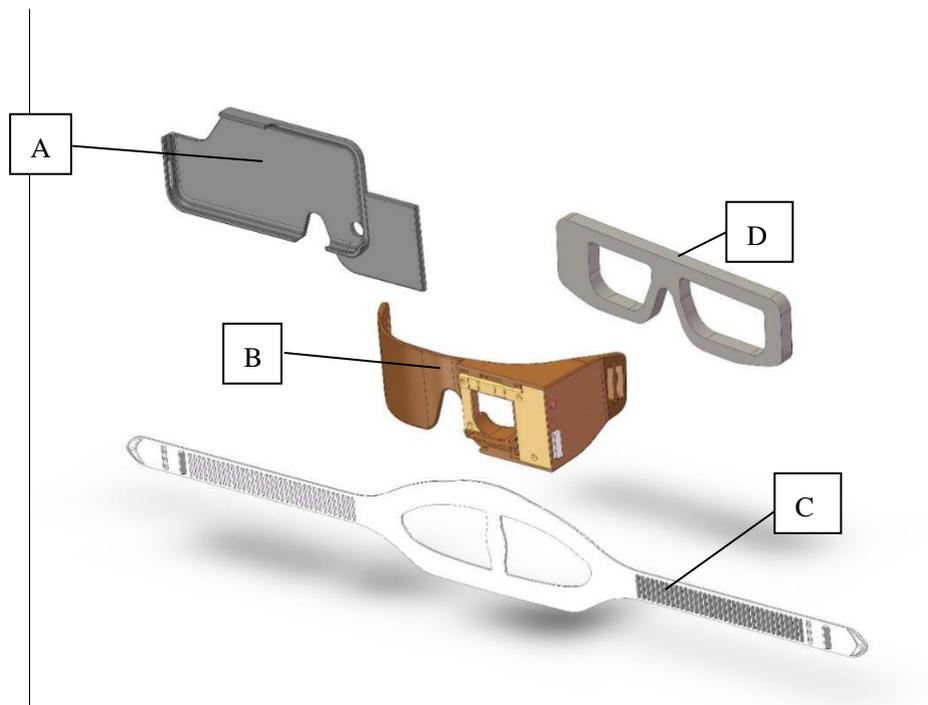
Parts of VertiMobile Goggles

LED Switch: Turns on/off the illumination LEDs.

USB Charging port: Please use the standard 5.0 V USB port and micro USB cable offered with VertiMobile Goggles for recharging. Please make sure to seal the dust plug after recharging to prevent dust from entering.

Indication LED:

Solid green	Illumination system is On.
Blinking green	Low battery, please recharge immediately.
Blinking blue	Recharging.
Solid blue	Battery is fully charged.

Fully charged VertiMobile Goggles provide some 20 hours of continuous illumination.

Recharging the device every 2 weeks is recommended to prevent low battery during use.

Instructions:

a. Make sure you have purchased the correct VertiMobile Eye Movement Recording Goggles that correspond with your smartphone (i.e. iPhone 6/6s/7/8/X/Xs).

b. If you currently have a smartphone case/protector on your smartphone, you must remove the case/protector prior to inserting your smartphone into the VertiMobile Eye Movement Recording Goggles.

c. Place the smartphone into the Phone Holder of VertiMobile Goggles.

d. Put the VertiMobile Goggles over the patient's or test subject's head. Make sure to adjust the head-strap for a snug fit over the patient's or test subject's face such that the goggles do not shift easily when the patient or test subject lies down or sits up.

e. Switch the illumination light on by pressing the LED button located on the side of the frame of the goggles.

f. Launch the VertiMobile app and adjust the goggles to make sure the eye is well illuminated and showing in the center of the screen. Then start recording.

5.2 VertiMobile App

VertiMobile App is an app that allows the user to record eye movements, replay those recordings and send them wirelessly to the PC for further processing in VertiPACS. VertiMobile App is offered for free download from the App Store. Please contact ZEHNIT team to find out if your country/region is supported.

Instructions:

a. The Main screen:

Name	DoB	ID	Last
test	1978/10/24	231447	2018/08/01 11:42
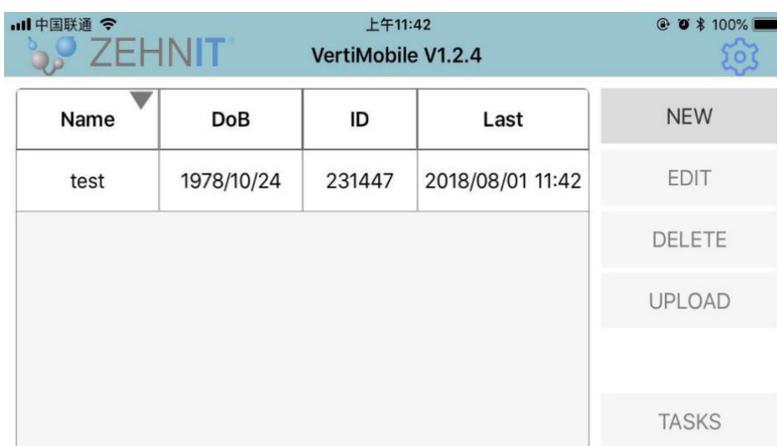
NEW — Create a new patient

EDIT — Edit the selected patient

DELETE — Delete the selected patient

UPLOAD — Upload the selected patient recordings to VertiAppsServer

TASKS — Go to the tasks connected with the selected patient

Settings

The header area displays the company info, the version number of the VertiMobile App, and an icon to go to the settings.

The main area displays the list of patients and buttons for all functions.

The list of patients may be sorted by the various columns; an arrow in the column header displays the current sort order.

b. Settings:

Resolution: Sets the available resolution for the recordings.

VertiApps Server Name: The name of the PC on which the VertiApps Server is running. After entering the name or IP address, please click the 'Search' button. When the connection has been established successfully, the IP address of the PC is displayed.

NOTICE: This setting is only available when VertiApps Server is installed on a PC in the local network. Please contact ZEHNIT team for further instruction in the VertiApps Server and network setup.

To leave the Settings screen, click the back arrow icon in the header or on the phone.

c. New Patient:

The name and the date of birth are mandatory fields. The name has to consist of at least three letters, the birth date has to lead to a reasonable age. The format of the date depends on the phone settings but is displayed in the hints. ID is optional.

In case VertiMobile has access to the VertiApps Server in the local network (see 'Settings') clicking the 'Select' button will bring up a list of previously stored patients.
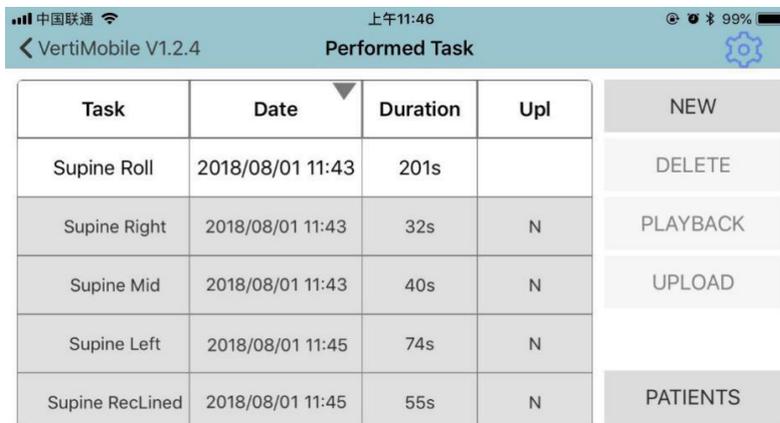
d. Tasks:

| Perform a new task |
| Delete the selected task |
| Play back the task |
| Send to VertiApps Server |
| |
| Go back to Patients list |

The list of tasks displays the task caption, the date and time the task was performed, the duration of the recorded video and a flag indicating whether the task has been uploaded to VertiApps Server.

Clicking on 'New' brings up a list of available tasks, where the user can select a task and start the camera.

e. Recording:
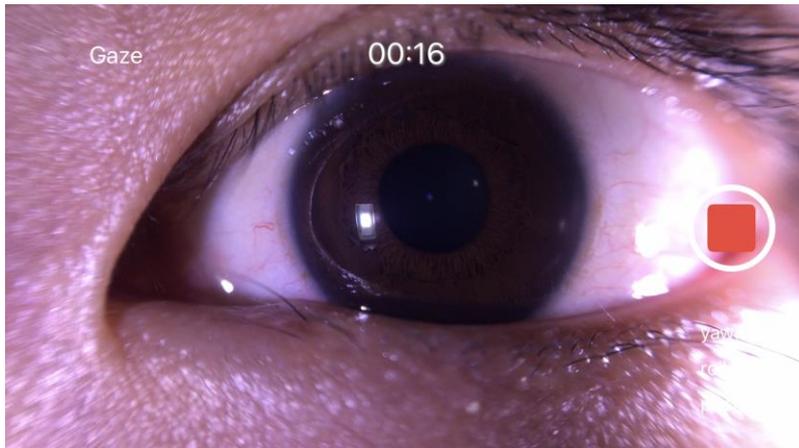
Cancel recording
Timer
Go from preview to recording mode/Save the video and go to next position

.

f. Playback and export:
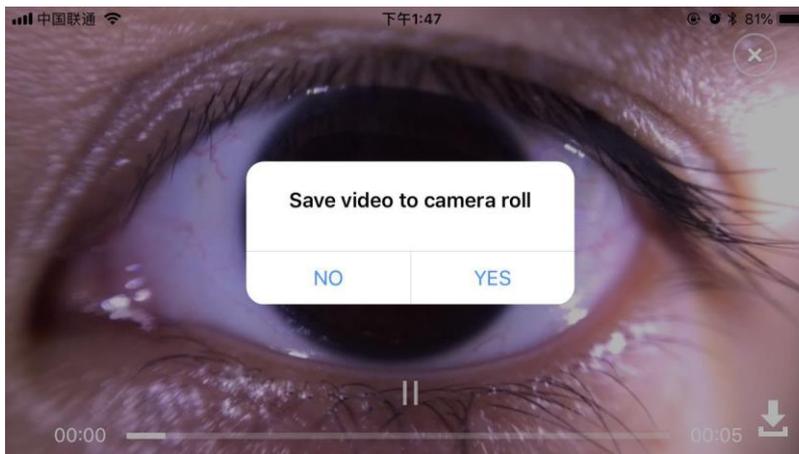
Cancel playback
Pause/resume
Export to camera roll

5.3 VertiPACS(optional)

VertiPACS is the integrated software platform for all ZEHNIT vestibular products. The VertiMobile App can send its recordings wirelessly to VertiPACS, where they can be analyzed, displayed and printed or sent over the internet.

Instructions:

1. In the menu, go to Settings - VertiApps.
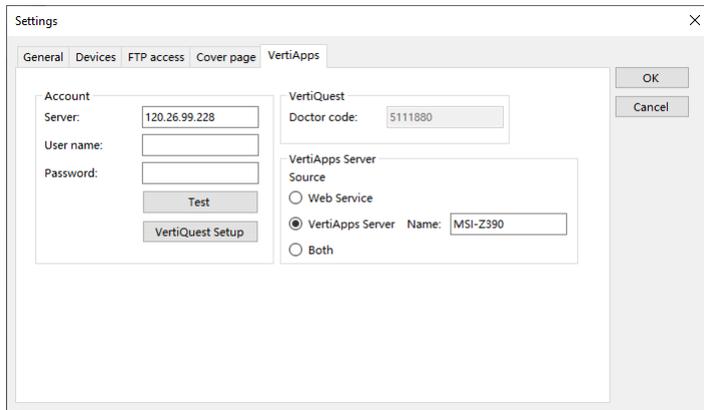
Select VertiApps Server as source for the VertiMobile. Enter the name of the PC that runs the VertiApps Server. The current PC is set by default, but it can also be another PC in the LAN.

2. In the menu, select the VertiMobile Icon.
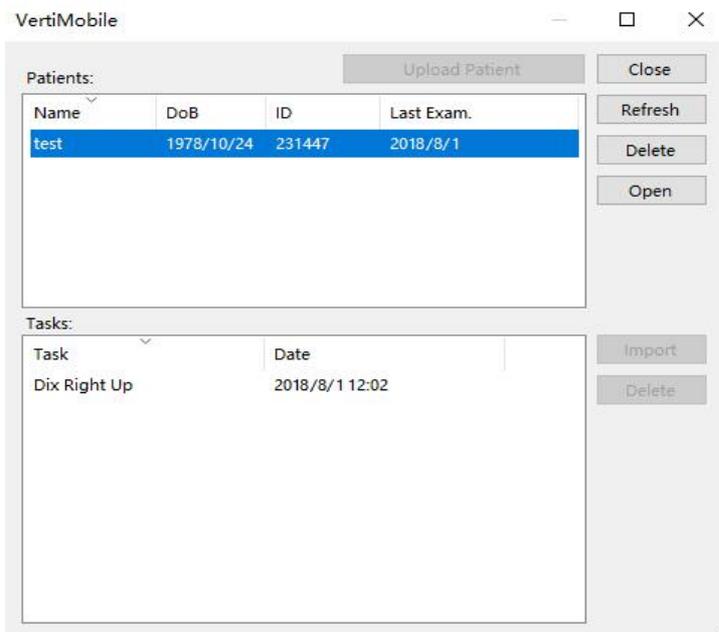
3. Select one patient (top window) and then select a task (bottom window) and click Import to import the task to VertiPACS. VertiPACS will load the task to corresponding test according to task name and date of task.

4. Click 'Open' to import the selected tasks. These will then be analyzed and the traces will be displayed on the main panel. Data editing and report printing can also be done in VertiPACS.
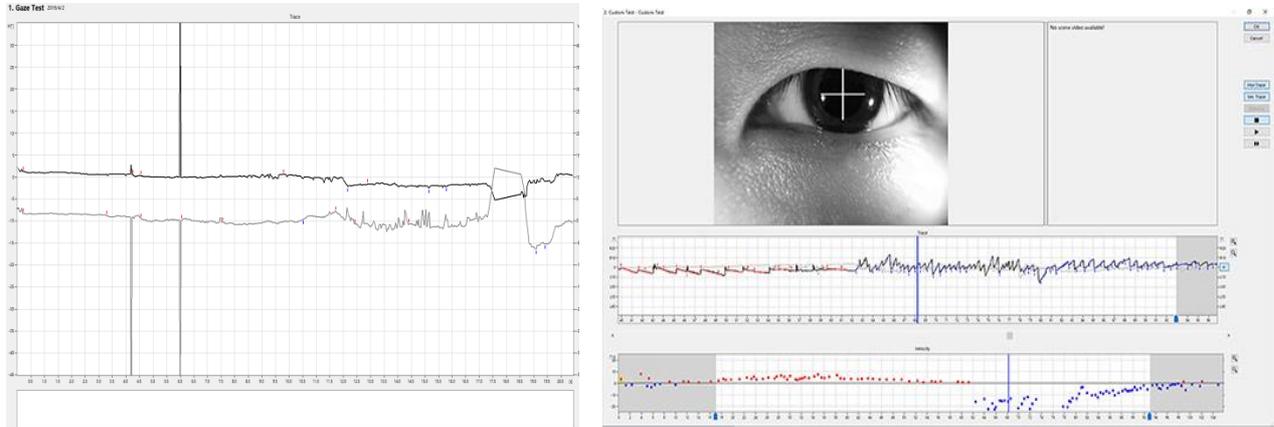
6．Standards

6.1 Operation and Storage Specifications

Operating environment: Operating Temperature: 5 °C to 40 °C

                              Relative Humidity: 30% ~ 90%

Transport & Storage: Storage Temperature: 0 °C ~ 50 °C

                              Transport Temperature: -20 °C ~ 50 °C

                              Relative Humidity: 10% ~ 90%

6.2 Dimensions

Box dimensions：220 x 110 x 90 mm

Product dimensions: 180 x 90 x 80 mm

6.3 Weight

Goggles weight: 126g (without smartphone)

6.4 Battery specifications

Battery: Lithium-ion

Capacity: 500mAh

Charging time: 1~1.5 hours

Charging port: Micro-USB

6.5 Software specifications

iOS Application   VertiMobile V1.2

Android Application   VertiMobile V2.15

PC software   VertiPACS V6.1

6.6 VertiPACS/VertiApps Server system requirements

Operating system: Windows 10

CPU processor: Quad-core or higher

Hardware disk: 120GB or higher

RAM: 4GB or higher

6.7 Device class

This product is self-declared as a Class I in accordance with Council Directive 93/42/EEC, Article 1 (MDD).

6.8 Notes on EMC (Electromagnetic Compatibility)

• VertiMobile Recording Goggles are part of a medical electrical system and are thus subject to special safety precautions. For this reason, the installation and operating instructions provided in this document should be followed closely.

Guidance and manufacturer's declaration – electromagnetic emissions for all equipment and systems		
VertiMobile Recording Goggles are intended for use in the electromagnetic environment specified below. The user of VertiMobile Recording Goggles should ensure that the device is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Class A	VertiMobile Recording Goggles use RF energy only for their internal functioning. Therefore, their RF

| Harmonic emissions IEC 61000- 3-2 | Class A | emissions are very low and are not likely to cause any interference with nearby electronic equipment.

VertiMobile Recording Goggles are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
|---|---|---|
| Voltage fluctuations/ flicker emissions IEC 61000-3-3 | Complies | |

Immunity – All Equipment and Systems

VertiMobile Recording Goggles were not tested for immunity to electromagnetic disturbances.

7. Maintenance and Troubleshooting

7.1 General maintenance information

The VertiMobile Eye Movement Recording Goggles are made of durable plastic material. The silicon head strap is made of bio-compatible material and designed for long-term wear. The electronic illumination system has been tested for shock resistance and durability. Within reasonable limits of use as intended by the labeling, the VertiMobile Goggles are essentially maintenance-free.

If the surface of the device is soiled, it can be wiped clean using a soft cloth moistened with a mild solution of water and dishwashing liquid or similar. The use of organic solvents and aromatic oils must be avoided. Always switch off and disconnect the USB charging cable during the cleaning process, and be careful that no fluid enters the housing containing the illumination system and the rechargeable lithium battery. If

the VertiMobile Goggles are accidentally submerged or exposed to liquids that may have entered the housing of the illumination system, do not use them. Test the illumination system before putting on the VertiMobile Goggles for recording.

The replaceable face cushion is made of bio-compatible medical sponge. It is designed for single use. We suggest exchanging it between patients to avoid the possibility of cross infection.

In case of malfunction, non-authorized personnel is not allowed to open the device. Repair should be performed under the instruction of the technical personnel of Shanghai ZEHNIT Medical Technology Co., Ltd.

7.2 Troubleshooting

What if the strap is too loose?

- Pull on the end of the strap to tighten it so that it fits snugly on the patient's or test subject's head.

What if the strap breaks?

- Do not use the VertiMobile Goggles. Contact the ZEHNIT team or authorized dealer for a replacement strap.

What if the face cushion comes off?

- Do not use the VertiMobile Goggles without the cushion, as they could cause injury. Replace the face cushion.

What if there is a blurry image on the videos?

- Remove your smartphone and carefully clean the lens with a standard glass cleaner, then dry with a microfiber towel.

What if the illumination LEDs cannot be turned on?

- Recharge the device and try again. If the problem persists, please contact the ZEHNIT team for repair.

What if I no longer have the same smartphone?

- If you get a newer-model smartphone, you can purchase a new set of VertiMobile Goggles that correspond with your current smartphone.

Are the VertiMobile Eye Movement Recording Goggles compatible with any smartphone?

- The VertiMobile Eye Movement Recording Goggles are compatible with iPhone 6, 6s, 7, 8, X and Xs. More smartphone models may be supported – please contact the ZEHNIT team for more information.

8. Warranty

VertiMobile Goggles are warrantied against all manufacturing defects for a period of 6 (six) months from the date of delivery by ZEHNIT to the first purchaser. ZEHNIT does not provide a warranty against loss of the device or against lens scratching. The warranty is valid only if purchased through Shanghai ZEHNIT Medical Technology Co., Ltd. or an authorized dealer. The estimated life of the Lithium-Ion battery is three years or 300 charge cycles, whichever occurs first.

9. Packaging list, storage and transportation

9.1 Packaging list

    VertiMobile Eye Movement Recording Goggles
    USB charging cable
    Additional replaceable face cushion
    Storage bag
    Instruction for use

9.2 Storage

Please store the VertiMobile Goggles in the original carton box or in the microfiber optics bag provided. Do not expose your VertiMobile Goggles to prolonged direct sunlight such as inside a vehicle.

The packaged VertiMobile Goggles should be stored in a well-ventilated room free of corrosive gas.

VertiMobile Goggles unpacked should be put indoors to avoid dust.

9.3 Transportation

The lithium battery of the VertiMobile Goggles is of the type proven to meet the requirement of each test in the UN Manual of Tests and Criteria, Part III, subsection 38.3; and is manufactured under a quality management program according to 59 DGR 3.9.2.6(e). The tested package is capable of withstanding a 1.2m drop test in any orientation (except PI967&PI970).

10.   Markings

The following markings can be found on the device.

SN	Serial number
	Follow instructions for use.
⚠	Warning, please refer to the instruction manual.
EC REP	European Union authorization representative
	Date of manufacture
	Keep dry
	Symbol for "use until".
	Indicates the medical device manufacturer, as defined in the EU Medical Device Directive 93/42/EEC
	Do not discard with household waste.
CE	The CE mark on this product indicates it has been tested and conforms to the provisions noted within the Medical Device Directive 93/42/EEC.