VERTIGENIUS™

Better Balance with Technology©

USER MANUAL

Vertigenius™ VG01 Instructions for use
Date of issue: 24th Apr 2025 Rev 3.2

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1 Introduction to this instructions for use (booklet)

This booklet guides you on how to use and maintain your new Vertigenius™ head-sensor. Ensure you read this booklet carefully, including the Warnings section. This will help you get the most benefit from your head sensor.

Your clinician has personalised your prescription, setting the metronome beats per minute (the speed at which you need to move your head during your exercises) to meet your requirements. If you have any questions regarding the settings, contact your clinician.

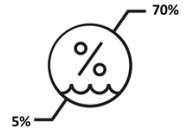
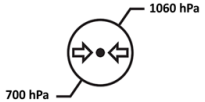
A clinician (physiotherapist, medical professional) is defined as a person who is appropriately educated and has proven competency in professional assessment and rehabilitation of balance impairment, dizziness and vertigo, in selecting and prescribing the appropriate rehabilitation exercises for your clinical needs. The education and regulation of the clinician in accordance with national or regional regulations. This type of treatment is known as Vestibular Rehabilitation.

2 Medical device symbols

The table below explains the meaning of the medical device symbols used in this instruction booklet, on sensor and packaging labelling, in accordance with EN ISO 15223-1: 2021 Medical devices symbols to be used with medical device labels, labelling and information to be supplied, Part 1: General requirements and in accordance with Directive 2012/19/EU WEEE.

Symbol	Symbol title	Additional information
	Manufacturer	This product is manufactured by Digital Rehabilitation Ltd. The symbol indicates the manufacturer, identified by the manufacturer name and address adjacent to this image.
	Date of manufacture	This symbol is unfilled or can be combined with the ISO 3166-1 country code to indicate the country of manufacture. It indicates the date of manufacture. The numbers below the symbol indicate the year and month of manufacture. e.g. 2021 - 03 indicates manufactured in March 2021.

	Distributor	This product is distributed by different parties per regulatory jurisdiction. Check the Feedback, Returns and Warranties section of this manual for returns information for your area.
	Serial number	Numbers after or below the image indicate the unique serial number of the Device. e.g.; D1071.
	Unique device identifier (UDI)	Unique code that identifies the device manufacturer, model and production information
	Container contents	Indication of how many units in a package - number of units appears within the symbol
	Prescription only	This device is prescription only. Consult instructions for further details.
	BF Applied Part	In normal operation this battery powered device is worn on the ear.
	Single patient multiple use	This device is intended to be reused by a single patient. Consult the instructions further for care and maintenance of your device.
	Keep dry	This symbol indicates that the device must not get wet.
	Temperature limit	This symbol indicates the upper and lower temperature limits.

	Humidity limit	This symbol indicates the upper and lower humidity limits.
	Pressure limit	This symbol indicates the upper and lower pressure limits.
	Consult instructions for use	This symbol indicates that the user should consult the instructions of use. A synonym for “Consult instructions for use” is “Consult operating instructions.”
	Non-ionizing electromagnetic radiation	This symbol is used to indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems, e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	WEEE wheelie bin	This symbol is used because the product contains electrical and electronic components that may contain materials which, if disposed of with general waste, could be damaging to the environment. Residents of the European Union must follow specific disposal or recycling instructions for this product. Residents outside the European Union must dispose or recycle this product in accordance with local laws or regulations that apply.
	European conformity mark	The product conforms to applicable requirements for the European market. If the mark is accompanied by a number, conformity is verified by the indicated notified body.
	Universal serial bus (USB) port	This symbol is used to indicate a USB port. USB Implementers Forum, Inc. standard icon.
	Medical device	This is the symbol to indicate that this product is classified as a medical device.

3 About your head sensor and intended use

Intended use (EU)	The Vertigenius™ head sensor is intended to assist in the delivery and tracking of a prescribed exercise regime for Vestibular Rehabilitation. The Vertigenius™ system comprises a sensor that is worn behind the ear that detects head movement and a companion smart phone app. Vestibular rehabilitation exercises are prescribed by a clinician for their patient using the Vertigenius™ Application platform. The head sensor is worn whilst the patient is carrying out the prescribed head movement exercise regime for Vestibular Rehabilitation. The head sensor is used to provide real-time feedback to the patient so that they can see if they are carrying out the prescribed exercises correctly. The sensor and connected app provide feedback to the prescribing HCP on the quality of exercise performance and adherence of the patient to the prescribed exercises, enabling the HCP to remotely monitor progress.
Intended use (US)	The Vertigenius™ system is intended to assist in the delivery and tracking of a prescribed exercise regime for Vestibular and Balance Rehabilitation. The Vertigenius™ system comprises a sensor that is worn behind the ear that detects head movement, a companion smart phone app and clinician platform. Vestibular rehabilitation exercises are prescribed by clinicians for their patient using the Vertigenius™ application platform. Vertigenius™ can be used with or without the head sensor. The companion app delivers the prescribed exercise regime, provides auditory and visual cues, tracks symptoms and monitors adherence. The head sensor is worn whilst the patient is carrying out specific prescribed head movement exercises for Vestibular and Balance Rehabilitation. It is used to provide real-time feedback to the patient so that they can see if they are carrying out the prescribed exercises correctly. The sensor and connected app provide feedback via the clinician platform to the prescribing clinician on the quality of exercise performance, changes in symptoms and adherence of the patient to the prescribed exercises, enabling the clinician to remotely monitor progress.
Indications for use	Vertigenius™ is indicated for use with patients experiencing acute or chronic central and/or peripheral vestibular dysfunction. The Vertigenius™ head sensor is indicated for use when real-time corrective feedback is required during rehabilitation exercise performance.
Intended user	1. Appropriately qualified clinicians who are responsible for prescribing use of the sensor and modifying rehabilitation prescriptions based on interpretation of patient performance data provided by the sensor. 2. The end users are persons receiving treatment for balance impairment, dizziness and vertigo.
Intended user group	Adults older than 18 years.

Use environment	In clinic or at home, in conjunction with the Vertigenius™ application platform.
Contraindications	Not suitable for adults under the age of 18 years. Users of active implants must pay special attention when using the head sensor. For further information, see the Warnings section. In the event of queries, discuss with the prescribing clinician. Do not place the head sensor directly onto broken, or damaged skin.
Clinical benefits	The clinical benefits of the Vertigenius™ system, including the use of the head sensor, are to: 1. Provide a reminder and illustrations of the prescribed head movement exercises to the patient. 2. Provide objective measurable outcome data for each patient, for view by the clinician and patient, on symptom severity, exercise adherence and performance accuracy. 3. Provide opportunities for the clinician to remotely adjust the rehabilitation prescription, based on data trends provided from the sensor and symptoms digitally reported by the patient. 4. Improve clinician workflow by reducing overall clinician time required to treat patients requiring vestibular rehabilitation. 5. Provide real-time feedback to the patient on motor performance during prescribed exercises, improving the patient experience and exercise accuracy when participating in Vestibular Rehabilitation, whether performed in clinic or remote from clinic. 6. Provide corrective feedback on exercise performance to enable improvements in vestibular function.
Undesirable side effects	Vertigenius™ is not to be used without clinical guidance. Consult your prescribing clinician should any side effects persist more than 24 hours. 1. An increase in subjective symptoms of vertigo/dizziness/nausea/anxiety - Increased symptoms are common with exercises, and are discussed by the prescribing clinician with the patient in advance of the prescription, within the prescribed reading material and during clinical reviews. If they persist, your prescription may need to be adjusted. 2. An increase in headache or neck pain - Increased symptoms are common with starting a new exercise regimen, and are discussed by the prescribing clinician with the patient in advance of the prescription and during clinical reviews. If they persist, your prescription may need to be adjusted. 3. Fall - Falls are very uncommon/rare when exercises are performed as prescribed by the clinician. Falls prevention during therapy is discussed by the prescribing clinician with the patient in advance of the prescription, and is addressed within the prescribed reading material, within exercise instructions where appropriate and during clinical reviews. In the event of a fall where injuries have been sustained, seek medical attention. In the event of a fall where no injuries have been sustained, inform and consult your prescribing clinician.

Note: For a full list of warnings and precautions consult section 11 and 13 respectively of this manual

IMPORTANT NOTICE
Your clinician is responsible for prescribing your treatment, including your personalised exercise program. They will decide for you which exercises are required, how often and at what speed they are performed. The head sensor will enable real time feedback on your head movements for certain exercises but is not responsible for your treatment prescription.

FCC ID: 2BNLD-VG01.
The FCC ID is also available on the VG01 box label, and on the VG01 head sensor itself.

FCC WARNING STATEMENT
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

WARNING: Changes or modifications not expressively approved by the party responsible for compliance could void the user's authority to operate the equipment.

Radiation Exposure
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment can be installed and operated with a minimum separation distance of ≤ 5 mm between the equipment and users/bystanders.

4 Fast set-up guide

4.1 Charging

The head sensor requires charging when the LED will not turn ON. When a charged head sensor is powered ON the LED will be Blue. It takes 1.5 hours to fully charge the head sensor battery. In normal charging mode, the LED will be Purple (Blue & Red). In cases where the unit has been fully discharged and then left uncharged for an extended period of time, the LED will be Blue to indicate Precharge mode.

Charge state	**LED colour**
Precharge active	Blue (ON)
Fast charge active	Blue+ Red = Purple (ON)
Charge complete	None (OFF)
Temperature suspend	Red (ON)
Timer fault	
No input voltage	None (OFF)

4.2 ON / OFF

The head sensor turns ON by a short press of the button and is indicated by the Blue LED flashing (Figure 1). When the sensor is ON and correctly connected to the app, it is indicated by the sensor LED light changing from a flashing display to a continuous ON display (solid Blue). The head sensor also turns OFF by a long press on the button (more than 2 seconds).

The head sensor turns OFF automatically after 70 seconds, indicated by the LED going OFF:

- When the Vertigenius™ application is closed.
- Or, when there is no phone connected to the head sensor.
- Or, when the head sensor is turned ON and then left idle (not connected to a phone).

Even when connected to a phone App, the head sensor will turn off after 5 minutes of complete inactivity (a feature for extended battery life).

5 How to start and use

5.1 Your wearable Vertigenius™ head sensor

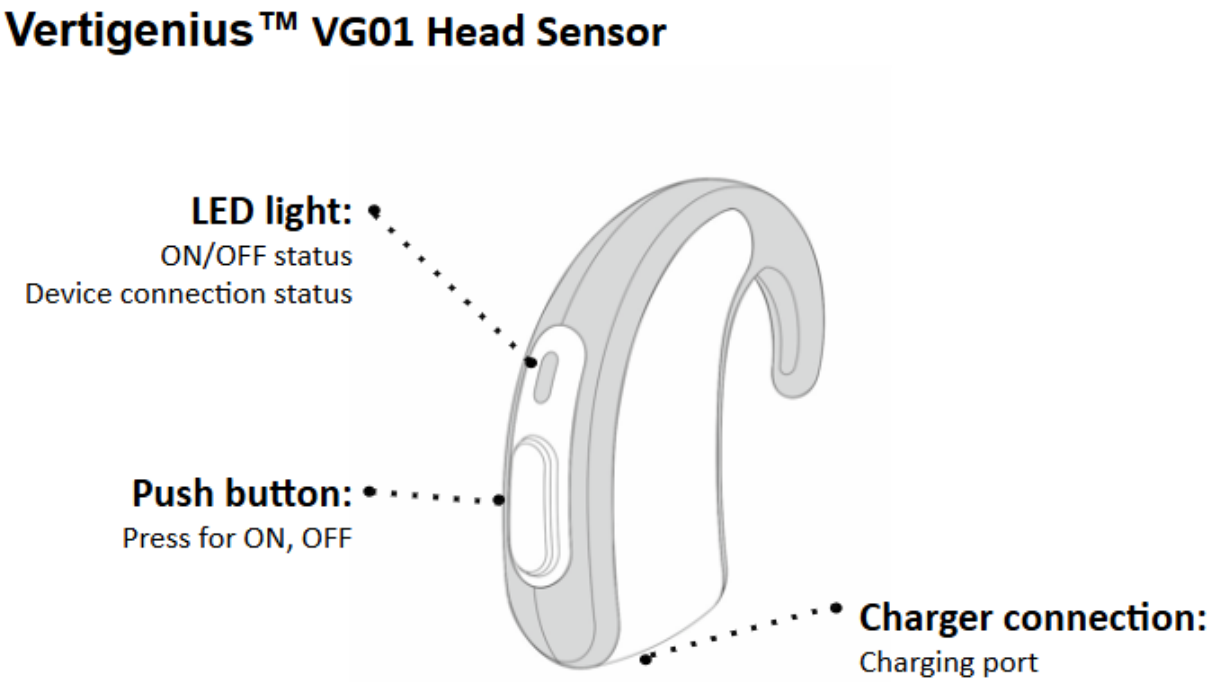


Figure 1: Vertigenius™ head sensor

5.2 Charging instructions

Connect the cable/lead to the charging port (USB type C connector) on the Vertigenius™ head sensor and the other end to a USB charger device (not provided). USB A to USB C, or USB C to USB C charging cables will work with the head sensor (Figure 2).

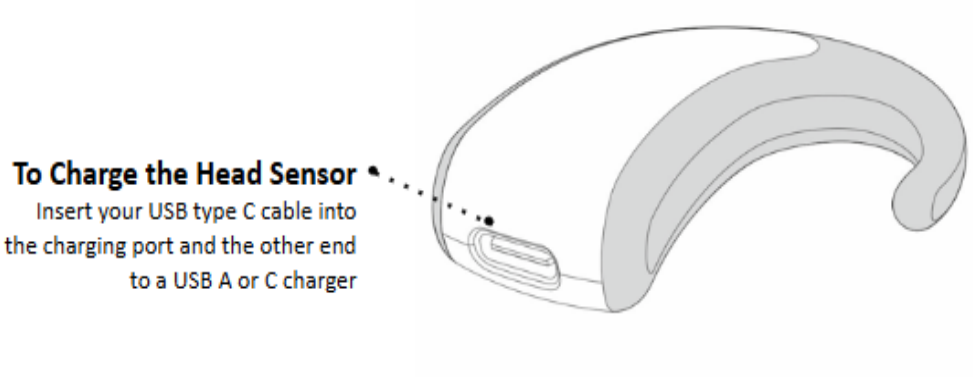


Figure 2: Charging port for the Vertigenius™ head sensor

5.3 Charging time

Ensure you fully charge your head sensor battery before first time use. If your head sensor's battery is completely drained, the normal charging time is as follows:

1.5 hour	1 hour	30 minutes
Fully charged	90% charged	50% charged

When the battery is fully charged, the charging process stops automatically. Leave the head sensor in a secure place when not in use. The LED turns OFF to indicate that charging is complete. Be aware that charging time may vary depending on the remaining capacity of the battery. For instructions on how to use your charging lead, see the previous section.

5.4 Battery performance

The daily battery performance varies depending on your individual use, the number and type of exercises, the number of exercise sessions each day and the time taken to perform the exercises that require the head sensor. The longer the exercise time, the more sensor battery is being used.
If your head sensor runs out of battery charge, the LED signal will not display ON, no light will be visible. In this case, be sure to recharge it by connecting the sensor to the lead and the lead to a USB charger.

For optimal usage and charging conditions, ensure the sensor is operating in a room temperature within the range of +5°C to +35°C (41°F - 95°F).

It is recommended to charge the head-sensor battery when the head sensor LED does NOT flash nor display continuously when the ON/OFF button is pressed. If your head sensor does not perform for a full day, please contact your clinician.

LED charging indications:

When a head sensor is plugged into charge and the battery is not in deep discharge:

- The LED colour while charging will be Purple. When the head sensor is fully charged, the LED will turn OFF, indicating charging is complete.

When a head sensor is plugged into charge and the battery is in deep discharge:

- The LED will be Blue while in pre-charge (while the battery recovers from deep discharge)
- However, if the battery is discharged to the point where it can't even power the LED, then the LED will not turn ON when initially plugged in to charge. Only when the battery is charged enough will the Blue LED turn ON while in pre-charge mode.
- If pre-charge isn't completed in 30 minutes, then charging will stop and the LED will turn Red.
- If pre-charge completes successfully then the LED colour will change from Blue to Purple to indicate it has entered normal charge mode.
- When the head sensor is fully charged, the LED will turn OFF, indicating charging is complete.

Charge state	**LED colour**
Precharge active	Blue (ON)
Fast charge active	Blue+ Red = Purple (ON)
Charge complete	None (OFF)
Temperature suspend	Red (ON)
Timer fault	
No input voltage	None (OFF)

5.5 Shelf & product life

The expected product lives are:

- Shelf life: 5 years
- Product use life: 3 years from first activation

The 3 year usage life is based upon estimated battery recharge performance.

5.6 Turn head sensor ON / OFF by using the push button

The head sensor can be turned ON by pressing the push button and holding it for less than one second (Figure 3). When the sensor is ON, it will be indicated by the LED displaying a blue flashing light. When connected to the App the blue light will be ON continuously.

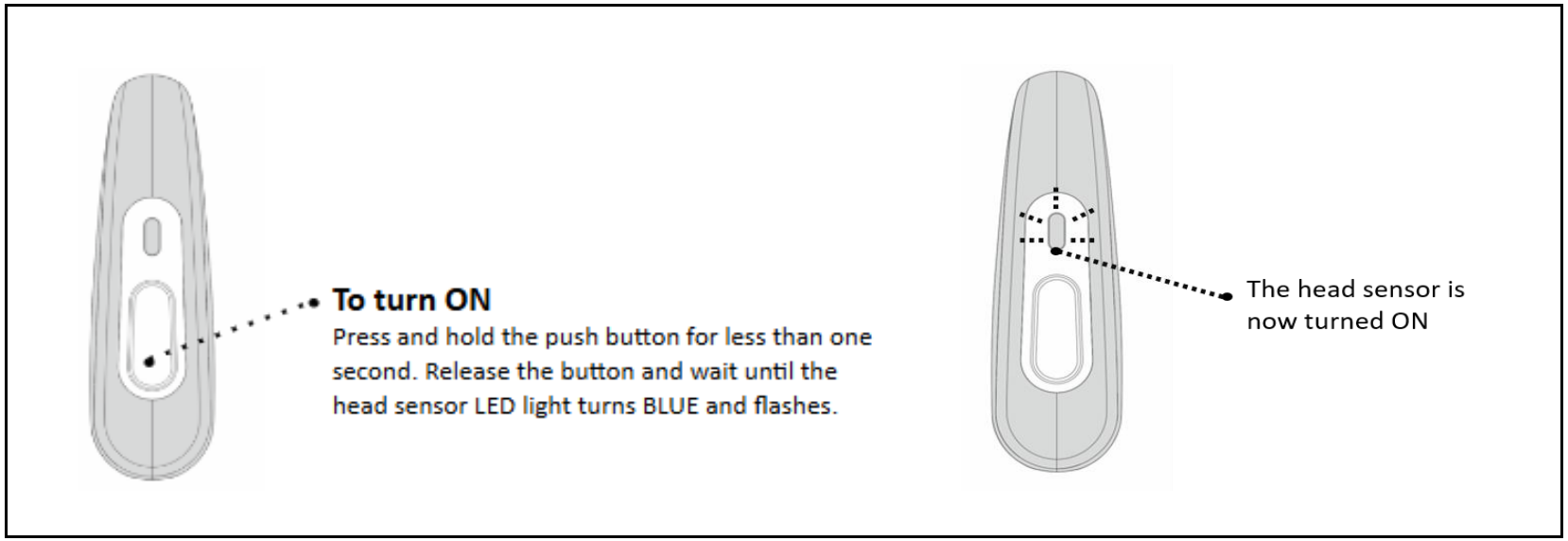


Figure 3: Turning on the head sensor

The head sensor can also be turned OFF by pressing and holding the push button for more than two seconds (Figure 4).

The head sensor turns OFF automatically after 70 seconds, indicated by the LED going OFF:

- When the Vertigenius™ application is closed.
- Or, when there is no phone connected to the head sensor.
- Or, when the head sensor is turned ON and then left idle (not connected to a phone).

Even when connected to a phone App, the head sensor will turn off after 5 minutes of complete inactivity (a feature for extended battery life).

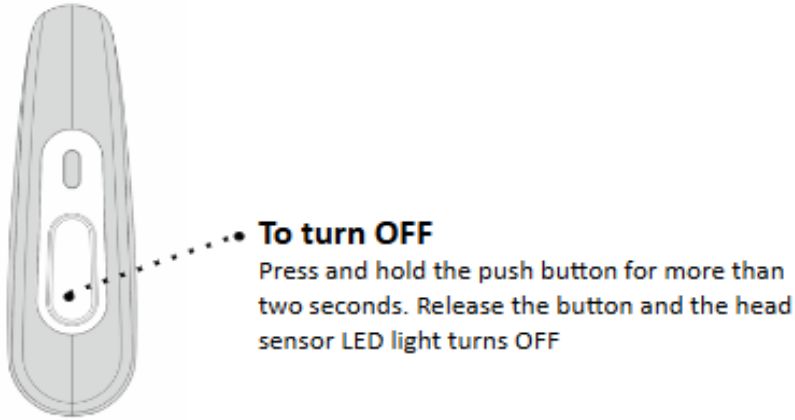


Figure 4: Turn off the head sensor

LED functionality and sensor status

LED	No light	Fast blinking	Slow blinking	Steady light
Sensor status	Sensor OFF	Ready for connection	Ready for connection	Connection established

5.7 Putting on the head sensor

The head sensor can be worn on either ear, right or left. Place the head sensor gently on your ear (Figure 5). Make sure the green hook is positioned at the front of your ear with the large body of the sensor resting behind your ear. The green hook, if resting at the front of your ear will be visible to yourself when facing a mirror. The ON/OFF push button is positioned at the back of the sensor, behind your ear. The sensor should fit neatly and easily onto all ears. It does not matter whether the writing on the side of the sensor is resting against your head or facing outwards.

The head sensor can be used while wearing other head worn devices such as hearing aids or glasses while exercising. With glasses, it may be easier to place the sensor on first and place the glasses on afterwards. With hearing aids, it may be easier to leave it/them in place and position the sensor on top. When one hearing aid is in use, it may be easier to place the sensor on the other ear where no hearing aid is being used. When two hearing aids are used, they can be left in place, with at least one switched on. Alternatively, one can be removed if preferred to allow for placement of the sensor during exercise.

If active devices, such as cochlear implants, are in use, please consult the Warnings section of this document. In the event of queries, discuss with your prescribing clinician.

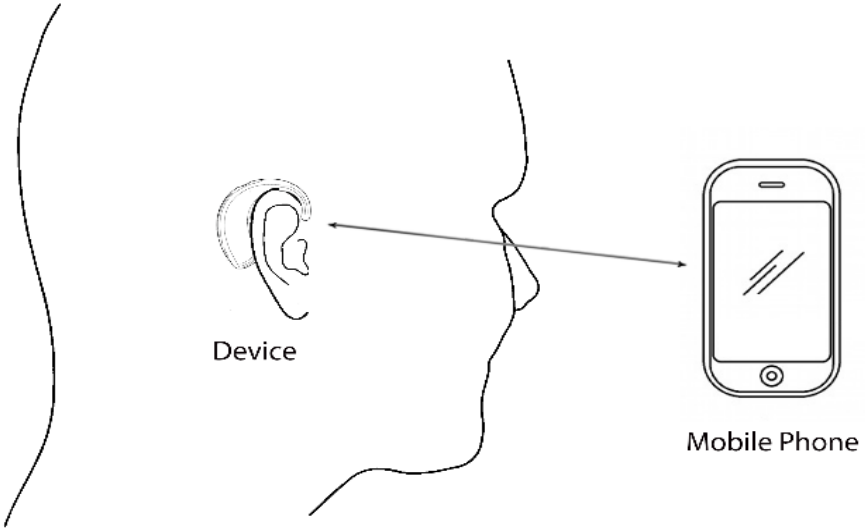


Figure 5: Putting on the head sensor

5.8 Connecting Vertigenius™ head sensor to the Vertigenius™ Application

The head sensor connects to the application via Bluetooth® communication between the sensor and the phone.

Ensure when installing the Vertigenius™ Application (app) to 'accept' the conditions prompted by your phone relating to application permissions. And allow Vertigenius™ to access Bluetooth®.

You will be asked to 'log in' with your email/phone number and OTP (One time Password) number which will be sent to you via SMS/email (Figure 6).

Once logged in, the application opens the **Main page** where there are three main options available for selection (Figure 7):

- **My Program**
- **My Reading**
- **My Progress**

In addition to the three main options, in the top-left corner of the screen,
there is a small Menu icon (three horizontal short lines), which if selected by tapping on it, opens the Menu below with the App features (Figures 7 & 8) .

- **Notification**: Allows to receive App and Program notifications.
- **Reminder**: Patient can set times and days of the week to get reminders to complete the exercises.
- **Device Connection**: Allows to connect the head sensor with the App manually.
- **DVA Test**: This allows your clinician to perform a clinical test called the dynamic visual acuity test using the head sensor
- **About**: Provides information about Vertigenius™ App version.
- **Logout**: Close the patient session with the App (not recommended if in treatment).

Figure 6: Log on page of Vertigenius™ App

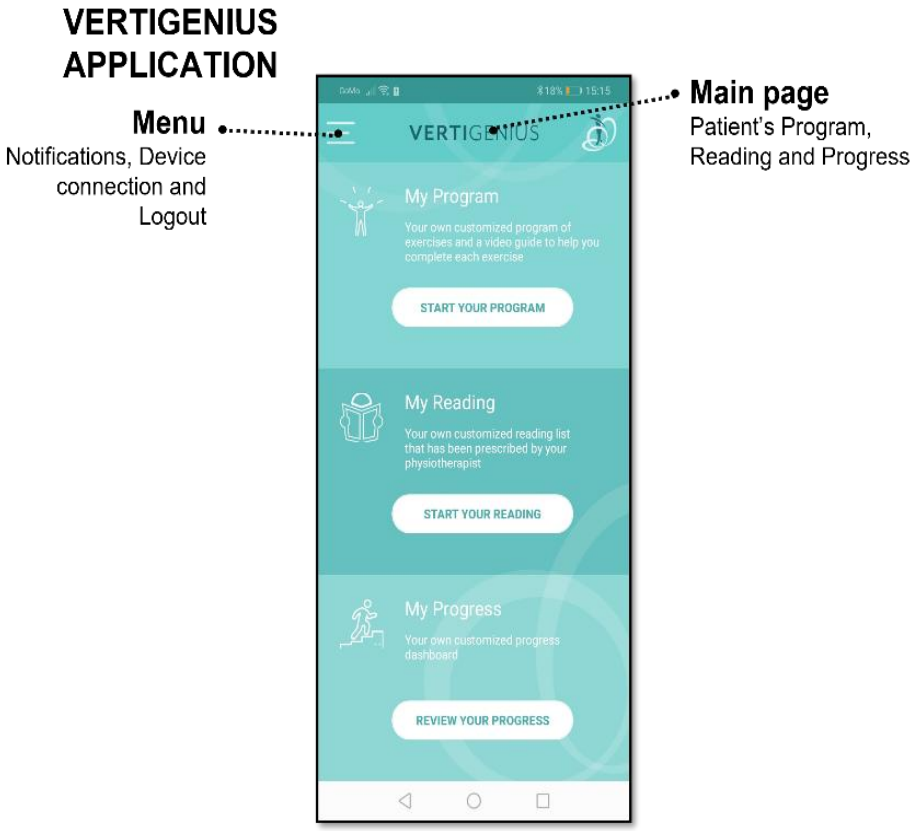


Figure 7: Main page of Vertigenius™ App

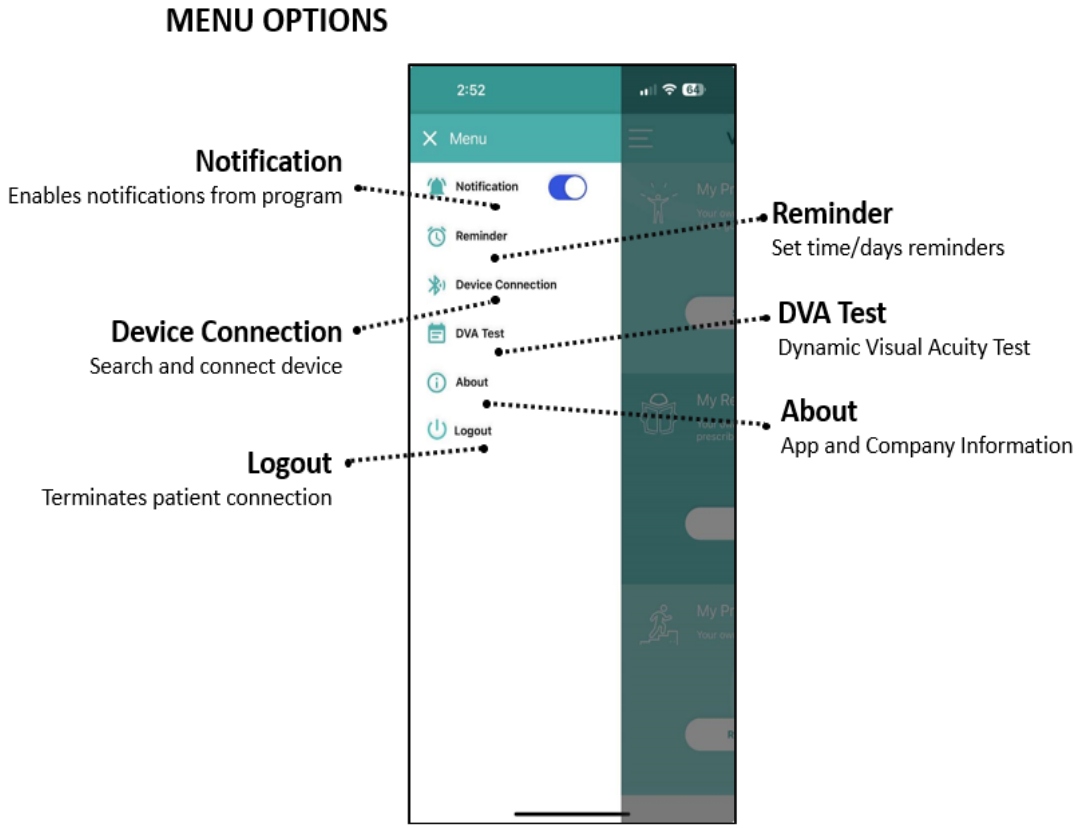


Figure 8: Menu bar of Vertigenius™ App

5.9 Connecting the head sensor

To connect the sensor to the App, select the Menu icon by clicking or tapping on it. It then displays the following Menu options, from which the app can connect to the sensor by selecting '**Device Connection'** (Figure 9)

Once the "**Device Connection**" option is selected, this automatically opens a new screen window showing that the app is scanning to find new Bluetooth® devices, including the sensor. Search results will automatically be displayed on this screen when the app finds the Vertigenius™ head sensor and other Bluetooth® devices. Once the Vertigenius™ sensor device appears listed, select/click on the "**Connect**" option (Figure 9). This will connect the Vertigenius™ head sensor to your phone. When this happens, it will be indicated by the sensor LED light changing from a flashing display to a continuous ON display, indicating the head sensor is connected correctly.

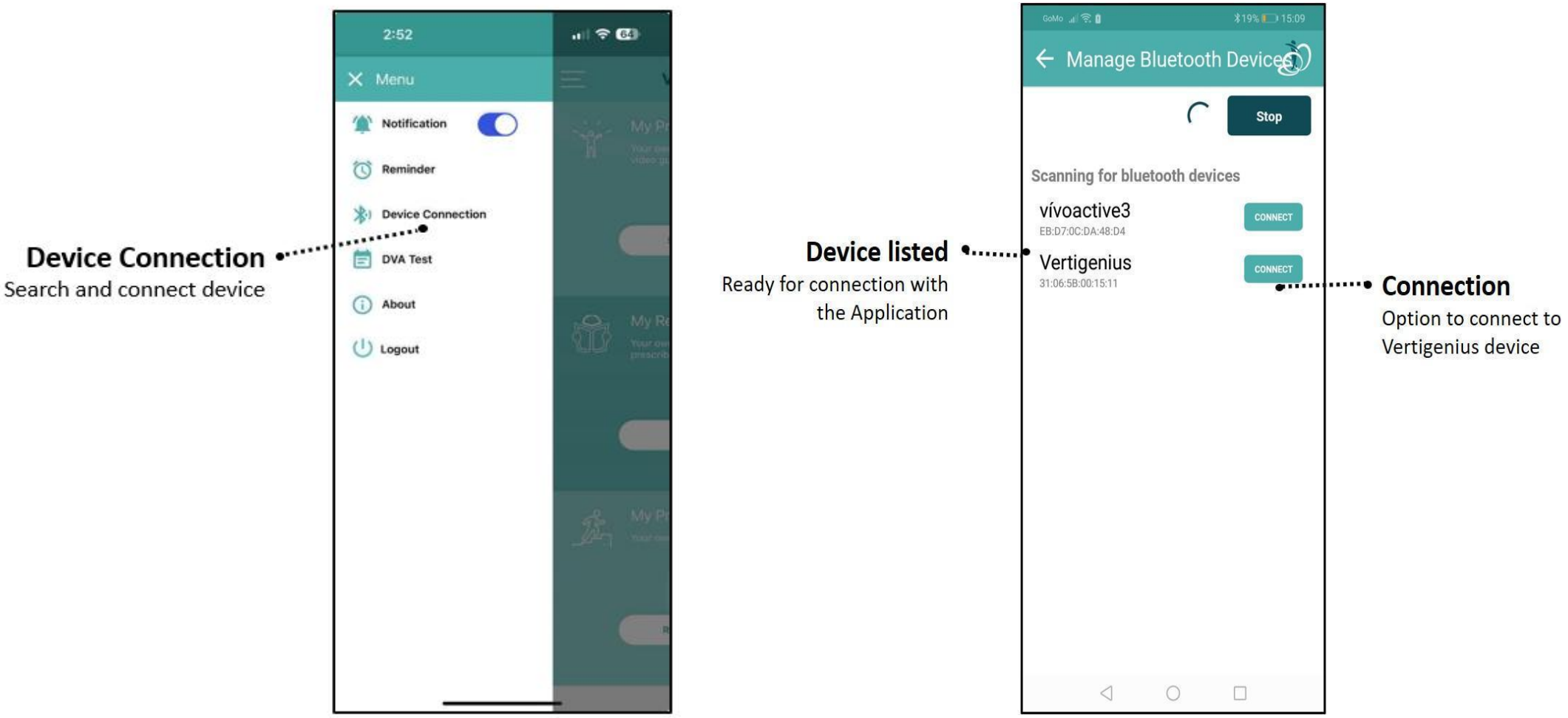


Figure 9: Device Connection Menu and Device List

5.10 Starting with exercises and connecting head sensor

Once the head sensor has been connected with your device, it will connect automatically each time that the head sensor is turned on and the user is at the '**My Program' page** of the Vertigenius™ Application. The successful connection is indicated in the head sensor with a continuous LED light. See next steps to get to the '**My Program' Page**'.

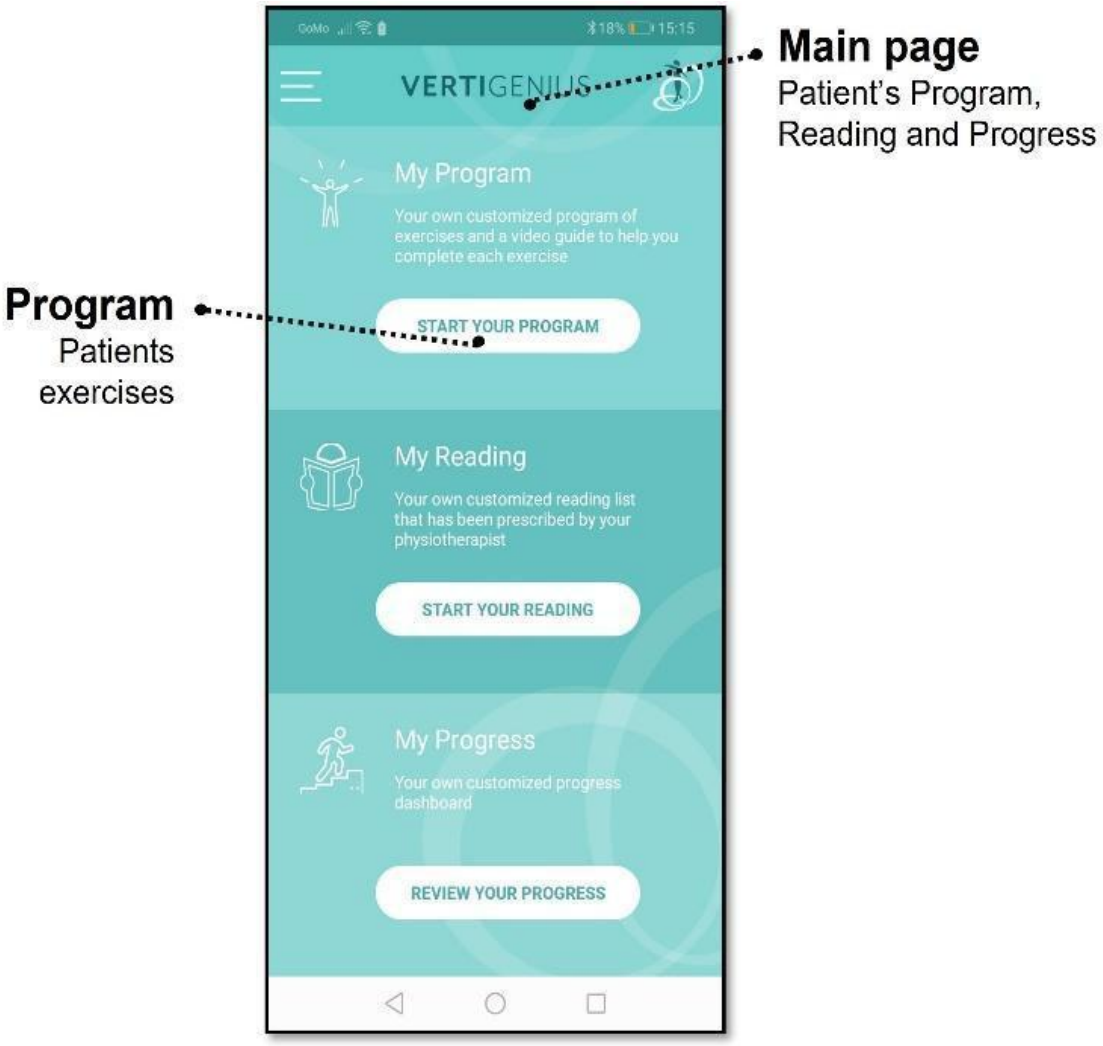


Figure 10: Starting program from main page

To start your exercises, go to the '**Main page**' and select '**Start your program'**(Figure 10). This menu also includes prescribed reading 'My Reading' for you about vertigo, dizziness and other related effects to inform you about the symptoms and how the treatment can help. At the bottom of the main page, there is a tab '**My Progress**' where you can check your progress with the treatment program (Figure 10).

'**My Program**' page lists all the exercises prescribed by your clinician through the Health Care Professional platform Figure 11. Click on an exercise, the Application will display all of the information relating to that exercise. Once all the sessions of an exercise have been completed, the exercise will be greyed out.

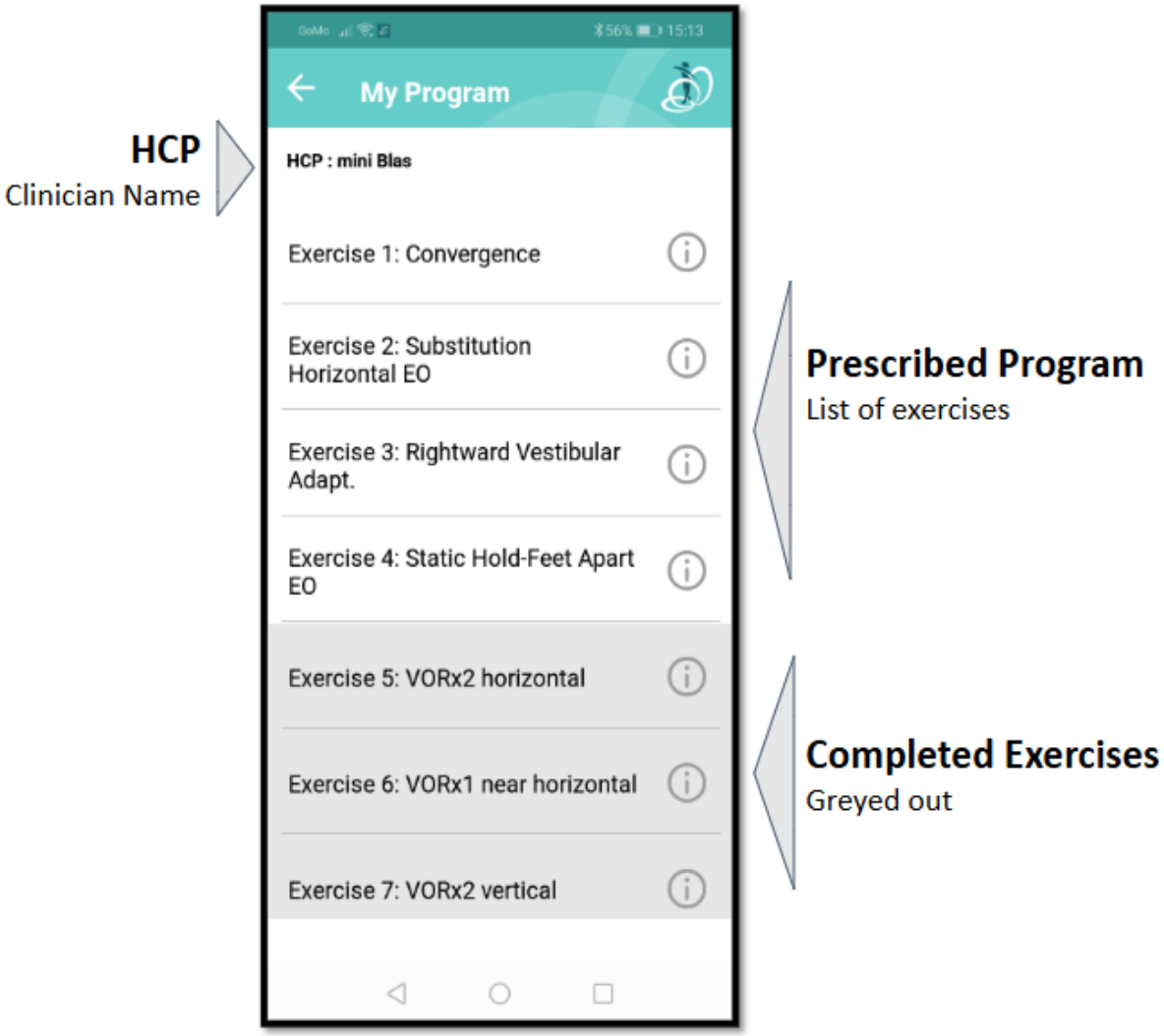


Figure 11: Exercise list on the Vertigenius™ App

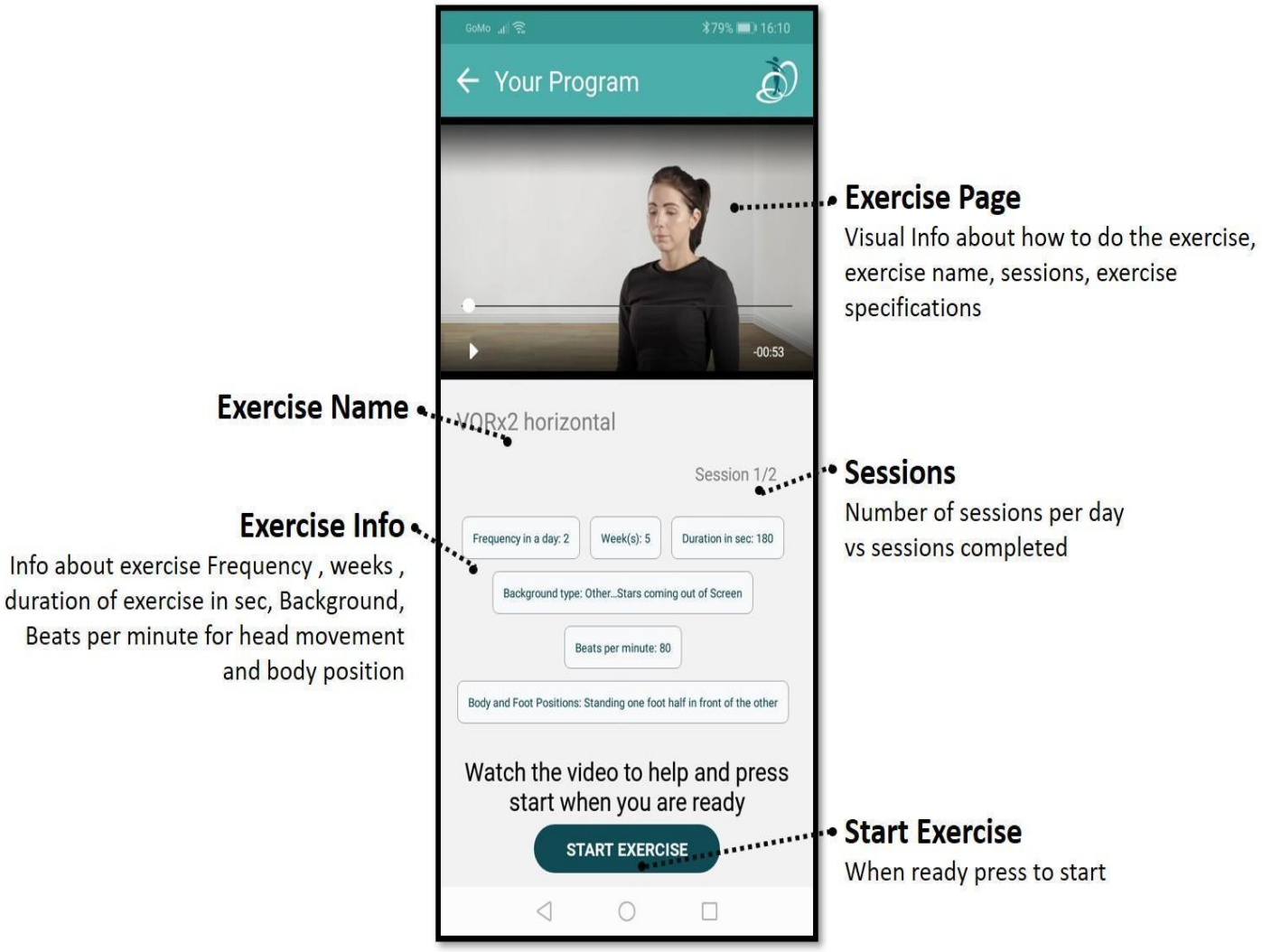


Figure 12: Exercise page of Vertigenius™ App

The '**Your Program' Page**' contains an instructive video with a voice over explaining how to do the exercise (Figure 12). It provides the name of the exercise, the session number underway as a proportion of the sessions to be completed (1/2) and information about your personalised prescription requirements:

- Frequency / Number of sessions per day
- For how many weeks has the exercise been prescribed
- Duration of the exercise in seconds
- Background display on the app (patterned or plain - fixed or moving)
- Prescribed head speed (beats per minute)
- Prescribed body position to perform the exercise
- Any additional notes about the exercise, specific to you, that your clinician has prescribed.

It is at this point when the head sensor will connect automatically with the Vertigenius™ application. This is indicated with a continuous LED light.

In the event that the exercise requires the head sensor and this has not been connected successfully, the exercise will prompt a pop-up window giving instructions to the user to check that the head sensor is turned on and asking the user to try a manual reconnection with the head sensor (Figure 13).

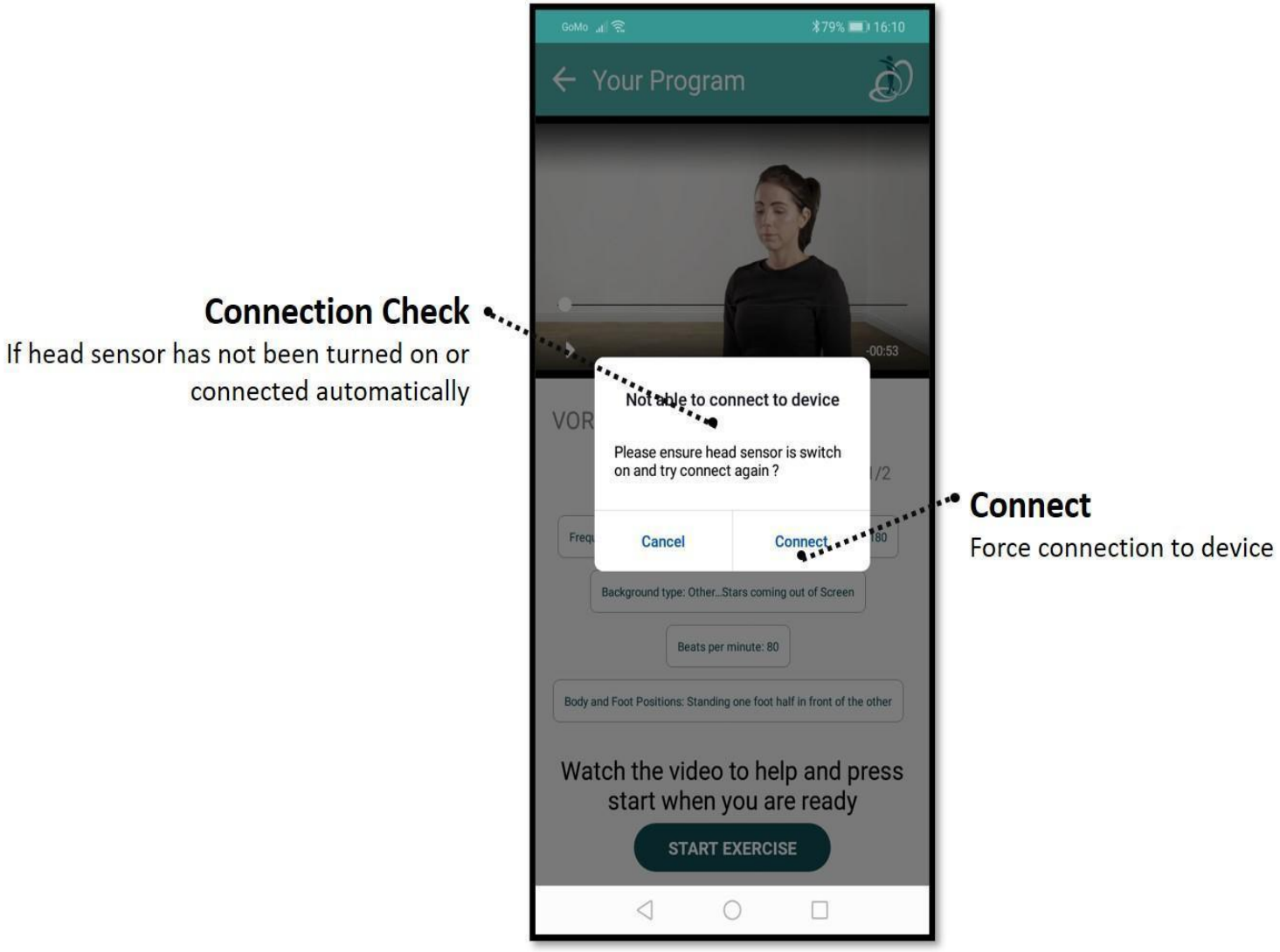


Figure 13: Head sensor connection

Once everything is ready, the app displays a countdown in seconds while preparing to start the exercise. The app display also shows performance related features such as: Timer for the exercise duration, Feedback Bar indicating real-time user head speed. It also displays the 'Back button' to return to '**My Program**' page (Figure 14).

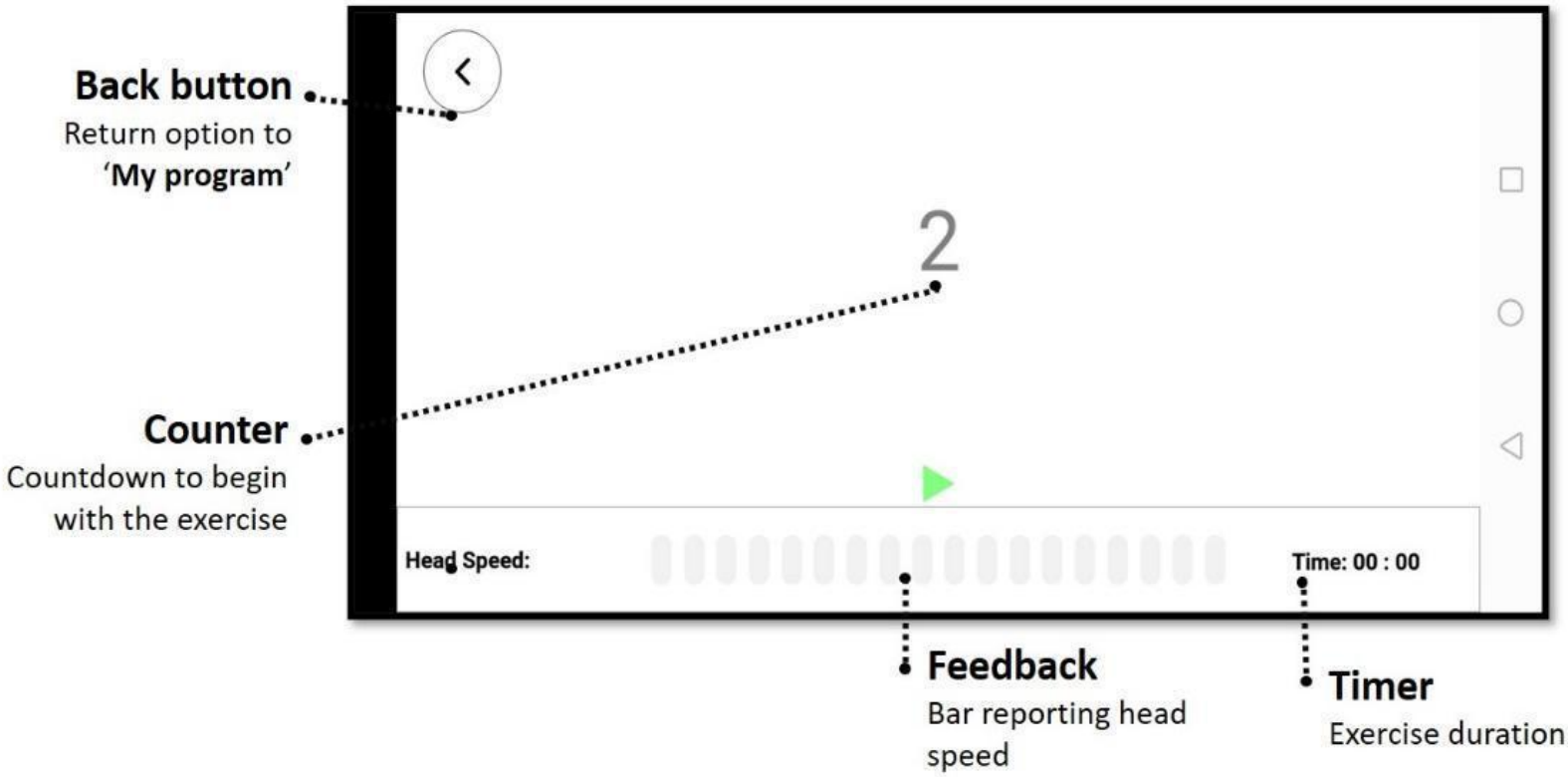


Figure 14: Feedback screen during exercise with the sensor

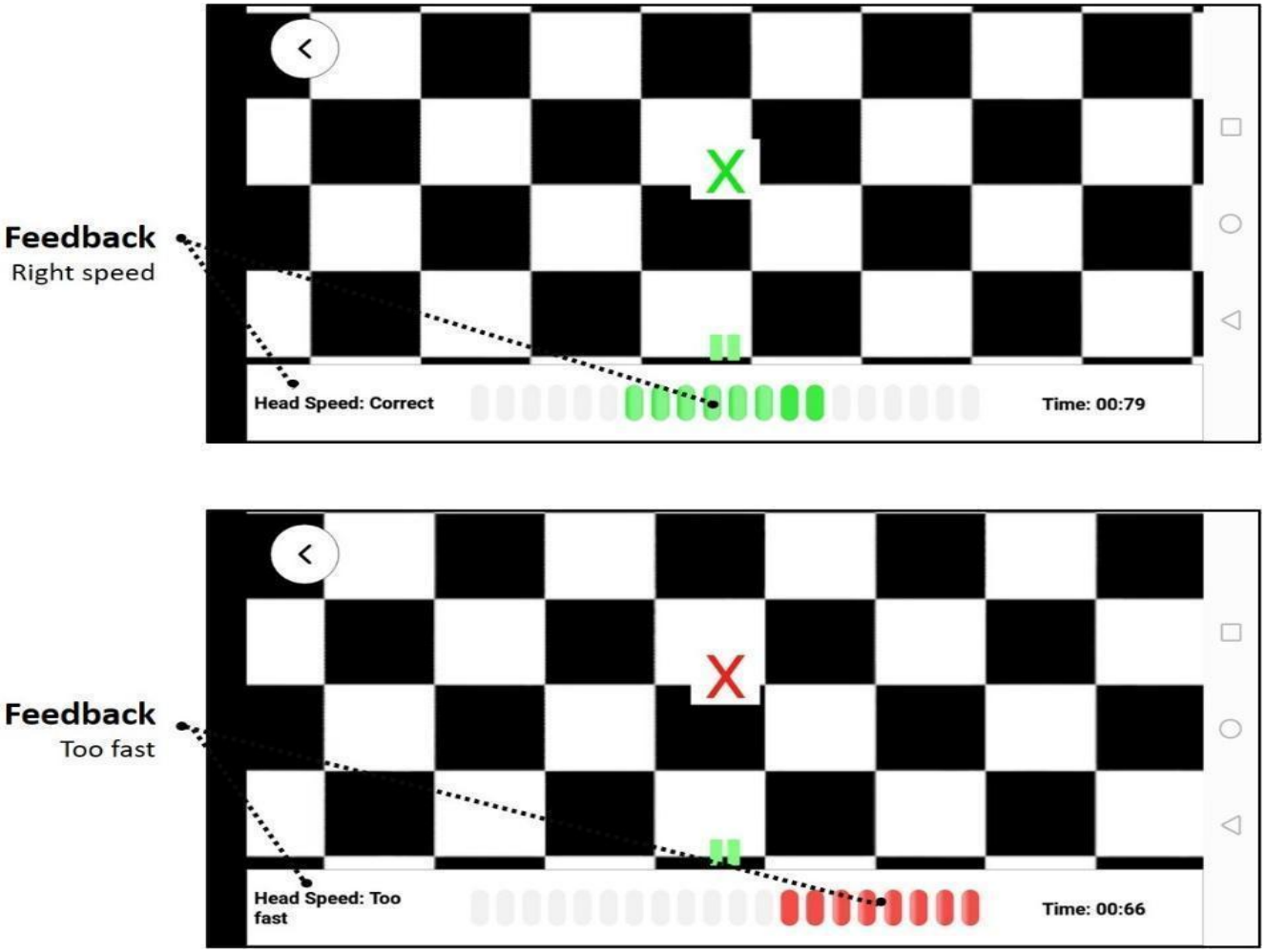
5.11 Feedback on exercise performance while using the head sensor.

Once the Vertigenius™ head sensor has been connected, if the exercise prescribed requires use of the head sensor feedback feature, a horizontal status bar will appear at the bottom of the app exercise display. Feedback is provided to the patient on the speed/frequency of their head movement during the exercise performance and compares it to what was prescribed by the clinician (Figure 15).

Feedback is presented using a colour coded format both for the stripes in the feedback bar and for the X visual target as per Figure 15 below:

- Correct head speed – Green
- Head speed too fast - Red
- Head speed too slow – Yellow
- No movement - no colour

NB Individuals with colour blindness may need to read the text prompts on the bottom left of the screen to assist with maintaining the correct speed/frequency.



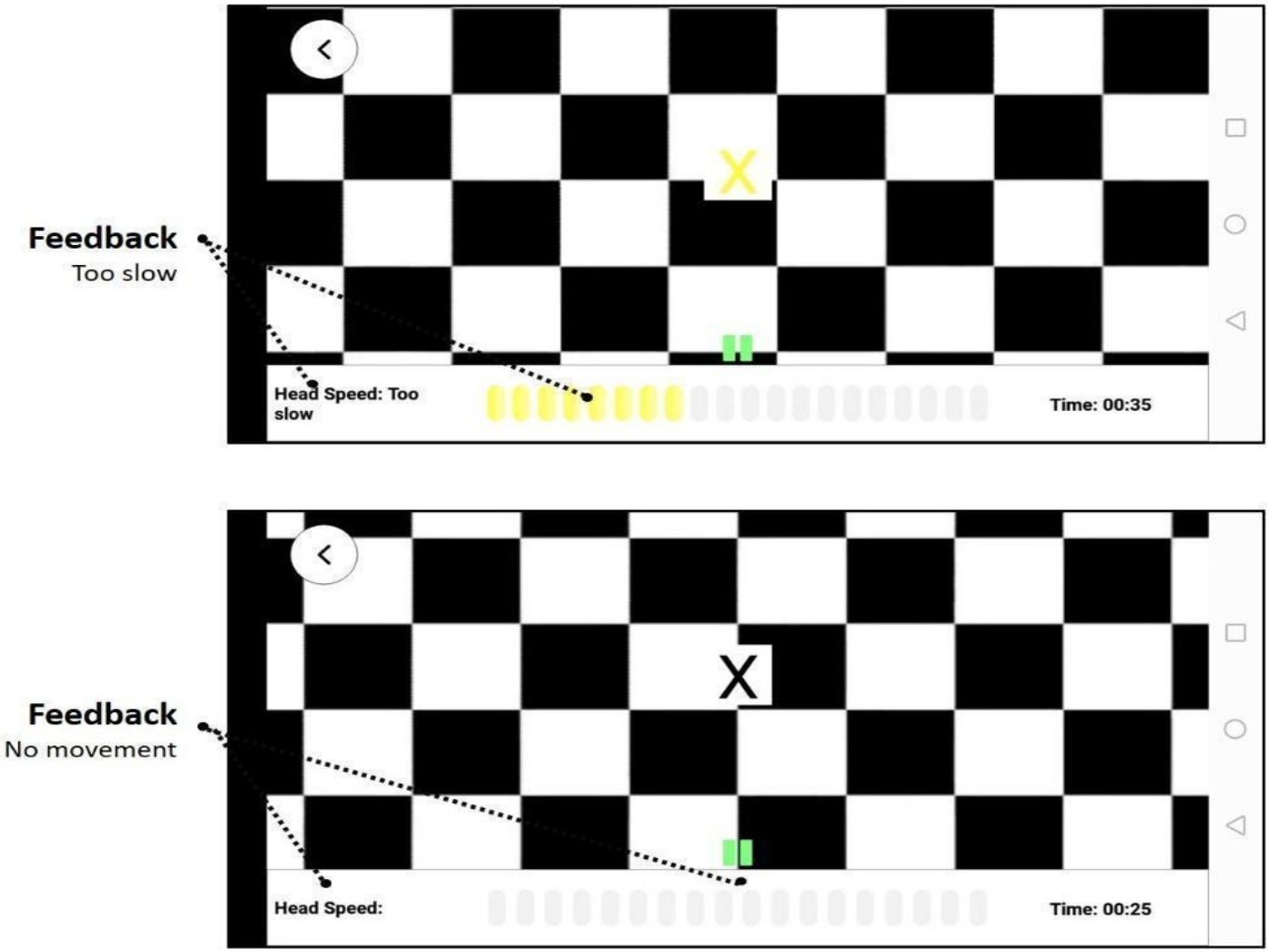


Figure 15: Colour coded corrective feedback from the head sensor during exercise

The prescribed head speed/frequency is defined by the audible metronome sound integrated into the exercise. The patient is required to match their head movement (horizontal or vertical) to the sound of the metronome to perform the exercise correctly as prescribed. Once the head speed achieved during the exercise meets the prescribed level, the target is green. Otherwise, the application will inform the patient in real time if the head speed is too fast or too slow.

At the beginning of each exercise, during the first few seconds where the patient is building up to the prescribed speed to be in time with the metronome, it is expected that the target X will remain black. Subsequently it may show that the movement is either too fast or too slow. As the patient becomes more familiar with doing the exercise, the display will show green more quickly (Figure 15).

In the event that the patient has persistent problems matching the metronome frequency, or if the system continuously indicates an incorrect frequency/speed via the on screen colour of the visual X target on screen, please consult with your clinician. The clinician can remotely adjust the prescription accordingly. Once prescription changes have been validated by the clinician on the clinician platform, they are automatically updated to the patient app.

At specific times, you will be asked to input your symptoms of dizziness/vertigo and nausea before and after an exercise with the head sensor. This information is requested every second day on the second session of the exercise. A screen will appear before the exercise with numerical rating scales (Figure 16)with scores from 0-10. 0 represents not experiencing the symptom at all, 10 represents that the symptom is as bad as it could be. For each of the symptoms select the number you feel is most appropriate at the time. Then select submit. When you have finished the exercise the symptom screen will appear again with a black ring around the numbers that you selected before you started (Figure 16), select (by tapping) on the number that your symptom has changed to (if at all).

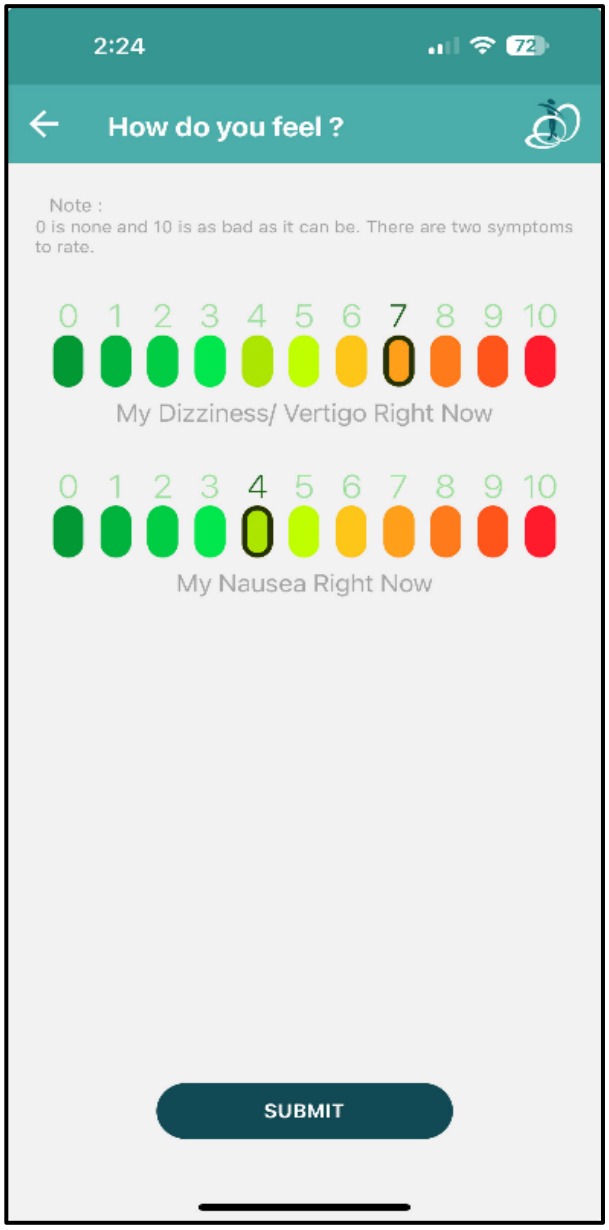
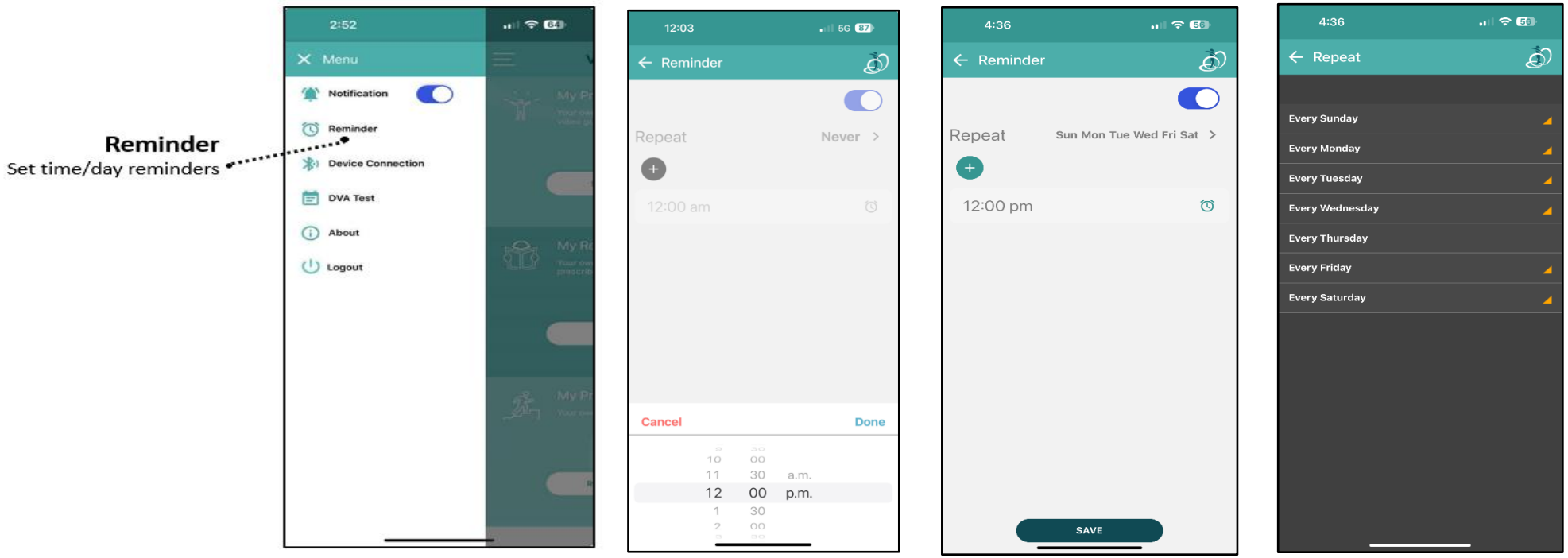


Figure 16: App symptom input screen

5.12 Setting reminders to exercise

Reminders to do exercises can be set in the app (Figure 17a-d)). Go to the app menu (three horizontal lines in the top left section). Select reminder. This will bring up a page where the reminder function can be turned on, time for reminders set and days of week selected. Slide the slider to on and select the + button (Figure 17b). Select the time you want the reminder and select done (Figure 17b). Then select repeat and then select the days on which you want to be reminded (Figure 17d). Once you have set the days of the reminder (Figure 17d) use the back arrow to go back and select save at the bottom of the screen (Figure 17c). The reminders can be amended at any time and deleted by swiping left on the individual reminder (Figure 17c).



(a) (b) (c) (d)

Figure 17: Setting Exercise Reminders in the App

6 Cleaning and handling

Use a damp cloth for cleaning the Vertigenius™ head sensor. If the head sensor has moisture/body fluids on the surface following cleaning, or use, remove by wiping with a clean dry cloth.

Take sufficient care not to drop your head sensor when handling it, in particular during cleaning. Ensure you position the sensor over a soft dry surface to avoid damage should it be dropped while cleaning.

7 Storage

When not in use, it is recommended to store the sensor in its original Vertigenius™ box. To ensure the optimal battery lifespan for the rechargeable battery in the sensor, do not expose it to excessive heat. For example, do not leave the head sensor in direct sunlight in front of a window or in a car, in particular while charging.

Long-term storage

Prior to storage for a prolonged period of time (more than 14 days), ensure the battery is fully charged. This will ensure that for future use the battery can be easily recharged.

Note

For optimal maintenance of the battery lifespan, it is recommended that you fully charge the head sensor at least once every six months.
For instructions on how to charge your head sensor, see the ‘Charging Head Sensor’ section in these instructions.

8 Using your head sensor with iPhone devices

Vertigenius™ head sensor can communicate directly with an iPhone device*. See further below to identify which versions of these devices are currently supported by Vertigenius™ head sensor. For assistance in using your head sensor with any of these products, please refer to your prescribing clinician.

Use of the ‘Made for Apple’ badge means that an accessory has been designed to connect specifically to the Apple products identified on the badge and that the accessory has been certified by the developer to meet Apple performance standards. However, Apple is not responsible for the operation of the accessory device nor its compliance with safety and regulatory standards. Please note that use of this Accessory with an iPhone may affect wireless performance.

9 Using your head sensor with Android devices

Vertigenius™ head sensor can communicate directly with selected Android™ devices*. See further below to identify which versions of these devices are currently supported by Vertigenius™ head sensor. For assistance in using your head sensor with any of these products, please refer to your prescribing clinician.

* Devices currently supported:

- Android: v8.1 or above
- Apple: iOS 12.4 or above

10 Water spray & touch resistance (IP22)

Your head sensor is a sealed unit, protected against ingress of dust and water droplets, but not running water, which means it is designed to be worn in all daily life situations. The water and dust resistance means you do not have to worry about your head sensor getting wet when it rains, or if it comes into contact with sweat. Before charging the head sensor make sure to wipe off any moisture.

Should your head sensor come into contact with water and stop working, gently wipe off any water and let the head sensor dry.

	**IMPORTANT NOTICE** Do not wear your head sensor while showering or participating in water activities. Do not immerse your head sensor in water or other liquids.

11 General warnings

For your personal safety and to ensure correct usage, you should familiarise yourself fully with the following general warnings before using your head sensor:

- Consult your clinician if you experience unexpected events, performance changes or incidents with your head sensor during use or because of its use. Your prescribing clinician will support you with handling the issue and, if relevant, provide assistance in reporting to the manufacturer and/or the national authorities.
- Please note that a head sensor alone will not restore normal balance and will not prevent balance impairment resulting from organic diseases/conditions. The head sensor is part of a system used for rehabilitation of vertigo, dizziness and imbalance, and needs to be supported by the care of a suitably qualified health professional. Furthermore, note that in most cases, sub-optimal use of the head sensor and prescription does not permit a user to attain its full benefit.
- This head sensor is supported by a non-removable rechargeable lithium-ion battery cell. Please ensure to charge the head sensor as guided in these instructions and familiarise yourself with the safety and handling information provided.
- Only charge the head sensor with a USB A to USB C, or USB C to USB C charging cable.

Use of head sensor

The head sensor should be used only as directed and prescribed by your clinician. It is designed for single patient use.
Only use your head sensor in areas where wireless transmission is permitted.

Active implants

The head sensor has been thoroughly tested and characterised for human health according to international standards for human exposure (Specific Absorption Ratio - SAR), induced electromagnetic power and voltages into the human body.
The exposure values are well below internationally accepted safety limits for SAR induced electromagnetic power and voltages into the human body defined in the standards for human health and coexistence with active medical implants such as pacemakers and heart defibrillators.
If you have a cochlear implant or an active brain implant, please contact the manufacturer of your implantable device for information about the risk of interference.

Explosives and oxygen-rich environments

The head sensor is safe to use under normal use conditions. The head sensor has not been tested for compliance with international standards concerning explosive environments. Therefore, do not use the head sensor in environments with danger of explosions e.g. mines, oxygen rich environments or areas where flammable anaesthetics are handled.

Choking hazards and risk of swallowing small parts

The head sensor should be kept out of reach of children and anyone who might swallow these items or their parts, or otherwise cause injury to themselves. If a head sensor or battery is swallowed, seek emergency medical attention immediately.

Fatality hazards and risk of swallowing lithium-ion batteries or placing them in body orifices

Never swallow lithium-ion batteries nor place them in any body orifice such as the ear or the nose, as this may lead to serious injury or death in as little as two hours. This could be caused by chemical burns, which can permanently damage the nose or ear or potentially lead to perforation of inner organs.
If a lithium-ion battery is swallowed or placed in the ear or nose, seek emergency medical treatment immediately.

Rechargeable battery

The head sensor is a sealed unit, so the user cannot replace the battery. Do not attempt to open the head sensor, as it may damage the battery or sensor device. Never attempt to replace the battery. If battery replacement is needed, please return your head sensor to your clinician. The service guarantee is void if there are signs of tampering with the sensor.
In case of battery leakage, do not wear your head sensor, as it may cause skin irritation due to acids from the leaking battery. If your skin has been in contact with leaked battery acids, use a wet cloth to wipe it off and ensure no acid is left on your skin. If you experience skin irritation, consult your doctor.
The safety of recharging batteries using a USB connector lead is determined by the external power source. When connected to external equipment plugged into a power socket (such as a USB charger), this equipment must comply with IEC 62368-1 or equivalent safety standards.

Sensor dysfunction

Be aware of the possibility that your head sensor may stop working without notice. Keep this in mind when you do the exercises with real-time feedback. Reasons the head sensor may stop functioning: if the battery has insufficient charge to operate, the battery has expired or if there is moisture inside the sensor. If the head sensor is not working, you can continue to carry out your exercises, but will lose the real-time feedback on your exercise performance.

Heat and chemicals

The head sensor must never be exposed to extreme heat, e.g. when left inside a parked car in full sun.
The head sensor must not be dried in a microwave oven or other ovens.
The chemicals in cosmetics, hairspray, perfume, aftershave lotion, sunscreen lotion, and insect repellent can damage/discolour the head sensor casing. Always remove your head sensor before applying such products and allow time for them to dry before use.

Possible side effects

The non-allergenic materials used in head sensors may in rare cases cause skin irritation or other side effects.
Please seek medical advice should this occur.

Interference

The head sensor has been thoroughly tested for interference according to the most stringent international standards. Electromagnetic interference may occur in the vicinity of equipment with the symbol illustrated adjacent to this text. Portable and mobile RF (radio frequency) communications equipment can affect the performance of your head sensor. If your head sensor is affected by electromagnetic interference, move away from the RF source to reduce the interference.

	**IMPORTANT NOTICE** It is recommended that this device is not used in close proximity to strong magnetic fields. Strong magnetic fields are unlikely to occur in a normal home or clinic use environment. Do not wear your head sensor while undergoing any medical imaging.

Distracted user

Using your head sensor can distract you from your physical surroundings. For your own safety, be aware of your surroundings while using your head sensor and use it in a suitable environment as directed by your prescribing clinician.

12 Troubleshooting

Symptom	Possible causes	Solutions
The head sensor LED light remains turned OFF when the button is pressed	Head sensor is out of power	Recharge the head sensor until fully charged
The sensor LED light is RED 30 min after start of charging		Unplug and plug in again, and attempt recharge. If recharge fails three times, contact your clinician
The head sensor LED light is flashing when turned ON but the App reports unconnected sensor	Head sensor is not connected	Open the App and check the 'Device Connection' menu, if the device is not listed, refresh the connection. If problem persists, contact your clinician
The head sensor LED is fixed ON but the App reports unconnected sensor	App has not connected to the head sensor	Restart the App and the head sensor
The head sensor LED goes fixed ON and after a while goes flashing	Head sensor is not able to connect to phone	Recharge the head sensor until fully charged
		Restart the App and the head sensor
		Let the head sensor LED go OFF, then turn ON

13 Precautions

In case the device performance changes or stops functioning, please check the troubleshooting section of this document. If the performance does not improve as a result, then contact your clinician for assistance.

In the event of exposure to electric or magnetic fields, do not turn on the device until no longer exposed to such fields.

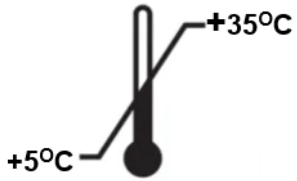
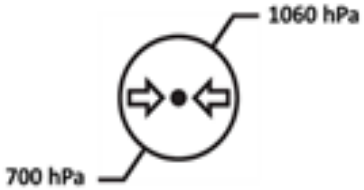
The device should not be used outside the operating conditions described in section 15.

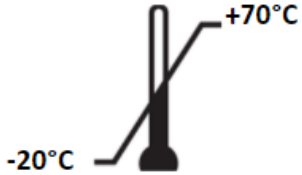
14 Disposal

This device contains a Li-ion battery and electronic components. As such the disposal of the device should be done properly in accordance with WEEE regulations for electronic waste disposal, available at a recycling centre or electrical retailer.

15 Specifications

Technical information	Vertigenius™ is a Class I medical device under the Medical Device Directive (93/42/EEC), Annex IX, Section III, rule 1, paragraph 1.1. Vertigenius™ is non-sterile and for single patient use only. MD
CE Mark and declaration of conformity	The manufacturer declares that this Vertigenius™ head sensor is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU. This medical device complies with Medical Device Directive (EU) 93/42/EEC concerning medical devices and with Article 4 of ROHS2 Directive (2011/65 EU).

	CE Declaration of Conformity is available from Vertigenius™ headquarters: Digital Rehabilitation Ltd Somerton House Rochestown Ave Dun Laoghaire Co. Dublin A96 HF30 Ireland www.vertigenius.com
Radio technology	Vertigenius™ Sensor contains a radio transceiver using Bluetooth® Low Energy operating at ISM band 2.4 GHz. The max radio transmitter power is 2 .2 mW (3.4 dBm).
Operating and charging conditions	Temperature: +5°C to +35°C (41°F to 95°F)  Humidity: 5% to 70% relative humidity, non-condensing  Atmospheric pressure: 700 hPa to 1060 hPa 
Transportation and storage conditions	

	Temperature, humidity and pressure shall not exceed the limits listed below for extended periods during transportation and storage: Temperature: -20°C to +70°C (-4°F to 140°F)  Humidity: 5% to 90% relative humidity, non-condensing  Atmospheric pressure: 700 hPa to 1060 hPa 
Battery charger	Not supplied
Battery charging input	Input voltages/current: 5.0V ---- 2.0A max
Electromagnetic compatibility (sensor)	EN 60601-1-2: 2015 +A1: 2021
Electrical safety (sensor)	EN 60601-1: 2006 A1: 2013 A2: 2021 EN 60601-1-11:2015 A1:2021

16 Feedback, returns and warranties

Complaints/Feedback on Vertigenius™ App or head sensor

If you suspect you or any other person has been injured by any part of the Vertigenius™ system please consult your physician immediately and request that they report to us and to the local medical device competent authority.

For all other queries

Web: http://www.vertigenius.com
Email : support@vertigenius.com

Head sensor

If requested by our support team to return the Vertigenius™ VG01 Sensor to Digital Rehabilitation Ltd for a warranty claim or investigation of a technical fault, then wrap the sensor in bubble wrap, double bag it in clear bags, before placing securely in a cardboard box or padded envelope and dispatching to our returns partner at the below address.

EU: Realtime Technologies Ltd.
The Realtime Building,
Clonshaugh Business &
Technology Park, Dublin, D17
H262, Ireland

Warranty contact: sales@vertigenius.com

Version History

Version	DCR#	Change Description	Release Date
1.0	n/a	Initial release of the User IFU	July 2021
2.0	2422	Release of VG01-DOC04 User IFU onto the QMS	Refer to DCR for Release Date
3.0	24109	Release of VG01-DOC04 User IFU at version 3.0	Refer to DCR for Release Date
3.1	2519	Release of VG01-DOC04 User IFU at version 3.1 • Adding FCC related text • Assing Shelf and Product Life details • Updating Radio Technology text • Add Applied Part Symbol to Symbol table	Refer to DCR for Release Date
3.2		Release of VG01-DOC04 User IFU at version 3.2 • Adding FCC related “warning text on page 7	Refer to DCR for Release Date